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NO. 51489-3-II

**COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON**

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

Appellants,

v.

DOROTHY FROST TEETER, not individually, but solely in her official
capacity as Director of the WASHINGTON STATE HEALTH CARE
AUTHORITY; WASHINGTON STATE HEALTH CARE AUTHORITY,

Respondents.

RESPONDENTS' BRIEF

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I. INTRODUCTION

The Health Care Authority (“Authority”) is responsible for setting Medicaid reimbursement rates in Washington. In this case, with an erroneous interpretation of federal law, three pharmaceutical special interest groups seek to compel the Authority to pay pharmacies higher prices for overhead costs known as “dispensing fees.”

This Court should affirm the Authority’s dispensing fees and associated regulations. Federal law grants the Authority wide discretion in determining the fees, which the Authority used appropriately. In evaluating the two components of the overall reimbursement paid to pharmacies—ingredient costs and dispensing fees—the Authority adhered to federal law and carefully considered three independent studies regarding payment rates to pharmacies from various Washington insurers. The studies showed that the level of Medicaid’s dispensing fees meets or exceeds what pharmacies receive from private insurance companies and the Medicare program.

The pharmacy associations’ arguments to the contrary are based on a misreading of the governing federal statute and the implementing federal regulations. Those federal standards require only that states ensure—and provide adequate data to support—that the total reimbursement is in accordance with the Medicaid objectives of efficiency, economy, quality of care, and access to care. The federal regulations do not require that states

perform particular types of studies or arrive at results that meet with industry approval.

Because the pharmacy associations cannot meet their burden of demonstrating that the Authority's rules or dispensing fees are invalid, this Court should affirm.

II. COUNTER-STATEMENT OF THE ISSUES

1. Was it error of law for the Authority, when interpreting the governing federal rule at 42 C.F.R. § 447.518(d), to decide to retain the dispensing fees at their 2017 level after reviewing three independent analyses of overall pharmacy reimbursement in Washington, which showed Medicaid's fees meet or exceed those of other payors?

2. Was it error of law for the Authority, when interpreting 42 C.F.R. § 447.518(d), to rely on the three independent analyses as "adequate data such as a State or national survey" of pharmacies to support its decision on the level of fees, when the federal government did not mandate the use of any given type of survey?

3. Was it error of law for the Authority to rely on the three independent analyses to conclude that its overall reimbursement to pharmacies would meet the statutory and regulatory standards of efficiency, economy, quality of care, and access to care, when there continues to be no issue with the ability of Medicaid clients to access pharmacy services?

4. Was it arbitrary and capricious under the Administrative Procedure Act (“APA”), RCW 34.05, for the Authority to rely on the three independent analyses in deciding to maintain the level of dispensing fees, when (a) the studies show that Medicaid’s rates meet or exceed those from other payors; (b) the studies comply with federal requirements for the Authority to consider efficiency, economy, quality of care, and access to care; and (c) federal law does not require a “cost-of-dispensing” study in determining the rates?¹

III. STATEMENT OF THE CASE

A. Washington Offers the Medicaid Program and Receives Federal Matching Funds

1. The program offers healthcare benefits to low-income individuals

Congress created Medicaid in 1965 to offer “federal funding to States to assist pregnant women, children, needy families, the blind, the elderly, and the disabled in obtaining medical care.” *Nat’l Fed’n of Indep. Bus., v. Sebelius*, 567 U.S. 519, 541, 132 S. Ct. 2566, 183 L. Ed. 2d 450 (2012) (citing 42 U.S.C. § 1396a(a)(10)). Congress expanded Medicaid in the Patient Protection and Affordable Care Act of 2010 to cover anyone

¹ The Appellants have waived or withdrawn several issues, including (1) the adequacy of the ingredient cost reimbursement, (2) a Due Process claim under the APA, and (3) an allegation that the Authority failed to comply with APA requirements such as the filing of a small business impact statement and a cost-benefit analysis.

with an income below 133% of the federal poverty level. *Nat'l Fed'n of Indep. Bus.*, 567 U.S. at 576, 583. Washington has participated in Medicaid since 1967 and implemented the expansion in 2014. *See* RCW 74.09.500; Laws of 2013, 2d Spec. Sess., ch. 4, § 213(1).

Under federal guidelines, states determine who is eligible for Medicaid, the benefits that will be offered, and payment rates to healthcare providers. *Rite Aid of Pa., Inc. v. Houstoun*, 171 F.3d 842, 845 (3d Cir. 1999).

2. The State receives a significant degree of federal Medicaid funding if it satisfies federal requirements

To receive federal funding, the State must comply with federal Medicaid law. *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1382, 191 L. Ed. 2d 471 (2015); *Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007, 1010 (9th Cir. 2013). One requirement is to submit a “State Plan” describing how the State will administer Medicaid and assuring compliance with federal law. *See* 42 U.S.C. § 1396a(a); 42 C.F.R. § 430.12; *Armstrong*, 135 S. Ct. at 1382 (Spending Clause programs such as Medicaid are similar to contracts). The federal Centers for Medicare and Medicaid Services (“CMS”), within the Department of Health and Human Services, must approve the State Plan and any amendments. *See* 42 C.F.R. §§ 430.10, .14; *Douglas*, 738 F.3d at 1010.

A state receives federal matching funds when CMS approves its State Plan. *See* 42 U.S.C. § 1396b(a); 42 C.F.R. §§ 430.1, 447.304(c). CMS wields a considerable financial stick, because it can withhold all or a portion of a state’s Medicaid funding if it concludes the state is violating federal requirements. *See* 42 U.S.C. § 1396c; 42 C.F.R. §§ 430.1, 430.35(a), 430.40(a), 430.42(a), 447.304(c); *Nat’l Fed’n of Indep. Bus.*, 567 U.S. at 580. This is a strong enforcement tool, since the federal government funds at least 50% of expenditures under the original program and 90% under the Affordable Care Act. *See* 42 U.S.C. § 1396b(a)(1); *Nat’l Fed’n of Indep. Bus.*, 567 U.S. at 584. The Authority must take all steps necessary to receive federal funds. *See* RCW 74.04.050(3); RCW 74.09.500.

Courts routinely defer to CMS in matters involving State Plan Amendments. *Managed Pharm. Care v. Sebelius*, 716 F.3d 1235, 1246-47 (9th Cir. 2013); *Alaska Dep’t of Health and Soc. Servs. v. CMS*, 424 F.3d 931, 938-39 (9th Cir. 2005). If CMS rejects an amendment, the state can pursue a federal administrative appeal. *See* 42 C.F.R. § 430.18; *Managed Pharm. Care*, 716 F.3d at 1247.

The State Plan must designate a “single State agency” for its administration or supervision. *See* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10(b)(1). In Washington, the Authority is responsible for

administering Medicaid and obtaining federal approval for the State Plan. See RCW 41.05.021(1)(m)(i); RCW 74.09.530(1)(a).

3. Medicaid clients can receive care through two different delivery systems

Medicaid clients can receive their benefits through either a “fee-for-service” system or a “managed care” system. *G. v. Haw. Dep’t of Human Servs.*, 703 F. Supp. 2d 1078, 1084 (D. Haw. 2010). Under fee-for-service, “the state contracts directly with and pays healthcare providers . . . for services they provide to Medicaid beneficiaries.” *Id.* Under managed care, the state enters into contracts with companies that assume responsibility for furnishing services “through their own employees or by contracting with independent providers.” *Id.* The issues here pertain only to the fee-for-service component, which covers about 16% of Washington’s Medicaid clients. CP at 7, 8 (Pet. for Declaratory Relief and Emergency Stay, ¶¶ 20, 24); CP at 1141 (Decl. of Myra Davis dated November 6, 2017 (“Davis Decl.”), ¶¶ 4, 5).

B. Medicaid Pays for Prescription Drug Services

Federal Medicaid law requires the states to offer certain categories of benefits. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a); 42 C.F.R. §§ 440.210(a), .220(a). All other services are optional. See 42 U.S.C. § 1396d(a)(29); 42 C.F.R. § 440.225. Paying for clients to get prescriptions filled at a local pharmacy is an optional service for traditional Medicaid

clients (*see* 42 U.S.C. § 1396d(a)(29) and 42 C.F.R. § 440.225) and mandatory for those who gained coverage under the Affordable Care Act (*see* 42 C.F.R. §§ 440.305(b), .337). Washington covers prescription drug services for all Medicaid clients. *See* RCW 74.09.520(1)(k); WAC 182-530-1000.

C. In 2016, CMS Changed Certain Requirements Regarding How States Must Pay Pharmacies for Their Medicaid Services

CMS amended its rules on February 1, 2016, regarding how states must pay pharmacies for filling prescriptions for Medicaid clients. *See* 81 Fed. Reg. 5170 (February 1, 2016); *see also* 42 C.F.R. Part 447, Subpart I. States were required to comply by April 1, 2017. *See* 81 Fed. Reg. at 5173-74. The overriding requirement is that the rates must be consistent with efficiency, economy, quality of care, and access to care. *See* 42 U.S.C. § 1396a(a)(30)(A) (“Section 30(A)”); 42 C.F.R. § 447.518(d); 81 Fed. Reg. at 5310.

The substantive changes to the federal rules were to the ingredient cost methodology, not the dispensing fee methodology. The states must pay both (1) for a drug’s ingredient costs at an aggregate upper limit based on its *actual* acquisition cost and (2) a professional dispensing fee established by the state. *See* 42 C.F.R. § 447.512(b); 81 Fed. Reg. at 5290. CMS did not believe that changing the ingredient cost methodology would create access

problems for Medicaid clients or reduce pharmacy participation in the program. *See* 81 Fed. Reg. at 5291.

In addition, if a state wants to change either the ingredient cost or dispensing fee methodology, it must review both components to ensure the total payment meets the Section 30(A) standards. *See* 42 C.F.R. § 447.518(d). As part of the State Plan Amendment process, CMS reviews the data that the state considered in changing the methodology. *Id.*

D. The Authority Specifies the Payment Methodology in Regulations

1. The Authority changed the ingredient cost methodology in April 2017

As required by federal law, the Authority's payments to pharmacies include the drug ingredient cost and a dispensing fee. *See* WAC 182-530-7000(1); CP at 1142 (Davis Decl. ¶ 6). The Appellants are not challenging the ingredient cost payments, but a summary of the 2016 changes to the federal rules provides context to the dispensing fee dispute.

Until April 1, 2017, the Authority determined the ingredient cost for brand-name drugs by using an estimated acquisition cost method. CP at 1142 (Davis Decl. ¶¶ 8, 9). To comply with the amended federal rules, the Authority changed to an actual acquisition cost method as of April 1, 2017. *Id.*; *see also* 42 C.F.R § 447.512(b)(1); 81 Fed. Reg. at 5173-74. The goal of both methods is to closely approximate the real cost of the drug that is

being purchased. Under the former system, states had used a variety of methods. CP at 1142 (Davis Decl. ¶ 9).

CMS provided guidance on how to implement the new methodology. CP at 1143-44 (Davis Decl. ¶ 13). Washington chose to use the National Average Drug Acquisition Cost (“NADAC”). CP at 1142-43 (Davis Decl. ¶¶ 8-12); *see also* 81 Fed. Reg. at 5342 (CMS did not require states to perform cost surveys before changing to the actual cost method).

The Authority implemented the ingredient cost change through the APA’s rule-making procedures. CP at 888-91 (Decl. of Wendy Barcus dated Nov. 2, 2017 (“Barcus Decl.”) ¶¶ 4-17). It is also being implemented with CMS through a State Plan Amendment. CP at 993 (Decl. of Ann Myers dated Nov. 2, 2017 (“Myers Decl.”) ¶ 10, Attach. D).

2. The Authority took steps to address any possible adverse effects of changing the ingredient cost methodology

When it implemented the new payment method for ingredient costs, the Authority took steps to ensure the system would not adversely affect pharmacies. First, the Authority inserts a “pricing override” for a drug if research shows the NADAC rate is less than any Washington Medicaid pharmacy’s recently documented cost. CP at 1152 (Davis Decl. ¶ 32). The override causes claims for the drug to pay higher than NADAC, so pharmacies are paid their full cost. *Id.* Second, providers may request a

reimbursement correction whenever they believe the ingredient payment is insufficient to cover costs. *Id.*

The Authority had estimated the change would reduce industry-wide revenues to pharmacies by about \$1.1 million annually, or less than 0.5%. CP at 1150 (Davis Decl. ¶ 28). That figure is likely an over-estimate because of the remedial steps the Authority took to smooth the transition. *Id.*

3. The Authority changed the dispensing fee definition while retaining the existing payment level

CMS made no substantive changes to the dispensing fee component of the methodology, simply changing the name “dispensing fee” to “professional dispensing fee.” *See* 42 C.F.R. § 447.502; 81 Fed. Reg. at 5201-02. The Authority’s rules incorporate the new term. *See* WAC 182-530-1050. The change in terminology did not result in a substantive change in Washington because the Authority’s prior definition contained the relevant elements of the federal definition. CP at 1144 (Davis Decl. at 5:18-26).

In particular, the Authority’s definition already specified that the fee is payment only for dispensing and for the expenses involved in the practice of pharmacy. *Id.* In contrast, some states had used dispensing fees to pay for unrelated items, such as disease management, and to offset loss of revenue from ingredient costs. *Id.* Washington had not misused the dispensing fee in such a fashion, and so no adjustment was required. *Id.* The federal rule

did not require changing the fees, and in fact the level of the fees did not change. CP at 1146-47 (Davis Decl. ¶¶ 17-19).

4. The Authority evaluated the pharmacy rates as part of its regulatory amendment process

As required by the amended federal rules, the Authority evaluated both the ingredient costs and the dispensing fees before it adopted the NADAC methodology as of April 1, 2017. *See* 42 C.F.R. § 447.518(d); CP at 1147-48 (Davis Decl. ¶¶ 19-23). The evaluation was consistent with the federal rules and guidance from CMS, which directed that rates must meet the overarching Section 30(A) requirements of efficiency, economy, quality of care, and access to care. *See* 42 C.F.R. § 447.518(d); CP at 1146 (Davis Decl. ¶¶ 16-17).

The Authority reviewed studies from nationally recognized firms analyzing rates in Washington’s retail pharmacy market. CP at 1148 (Davis Decl. ¶ 21(b)). The Authority also obtained, from an independent actuarial firm, a survey of retail pharmacy reimbursement and dispensing fees from private insurance companies and the Medicare program. *Id.*

Following this analysis, the Authority decided to maintain the dispensing fees at their current level, concluding the fees are higher than other payers in Washington. CP at 1146 (Davis Decl. ¶¶ 17-18). The analyses indicated that the Authority’s overall rates are comparable to other

payers and would adhere to federal guidelines. CP at 1146-48 (Davis Decl. ¶¶ 17-21). The Authority's rates continue to be within the norms of well-accepted rates in Washington's pharmacy marketplace. *Id.*

The evaluation was part of a comprehensive APA rule-making procedure. Through the State Register, the Authority notified the public that it was considering amendments to the methodology. CP at 888 (Barcus Decl. ¶¶ 4, 5). The Authority invited interested parties to participate in the process, including a review of draft amendments. CP at 888-89 (Barcus Decl. ¶¶ 4-6). One the Appellants, the National Association of Chain Drug Stores ("Association"), received the drafts and offered suggestions. CP at 888-89 (Barcus Decl. ¶¶ 6-8). The Authority published drafts, solicited public comments, held a public hearing, and gave individualized notice to the Association. CP at 889-90 (Barcus Decl. ¶¶ 10-13). The Authority then published the amended rules and submitted a statement explaining details of the rules. CP at 890-91 (Barcus Decl. ¶¶ 15-17).

E. Procedural History

On March 29, 2017, the Appellants filed a Petition for Declaratory Relief and Emergency Stay in Thurston County Superior Court, attempting to block the amended rules from taking effect on April 1, 2017. CP at 1. The following day, the Authority removed the case to U.S. District Court in

Tacoma. CP at ____ (Notice to Thurston County Superior Court of Removal to Federal Court).

On April 4, 2017, the federal court denied the Appellants' Motion for a Temporary Restraining Order, thereby allowing the Authority to continue implementing the amended rules. *See* Appendix A. The federal court emphasized the importance of access to pharmacy services by Medicaid clients, in accordance with Section 30(A), and also noted the lack of evidence of alleged harm:

I don't know whose numbers are right, but whether it is a million dollars a year or \$12 million a year, I still don't have enough in the record that tells me that there will be an access problem here. The numbers seem to indicate just the opposite, that the amount is sufficiently small as to not interfere with either the large or small pharmacies.

See Appendix B (April 4, 2017 TRO hearing transcript at 33:19-25).

The federal court ultimately remanded the case to Thurston County Superior Court. CP at ____ (Order Remanding Case). On January 26, 2018, the Superior Court entered an order upholding the substantive and procedural validity of the amended rules. CP at 1575-77. The Court held that the Appellants had not met their burden of proving the Authority exceeded its statutory authority, acted in an arbitrary and capricious manner, or violated the APA's procedural requirements. CP at 1576. The Appellants

unsuccessfully sought reconsideration and to supplement the record. CP at 2366-68. The Appellants then filed this appeal. CP at 2369-71.

IV. STANDARD OF REVIEW AND BURDEN OF PROOF

The Appellants claim the Authority's amended rules are invalid because they violate the federal rules and were enacted in an arbitrary and capricious manner. *See* Br. Appellants at 26. Because these claims are brought under the APA, the Appellants bear the burden of proving the invalidity of the Authority's action. *See* RCW 34.05.570(1)(a); *Snohomish Cty. v. Pollution Control Hearings Bd.*, 187 Wn.2d 346, 357, 386 P.3d 1064 (2016). This Court sits in the same position as the Superior Court in reviewing the administrative record. *Estate of Ackerley v. Wash. Dep't of Rev.*, 187 Wn.2d 906, 909, 389 P.3d 583 (2017).

A rule is invalid if it exceeds the agency's authority. *See* RCW 34.05.570(2)(c); *Ass'n of Wash. Spirits & Wine Distribs. v. Wash. State Liquor Control Bd.*, 182 Wn.2d 342, 350, 340 P.3d 849 (2015). "[W]here the Legislature has specifically delegated rule-making authority to an agency, [its] regulations are presumed valid, and only compelling reasons demonstrating that the regulation conflicts with the intent and purpose of the legislation warrant striking down a challenged regulation." *Armstrong v. State*, 91 Wn. App. 530, 536-37, 958 P.2d 1010 (1998).

“Thus, the regulation will be upheld if reasonably consistent with the statute being implemented.” *Id.* at 537.

The Court reviews the Authority’s interpretation of federal law under the “error of law” standard, which allows the Court to substitute its judgment for that of the Authority. *Jenkins v. Wash. State Dep’t of Soc. & Health Servs.*, 160 Wn.2d 287, 296, 157 P.3d 388 (2007). If Congress has directly spoken on the matter and clearly expressed its intent, the Court must give effect to that intent. *Skamania Cty. v. Columbia River Gorge Comm’n*, 144 Wn.2d 30, 43, 26 P.3d 241 (2001) (citing *Chevron U.S.A., Inc. v. Nat. Res. Def. Coun., Inc.*, 467 U.S. 837, 842–43, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984)). If the statutes are silent or ambiguous, the question is whether the agency’s interpretation is “based on a permissible construction of the statute.” *Id.* (quoting *Chevron*, 467 U.S. at 843). The Authority is entitled to deference if the interpretation is within its area of expertise. *Id.* The Court should uphold the agency’s interpretation if it is “sufficiently rational to preclude [the reviewing court] from substituting [its] judgment for that of the agency.” *Skamania*, 144 Wn.2d at 43.

In their challenge under the arbitrary and capricious prong, the Appellants must prove the Authority’s action was “willful and unreasoning and disregards or does not consider the facts and circumstances underlying the decision.” *Karanjah v. Dep’t of Soc. & Health Servs.*,

199 Wn. App. 903, 925, 401 P.3d 381 (2017). The scope of review is “very narrow[,]” and the Appellants “carry a heavy burden.” *Id.* An action is not arbitrary and capricious “if there is room for more than one opinion and the decision is based on honest and due consideration, even if [the appellate court] disagrees with it.” *Id.* Additionally, “[n]either the existence of contradictory evidence nor the possibility of deriving conflicting conclusions from the evidence renders an agency decision arbitrary and capricious.” *Squaxin Island Tribe v. Wash. State Dep’t of Ecology*, 177 Wn. App. 734, 742, 312 P.3d 766 (2013) (quoting *Rios v. Wash. Dep’t of Labor & Indus.*, 145 Wn.2d 483, 504, 39 P.3d 961 (2002)).²

V. ARGUMENT

A. Summary of Argument

The Court should uphold the Authority’s actions because the Authority complied with federal requirements and the APA in amending its rules and determining the payment rates. As required by the plain language of the federal rule, the Authority (1) evaluated the proposed changes in accordance with all federal requirements; (2) considered both the ingredient

² At the trial court, the Appellants could not explain with clarity whether they were seeking summary judgment, judicial review of agency action under the APA, or some combination. *See* Appendix C (RP at 9:1-3, 52:15 to 53:12). The Appellants still appear to suggest the current posture of the case is summary judgment. *See* Br. Appellants at 1 (discussing whether there are “questions of fact”). To the extent this is deemed a summary judgment action, there clearly are questions of fact that would preclude a ruling in the Appellants’ favor, such as whether the Authority “select[ed] data favorable to its conclusion and ignor[ed] that which was not.” *See* Br. Appellants at 1.

costs and the dispensing fees as part of changing the ingredient cost methodology; (3) ensured that the resulting rates comply with Section 30(A); (4) relied upon adequate data to support the change to the ingredient cost methodology; and (5) submitted the changes to CMS through a State Plan Amendment. *See* 42 C.F.R. § 447.518(d).

The Appellants' argument rests on three misunderstandings of the federal law. They incorrectly assert that (1) the dispensing fees must cover a pharmacy's actual costs, which the law does not say; (2) the Authority was required to conduct a cost-of-dispensing study, which the law does not say; and (3) the Authority was precluded from considering factors other than costs, such as access to services, an assertion directly contrary to Section 30(A) and 42 C.F.R. § 447.518(d).

In addition, it was not arbitrary and capricious for the Authority to rely on three Washington marketplace studies when amending its rules and determining the rates, when (1) the studies show the Medicaid rates are competitive with and often higher than Medicare and commercial payors; (2) the federal rule requires the Authority to consider the rates in light of the governing standards of Section 30(A), which the Authority did; (3) the federal rule gives great flexibility to the Authority in devising the methodologies; and (4) CMS does not require cost-of-dispensing studies in determining the rates.

B. The Authority’s Rules and Dispensing Fees Comply with Federal Regulations

1. The amended federal rule includes five requirements

The Court should uphold the Authority’s actions because it satisfied all requirements imposed by CMS in its amended rules. The applicable rule provides as follows:

When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to *evaluate* their proposed changes in accordance with the requirements of [42 C.F.R. Part 447, Subpart I], and States must *consider both* the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the [Social Security] Act [which is 42 U.S.C. § 1396a(a)(30)(A)]. States must provide *adequate data* such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process.

See 42 C.F.R. § 447.518(d) (emphasis added).

As shown, the rule imposes five requirements. First, the Authority must “evaluate” proposed methodology changes in accordance with the regulatory chapter. Second, the Authority must “consider” both aspects of the methodology when proposing changes to either component. Third, the Authority must ensure that the resulting rates satisfy the Section 30(A)

standards of efficiency, economy, quality of care, and access to care. Fourth, the Authority must provide CMS with data that, depending on its nature, is considered either “adequate” or “reliable” to support any methodology changes. Fifth, the Authority must submit the changes to CMS through a State Plan Amendment.

As explained below, the Authority satisfied all five requirements when amending its rules and deciding to retain the level of dispensing fees. Meanwhile, the Appellants mischaracterize the amended federal rule in three crucial respects, incorrectly claiming the Authority was (1) required to cover a pharmacy’s actual costs; (2) required to conduct a cost-of-dispensing study; and (3) precluded from considering factors other than costs, such as access to services.

The Authority has the responsibility to issue rules regarding the Medicaid program. *See* RCW 41.05.021(1)(m)(i), (iv); RCW 41.05.160. The fact that the Legislature has “specifically delegated rule-making authority” means the Authority’s rules are “presumed valid, and only compelling reasons demonstrating that [they] conflict[] with the intent and purpose of the [Medicaid statutes] warrant striking [them] down[.]” *Armstrong*, 91 Wn. App. at 537. The Appellants have not offered any such “compelling reasons.” *Id.*

2. The Appellants mischaracterize the federal rule in three crucial respects

a. The amended federal rule focuses on a pharmacy's costs for the ingredient cost component but not the dispensing fee component

The Appellants misstate the nature of the amendments to the federal rules, a characterization that permeates and undercuts their argument. In their defined term “CMS Rule,” the Appellants claim the “centerpiece” of the amended rule is that states now “must reimburse pharmacies for their *actual costs in dispensing* drugs to Medicaid patients.” *See* Br. Appellants at 1-2 (emphasis added). It is true that the ingredient cost component was changed so that states must pay the “actual” cost instead of an estimate. *See* 42 C.F.R. § 447.502; 81 Fed. Reg. at 5174-76; CP at 1142-43 (Davis Decl. ¶¶ 8, 12). But the amendments did not change the substance of what states must do with respect to dispensing fees. *See* 81 Fed. Reg. at 5201; CP at 1144-46 (Davis Decl. at 5:17 to 7:5). Instead, the rule simply inserted “professional” in front of “dispensing fee” and changed a reference from “recipient” to “beneficiary.” *See* 42 C.F.R. §§ 447.502, .518(d); 81 Fed. Reg. at 5349; CP at 1144 (Davis Decl. at 5:17-22).

Based on their inaccurate description, the Appellants imply that a consideration of a pharmacy's actual costs is a new feature of the rules for dispensing fees, which the Authority failed to satisfy. *See, e.g.,*

Br. Appellants at 8, 11, 17. As noted, the Authority did not change the dispensing fees. CP at 1146 (Davis Decl. ¶ 17). There was no requirement to do so, as the federal law has not changed. Furthermore, in accordance with those same standards, CMS has approved the dispensing fees as part of Washington’s Medicaid State Plan since April 2009. The Authority’s rules and rates have been, and continue to be, in compliance with federal requirements.³

b. The federal rule does not require a cost-of-dispensing study

The Appellants assert the Authority was required to conduct a formal “cost-of-dispensing” study before finalizing its amended rules, presumably as a means to the end of increasing the dispensing fees. *See, e.g.*, Br. Appellants at 17, 34. The Appellants are incorrect; there is nothing in the plain language of Section 30(A), the federal rules, the Federal Register, or CMS guidance requiring any such study. Further, the Appellants conceded at the trial court that a cost-of-dispensing study is not required. *See* Appendix C (RP at 48:23 to 49:3). They should not be allowed to backtrack now.

³ *See* State Plan at <https://www.hca.wa.gov/about-hca/apple-health-medicaid/medicaid-title-xix-state-plan> (last visited July 9, 2018). The dispensing fees are found in Attachment 4, Supplement A to Section 4.19-B (page 209 of the pdf document). It is appropriate for the Court to take judicial notice of this government publication. *See* Evidence Rule 201; *Pudmaroff v. Allen*, 138 Wn.2d 55, 65 n.5, 977 P.2d 574 (1999).

In addition, upon an inquiry from the Authority, CMS did not say that a cost-of-dispensing study was required. *See* CP at 1148 (Davis Decl. ¶ 24). Indeed, CMS has explicitly rejected the notion, emphasizing the importance of the Section 30(A) standards:

[W]e do not agree that states must conduct surveys to revise dispensing fees. Rather, they have the option to submit data, other than a survey, which demonstrates that the total reimbursement to the pharmacy provider is in accordance with [Section 30(A)].

See 81 Fed. Reg. at 5310.

[S]tates are not required to conduct cost studies or use an inflation update where cost studies are not conducted; however, states should ensure that pharmacy providers are compensated in accordance with the requirements [of Section 30(A)].

See 81 Fed. Reg. at 5311.

We do not agree that the [regulation's] text should be revised to require an annual cost of dispensing study or that fees should vary based on setting, but rather we will continue to allow the states the flexibility to adjust their dispensing fees as necessary.

See 81 Fed. Reg. at 5202.

As these entries show, the Appellants are simply incorrect in claiming that the Authority was required to conduct a formal cost-of-dispensing study.

c. The Authority was required to consider non-cost factors when finalizing the rules and the fees

The Appellants claim that federal law prohibits the Authority from considering any factors other than a pharmacy's costs when determining a payment rate. *See* Br. Appellants at 30. The Appellants are incorrect. The federal rules are expressly tied to the Section 30(A) standards of efficiency, economy, quality of care, and access to care. *See* 42 C.F.R. §§ 447.500(a)(5), .518(d). Plus, as described above, CMS did not change the pertinent provisions of its rules regarding dispensing fees. As such, the Authority was required under federal law to consider a variety of factors before making its decisions, which it did. CP at 1146-48 (Davis Decl. ¶¶ 17-21).

3. The Authority evaluated its changes in accordance with federal regulations

The federal rule requires the Authority to “evaluate” any proposed changes in its payment methodology “in accordance with” the regulatory chapter. *See* 42 C.F.R. § 447.518(d). The Authority satisfied this requirement.

Before finalizing the amendments, the Authority “engaged in a year-long process of studying the [federal rules], evaluating [its] rates, and requesting explicit written clarifications from CMS.” CP at 1146 (Davis Decl. ¶ 17). The entire process was conducted in light of the Section 30(A)

standards. *Id.* The Authority determined the rates were “sufficient in the aggregate to maintain strong pharmacy participation and client access” and to therefore meet the standards of Section 30(A) and the federal rules. *Id.*; *see also* CP at 1142 (Davis Decl. ¶ 7).

The process included “an examination of commonly accepted rates in Washington for both ingredient costs and dispensing fees.” CP at 1147 (Davis Decl. ¶ 19). The Authority “also examined the impacts of rate changes in order to determine what amount would be sufficient to maintain strong client access and comply with all requirements of” Section 30(A). *Id.*

The examination was informed by three studies that analyzed how various payors in Washington reimburse pharmacies for their services. CP at 1148 (Davis Decl. ¶ 21(b)). The studies helped inform the Authority as to how its rules would ensure access to care and how the Authority would monitor compliance with federal standards. CP at 1148 (Davis Decl. ¶ 21(b), Attachs. B-D). There is no evidence that anything has happened since April 2017 to adversely affect access to care, quality of care, or the level of pharmacy participation in the Medicaid program.

The first study was conducted for the Office of the Insurance Commissioner. CP at 1165-1271 (Davis Decl. ¶ 21(b), Attach. B). The Commissioner examined data from the pharmacy benefit managers that serve nearly all of Washington’s fully insured commercial market.

CP at 1167. The Commissioner found that pharmacy benefit managers were paying a weighted average dispensing fee of \$1.88. CP at 1222-23 (Ex. 44); *see also* CP at 1146 (Davis Decl. ¶ 18). The Authority's dispensing fees are much higher, at \$4.24 to \$5.25. CP at 1149-50 (Davis Decl. ¶¶ 26, 27(b)). The Appellants claim the Authority "ignored" this report, *see* Br. Appellants at 2, which clearly is wrong. CP at 1165-1271 (Davis Decl. ¶ 21(b), Attach. B).

The second study was conducted by the Burchfield Group on behalf of Moda Health. CP at 1273-87 (Davis Decl. ¶ 21(b), Attach. C). The study showed that pharmacy benefit managers for private businesses were paying, for single-source drugs, an average dispensing fee of \$1.22 and an ingredient cost of Average Wholesale Price minus 15.83%. CP at 1279. The Authority's dispensing fees were much higher, at \$4.24 to \$5.25. CP at 1149-50 (Davis Decl. ¶¶ 26, 27(b)). The Authority's ingredient cost payments were roughly the same, at the Average Wholesale Price minus 16%. CP at 1384.

The third study was conducted by the actuarial firm of Milliman, Inc., on behalf of the Authority. CP at 1289-1301 (Davis Decl. ¶ 21(b), Attach. D). The study showed that the median dispensing fees from the Medicare program and private insurance companies were far lower than the Authority's fees. CP at 1295. The Medicare and commercial fees range from

\$0.49 to \$1.09 (CP at 1295) while the Authority's fees range from \$4.24 to \$5.25. CP at 1149-50 (Davis Decl. ¶¶ 26, 27(b)). With respect to ingredient costs, the Authority had been paying the Average Wholesale Price minus 16% for single-source drugs (CP at 1384), while the Medicare and commercial payors were paying roughly the same, at Average Wholesale Price minus 15.4% (CP at 1295).

Ignoring the flexibility granted to the states by Section 30(A) and the federal rule, the Appellants decry the studies upon which the Authority relied in maintaining the level of dispensing fees. *See* Br. Appellants at 12-14, 33-36. The Appellants' critique is misguided. As mentioned, there was no statutory or regulatory requirement for the Authority to increase the fees.

Further, the Appellants do not dispute the payment levels listed in the studies, thereby conceding that Washington pharmacies accept dispensing fees from Medicare and private payors that are far below the Authority's rates. The Authority had no desire to reduce the fees. CP at 1147 (Davis Decl. ¶ 20).

It is ironic that the Appellants criticize the Authority's reliance on the Insurance Commissioner, Moda, and Milliman reports as insufficiently tied to Washington's Medicaid program when the Appellants themselves rely on portions of those reports as well as on out-of-state rates and reports,

none of which pertain to Washington. *See, e.g.*, Br. Appellants at 15-16, 31, and 36 (Insurance Commissioner’s report), 21-24 (out-of-state rates); CP at 305 (Miller Decl. ¶ 27, Exs. B-H) (out-of-state reports). The Appellants suggest that Washington must increase its rates merely because the dispensing fees from other states might be higher. *See* Br. Appellants at 21-24. However, the issue is not whether the rates in other states meet the federal standards or might otherwise be adequate. The issue is whether the Authority complied with federal and state law in amending its rules and maintaining the level of the dispensing fees. The Authority appropriately relied on independent analyses of Washington’s marketplace.

Furthermore, the Appellants inaccurately portray the Commissioner’s findings. According to the Appellants, the Commissioner “unequivocally conclud[ed] that dispensing fees should be in the range of \$10.” *See* Br. Appellants at 36. That is incorrect. CP at 1152 (Davis Decl. ¶ 31). The Commissioner did note the fees in certain other states, CP at 1222-23, but there is no conclusion—“unequivocal” or otherwise—about what the Authority should pay, because such a conclusion would have been outside the scope of the Commissioner’s task. CP at 1167 (outlining elements of the study). Importantly, the Commissioner (like the Appellants’ expert) noted the importance of the governing law of Section 30(A), with its focus on access to care by Medicaid clients. *See* CP at 152 n.47.

In addition, the Appellants mischaracterize CMS's comments about the evaluation of the two components of the payment methodology. *See* Br. Appellants at 11. The Appellants assert that the ingredient cost and the dispensing fee “must be adjusted in tandem.” *Id.* (quoting 81 Fed. Reg. at 5201). But the quote is merely paraphrasing a comment submitted to CMS. *See* 81 Fed. Reg. at 5201. In response to the comment, CMS did not say that the two components “must be adjusted in tandem”; instead, CMS observed that states must “evaluate” both components but that they retain “flexibility” in determining the rates. *See* 81 Fed. Reg. at 5202.

The Appellants appear to suggest that the federal rules compel a certain outcome, specifically that the Authority must increase the dispensing fees. *See, e.g.*, Br. Appellants at 28. As noted, the regulations require the Authority to “evaluate” both components when changing either one. *See* 42 C.F.R. § 447.518(d). But an evaluation does not necessarily lead to a higher fee. And the Authority did evaluate. CP at 1146-48 (Davis Decl. ¶¶ 17, 19, 21(a)).

The federal rules do not mandate “a specific formula or methodology” to determine the dispensing fees and do not compel a specific result. *See* 81 Fed. Reg. at 5294 (noting that states “maintain flexibility to establish and, if necessary, revise [their] professional dispensing fee in

accordance with” the amended rules). The conclusion desired by the Appellants is not supported by the federal rules or CMS guidance.

4. The Authority considered both aspects of the methodology when changing the ingredient cost component

The federal rule requires the Authority to “consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement” as part of its rule-making process. *See* 42 C.F.R. § 447.518(d). As explained above with respect to how the Authority “evaluated” the rate components, the Authority also met the “consideration” requirement. CP at 1148 (Davis Decl. ¶ 21(a), (b)). The plain language of the rule requires the Authority to consider, but not necessarily to adjust, both aspects of the methodology when proposing changes to either one. *See* 42 C.F.R. § 447.518(d). The Appellants do not assert that the Authority failed to consider both aspects; they simply do not like the result.

5. The Authority ensured that the pharmacy rates satisfy the Section 30(A) requirements

The federal rule requires the Authority to consider whether its payment rates will be “in accordance with” the Section 30(A) standards. *See* 42 C.F.R. § 447.518(d); *see also* 42 C.F.R. § 447.500(a)(5); 81 Fed. Reg. at 5174. The Authority met this requirement. Under Section 30(A), the Medicaid State Plan must:

provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to *assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers* so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area[.]

See 42 U.S.C. § 1396a(a)(30)(A) (emphasis added); *Armstrong*, 135 S. Ct. at 1382.

The Authority's rates satisfy the Section 30(A) standards of efficiency, economy, quality of care, and access to care. The Appellants claim the Authority was restricted to examining pharmacy costs, but nothing else. *See* Br. Appellants at 30. By its plain language, Section 30(A) is concerned about much more than a provider's costs. As such, the federal rule, which incorporates the statute, requires the Authority to consider factors other than costs. *See* 42 C.F.R. § 447.518(d); CP at 1157-58, 1162 (Davis Decl., Attach. A (CMS letter dated February 11, 2016)).

Section 30(A) contains "flexible, administrative standards" for the setting of payment rates. *Sanchez v. Johnson*, 416 F.3d 1051, 1059 (9th Cir. 2005). The standards are "broad and nonspecific." *Armstrong*, 135 S. Ct. at 1388 (Breyer, J., concurring). This is because Section 30(A) "is concerned with a number of competing interests." *Sanchez*,

416 F.3d at 1059. In particular, the requirements for efficiency and economy could potentially conflict with the requirements for quality of care and access to care. *Id.* As a result, the statute “is concerned with [the] overall methodology” that the Authority employs. *Id.*; *see also* CP at 1146 (Davis Decl. ¶ 16).

The methods that states use to determine the sufficiency of rates under Section 30(A) may involve consideration of many factors, such as the personnel and operating costs involved in providing quality services, public expectations regarding those services, inflation, and comparing the state’s rates with neighboring states and with rates paid within the state by other public and private entities. *Armstrong*, 135 S. Ct. at 1388 (Breyer, J., concurring).

The out-of-state studies offered by the Appellants’ expert demonstrate that compliance with Section 30(A) is the primary determinant of the adequacy of pharmacy rates. CP at 454 (Decl. of Dr. Laura Miller dated April 20, 2017 (“Miller Decl.”), Ex. C at 9) (California study); CP at 555 (Miller Decl., Ex. E at 6) (Idaho study); CP at 700-01 (Miller Decl., Ex. G at 5-6) (Oregon study). One study cited by Dr. Miller concluded as follows:

Perhaps the most important factor to consider [in setting rates] is the need to maintain sufficient patient access to pharmacy services for Medicaid recipients throughout the

state. Medicaid pharmacy programs must be aware of the issue of accessibility of services and ensure that reimbursement levels are adequate to provide Medicaid recipients with reasonable levels of access to pharmacy services.

See CP at 555 (Idaho study) (citing to Section 30(A)).

An analysis of market dynamics, including the payment rates accepted by pharmacies from other payers) is an additional component of the assessment of Medicaid dispensing fees.

Id.

Using similar language regarding access to services, but with additional detail, another study cited by Dr. Miller concluded as follows:

One way to evaluate accessibility to services is to analyze pharmacy participation levels as well as any additional data sources available for tracking complaints about recipient access to services. A high level of pharmacy participation and low levels of complaints about access might suggest that there are not any problems regarding access to services under [the state's] reimbursement levels.

See CP at 700 (Oregon study) (citing to Section 30(A)).

The studies from the Appellants' expert support the process the Authority used to determine the rates in connection with its amended rules. The Authority adhered to what those reports advise, with a focus on access to pharmacy services and the level of pharmacy participation in the program, as part of overall compliance with Section 30(A). CP at 1142, 1146 (Davis Decl. ¶¶ 7, 17).

At the trial court, the Appellants attempted to back away from their expert and her reports. *See* Appendix C (RP at 48:15-22). The Appellants suggested their reports should be ignored because they predate the amended federal rules. *Id.* The Appellants repeat the effort here, claiming that federal law prohibits the consideration of any non-cost factors. *See* Br. Appellants at 30. But as noted, the federal rules are tied to the non-cost factors specified in Section 30(A). *See* 42 C.F.R. §§ 447.500(a)(5), .518(d). Plus, the pertinent provisions of the federal rules regarding the dispensing fee methodology have not changed since the reports were issued.

There is no evidence that Medicaid clients have had a problem with access to pharmacy services under the amended rules. A high percentage of licensed Washington pharmacies choose to participate in Medicaid's fee-for-service pharmacy network, with 1,477 pharmacies as active providers in the network. CP at 1153 (Davis Decl. ¶ 34). The Appellants presented no evidence that the amended rules have adversely affected this high level of participation. *Id.* (pharmacy participation has remained constant).

In denying the Appellants' Motion for Temporary Restraining Order four days after the effective date, the U.S. District Court correctly focused on access, one of the Section 30(A) factors:

I don't know whose numbers are right, but whether it is a million dollars a year or \$12 million a year, I still don't have enough in the record that tells me that there will be an access

problem here. The numbers seem to indicate just the opposite, that the amount is sufficiently small as to not interfere with either the large or small pharmacies.

See Appendix B (April 4, 2017, TRO hearing transcript at 33:19-25).

Furthermore, while any alleged financial harm to the pharmaceutical industry is irrelevant to the legal issues, the Appellants presented no evidence that the Authority's rules have caused any such harm. Dr. Miller had opined that pharmacies collectively might lose about \$12 million per year. CP at 310 (Miller Decl. ¶ 43); *see also* Br. Appellants at 25. The estimate was significantly inflated because it was based on a flawed understanding of the new method of paying for ingredient costs. CP at 1150 (Davis Decl. ¶ 28) (“[p]harmacies are not being paid less than they were last year”).

Dr. Miller also failed to consider the steps the Authority took to ensure pharmacies are paid their actual costs for the drug ingredients. CP at 1152 (Davis Decl. ¶ 32). Finally, Dr. Miller was merely speculating as to what might happen; there is no evidence that any pharmacy has lost money on Medicaid services since the amendments became effective.

The Authority was required to consider the Section 30(A) factors when amending its rules and deciding upon the rates. *See* 42 C.F.R. § 447.518(d). And it did. The Authority was not strictly limited to examining pharmacy costs. The Authority complied with the federal rule.

6. The Authority relied upon adequate data to support changing the ingredient cost methodology

The federal rule requires the Authority to provide CMS with “adequate data” (such as a survey) or “other reliable data” (if not a survey) when proposing changes to either component of the payment methodology. *See* 42 C.F.R. § 447.518(d). The Authority satisfied this requirement by relying upon three separate and independent studies when amending its rules and determining its rates, which constitute “adequate data.”

The Authority, as described above, evaluated the levels of its payments for ingredient costs and dispensing fees independently and in the aggregate to determine the sufficiency of the overall reimbursement. CP at 1147-48 (Davis Decl. ¶¶ 19, 20, 21(a)); *see also* 42 C.F.R. § 447.518(d). In its guidance letter, CMS stressed that it was “not intend[ing] to mandate a specific formula or methodology that states must use to determine the professional dispensing fee.” CP at 1161. The independent studies from the Insurance Commissioner, Moda, and Milliman are adequate data for purposes of establishing compliance with the federal rules and, in turn, Section 30(A).

The Authority undertook the necessary review and made the required conclusion that its amended rules comply with Section 30(A) and the federal rules. CP at 1147-48 (Davis Decl. ¶¶ 19, 20, 21(a)). There is no

evidence, under the Section 30(A) standards, of lack of access to care by Medicaid clients or a problem with quality of care.⁴

7. The Authority submitted the methodology changes to CMS through a State Plan Amendment

The federal rule requires the Authority to submit to CMS, through a State Plan Amendment, any proposed changes to its pharmacy payment methodology. *See* 42 C.F.R. § 447.518(d). It is undisputed that the Authority satisfied this requirement. CP at 993 (Myers Decl. ¶ 10, Attach. D). In the amendment, the Authority provided the necessary assurance that it is complying with federal standards. CP at 993, 1019 (Myers Decl. ¶ 10, Attach. D).

C. The Authority’s Rules and Dispensing Fees Are Not Arbitrary and Capricious

The Court should uphold the Authority’s actions because it was not arbitrary and capricious for the Authority to (1) rely upon three independent

⁴ Although styled as a challenge under the APA’s “error of law” standard, this case illustrates the wisdom of decisions from federal courts that Medicaid providers cannot sue the states in federal court over allegations of noncompliance with Section 30(A). The Appellants could not pursue a Section 30(A) claim under either the Supremacy Clause, *Armstrong*, 135 S. Ct. at 1384, or 42 U.S.C. § 1983, *Sanchez*, 416 F.3d at 1060-61. “[T]he sole remedy Congress provided for a State’s failure to comply with Medicaid’s requirements—for the State’s ‘breach’ of the Spending Clause contract—is the withholding of Medicaid funds by the Secretary of Health and Human Services.” *Armstrong*, 135 S. Ct. at 1385 (citing 42 U.S.C. § 1396c). In addition, the Appellants could ask CMS “to interpret its rules to [their] satisfaction, to modify those rules, to promulgate new rules or to enforce old ones[.]” *Armstrong*, 135 S. Ct. at 1389 (Breyer, J., concurring). The Appellants also could sue CMS if it approves the State Plan Amendment. *Hoag Mem’l Hosp. Presbyterian v. Price*, 866 F.3d 1072, 1075 (9th Cir. 2017). “The history of ratemaking demonstrates that administrative agencies are far better suited to [the] task [of rate making] than judges.” *Armstrong*, 135 S. Ct. at 1388 (Breyer, J., concurring).

studies to inform its decision-making in determining the methodology and rates and (2) review all of the Section 30(A) factors when examining the methodology and rates.

The Appellants allege that the Authority was arbitrary and capricious by (1) “cherry-picking” data that would support a certain level of dispensing fees; (2) using the Insurance Commissioner, Moda, and Milliman reports but not a cost-of-dispensing study; and (3) allowing its pharmacy rates manager to steer the agency toward a preordained result. *See Br. Appellants at 12, 17, 33-34.*

“[A]gency action is arbitrary and capricious if it is willful and unreasoning and taken without regard to the attending facts or circumstances.” *Wash. Indep. Tel. Ass’n v. Wash. Util. and Transp. Comm’n*, 148 Wn.2d 887, 905, 64 P.3d 606 (2003). It was not “cherry-picking” for the Authority to analyze and refer to the Insurance Commissioner and Moda studies, over which the Authority exercised no control. The mere fact that the Appellants can “deriv[e] conflicting conclusions from” those reports does not render the Authority’s decision arbitrary and capricious. *Rios*, 145 Wn.2d at 504.

Similarly, the Milliman report was valid in that it provided further information specific to Washington’s pharmacy marketplace. CP at 1289. By examining all factors relevant to Washington’s market, the report helped

the Authority to consider the Section 30(A) factors of efficiency, economy, quality of care, and access to care (which are incorporated into the federal rule) when determining whether to adjust the dispensing fees. *See* 42 C.F.R. § 447.518(d).

The Appellants also assert that it was arbitrary and capricious for the Authority to fail to conduct a cost-of-dispensing study before finalizing its rules. *See* Br. Appellants at 12, 17, 34. As discussed above, there is nothing in federal law or federal guidance requiring a cost-of-dispensing study, the amended federal rules did not change the substance of what constitutes the professional dispensing fee, and CMS has approved the fees under those standards since 2009.

To the Appellants, it also was arbitrary and capricious for the Authority's pharmacy rates manager to have an opinion on the level of the dispensing fee. *See* Br. Appellants at 12-13, 18, 34. The Appellants are incorrect. The actions were those of the Authority overall, not merely one individual. Plus, the rules were the product of a transparent public process done in accordance with the APA and federal requirements, which the Appellants do not challenge. *See* Br. Appellants at 25 n.8; CP at 888-91 (Barcus Decl. ¶¶ 4-17) (public notice and comment under the APA); CP at 992-93 (Myers Decl. ¶ 7) (public notice of State Plan Amendment).

In addition, it would be rather surprising for a manager with more than 17 years of experience with the Medicaid program, including 12 years in the complex area of pharmacy reimbursement, to not have a viewpoint on critical issues involving the very program she is responsible for administering. CP at 1140, 1146 (Davis Decl. ¶¶ 2, 17). In any event, the Court “should not probe the mental processes of administrative officials in making decisions.” *Nationscapital Mortg. Corp. v. State Dep’t of Fin. Insts.*, 133 Wn. App. 723, 762, 137 P.3d 78 (2006). Instead, courts “presume public officers perform their duties properly, legally, and in compliance with controlling statutory provisions.” *Id.* at 763 (quoting *Ledgering v. State*, 63 Wn.2d 94, 101, 385 P.2d 522 (1963)).

Finally, there is no evidence that any of Ms. Davis’s alleged beliefs influenced the independent analyses from the Insurance Commissioner, Moda, or Milliman. The Authority had no input into the reports of the Commissioner and Moda, and there is no evidence that the Milliman report was skewed by any alleged bias from the program manager.

The Authority took its actions with due regard to “the attending facts [and] circumstances” regarding the Washington marketplace and the Medicaid program. *Wash. Indep. Tel.*, 148 Wn.2d at 905. The actions were not arbitrary and capricious.

It also was not arbitrary and capricious for the Authority to not publish the dispensing fee amounts in its amended rules. While the Appellants have withdrawn their due process claim (*see* Br. Appellants at 25 n.8), they paint an inaccurate picture of the rule-making process by claiming they were unaware until after the process that the Authority would not be increasing the fees. *See* Br. Appellants at 15. The claim is inaccurate for two reasons.

First, the specific monetary amount of the dispensing fee has never been contained in published Medicaid rules but, instead, in subregulatory guidance. CP at 1149-50 (Davis Decl. ¶¶ 26-27). The APA does not require the fee amounts to be part of the rules. *See* RCW 34.05.030(4)(a) (exempting “[r]eimbursement unit values” and other “arithmetic factors” for Medicaid payments from rule-making requirements).

Second, as outlined above, the Authority engaged in a lengthy rule-making process that included all elements that the APA does require. The Association submitted comments regarding the draft rules, offering its views on both the ingredient cost and dispensing fee components, to which the Authority responded. CP at 889 (Barcus Decl. ¶ 8, Attach. E). The Association was aware that the dispensing fees would not increase. *Id.*

The federal rules do not provide a basis to grant any relief to the Appellants, and they have not met their “heavy burden” of proving the Authority’s rules should be invalidated. *Karanjah*, 199 Wn. App. at 925.

VI. CONCLUSION

The Court should uphold the Authority’s actions. The Authority complied with the federal rules and the APA in issuing its amended pharmacy payment methodology rules and deciding to maintain the level of dispensing fees. The Appellants have failed to meet their burden of proving the invalidity of the Authority’s actions.

RESPECTFULLY SUBMITTED this 24th day of July 2018.

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PROOF OF SERVICE

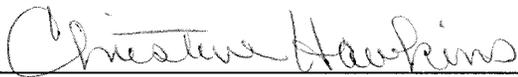
I certify that I served a copy of this document on all parties or their counsel of record on the date below as follows:

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I certify under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.

DATED this 24th day of July 2018, at Tumwater, WA.


CHRISTINE HAWKINS, Legal Assistant

APPENDIX A

Hawkins, Christine (ATG)

From: ECF@wawd.uscourts.gov
Sent: Wednesday, April 05, 2017 12:03 PM
To: ECF@wawd.uscourts.gov
Subject: Activity in Case 3:17-cv-05236-BHS National Association of Chain Drug Stores et al v. Washington State Health Care Authority et al TRO Hearing

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U.S. District Court

United States District Court for the Western District of Washington

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Case Name: National Association of Chain Drug Stores et al v. Washington State Health Care Authority et al
Case Number: [3:17-cv-05236-BHS](#)
Filer:
Document Number: 19(No document attached)

Docket Text:

MINUTE ENTRY for TRO Hearing held on 4/4/2017 before Judge Benjamin H. Settle - Dep Clerk: *Gretchen Craft*; Pla Counsel: *Virginia Nicholson*; Def Counsel: *Angela Coats McCarthy, William Stephens*; CR: *Barry Fanning*; Time of Hearing: 2:00; Courtroom: E; Court hears arguments and DENIES the [5] MOTION for Temporary Restraining Order, as stated on the record. Briefing on issue of jurisdiction is due by 4/21/2017. (MGC)

3:17-cv-05236-BHS Notice has been electronically mailed to:

Jeffrey S Eden jeden@schwabe.com, centraldocket@schwabe.com, gvance@schwabe.com, nsramek@schwabe.com, scrawford@schwabe.com

William T Stephens bills3@atg.wa.gov, Bstephens@harbornet.com, ChristineH1@atg.wa.gov, HilaryS@atg.wa.gov, NicoleB3@atg.wa.gov

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Angela D. Coats McCarthy AngelaC3@atg.wa.gov, ChristineH1@atg.wa.gov, NicoleB3@atg.wa.gov

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APPENDIX B

1 UNITED STATES DISTRICT COURT
2 WESTERN DISTRICT OF WASHINGTON
3 IN TACOMA

4 NATIONAL ASSOCIATION OF)
5 CHAIN DRUG STORES, et al.,)
6 Plaintiffs,) No. CV17-5236BHS
7 v.)
8 WASHINGTON STATE HEALTH)
9 CARE AUTHORITY, et al.,)
10 Defendants.)

11 TRO HEARING
12

13
14 April 4, 2017

15
16 BEFORE THE HONORABLE BENJAMIN S. SETTLE
17 UNITED STATES DISTRICT COURT JUDGE

18
19
20 APPEARANCES:

21 For the Petitioners: Virginia Nicholson
22 Jeffrey Eden
23 SCHWABE WILLIAMSON & WYATT

24 For the Respondents: Angela Coats-McCarthy
25 William Stephens
26 ATTORNEY GENERAL'S OFFICE
27 SOCIAL & HEALTH SERVICES

01:56:07PM 1 THE CLERK: This is the matter of the National
02:00:49PM 2 Association of Chain Drug Stores versus Washington State
02:00:53PM 3 Health Care Authority, Cause No. CV17-5236BHS. Counsel,
02:00:59PM 4 please make an appearance for the record.

02:01:01PM 5 MS. NICHOLSON: Good afternoon, your Honor. My
02:01:03PM 6 name is Virginia Nicholson, Schwabe, Williamson & Wyatt,
02:01:04PM 7 on behalf of the pharmacy associations.

02:01:06PM 8 THE COURT: Good afternoon.

02:01:07PM 9 MS. COATS-McCARTHY: Your Honor, my name is
02:01:08PM 10 Angela Coats-McCarthy. I am with the Washington Attorney
02:01:13PM 11 General's Office, representing the Health Care Authority.

02:01:15PM 12 MR. STEPHENS: Bill Stevens with the AG's office,
02:01:20PM 13 also representing the Health Care Authority.

02:01:22PM 14 THE COURT: Good afternoon, everyone. This
02:01:25PM 15 hearing was set by the court. Setting out a little bit of
02:01:29PM 16 procedural history first. Now, on March 31st, the
02:01:34PM 17 petitioners filed a motion to remand and a motion for
02:01:37PM 18 temporary restraining order, seeking to stay the
02:01:42PM 19 implementation by the respondents of the newly-adopted
02:01:47PM 20 rule that changes the method of establishing Medicaid
02:01:52PM 21 rates of cost reimbursement to retail pharmacies here in
02:01:55PM 22 the state.

02:01:56PM 23 The court, believing that there needed to be a
02:02:03PM 24 hearing on this matter, and that a TRO need not be entered
02:02:08PM 25 immediately last week, I, again, set this hearing.

—Barry L. Fanning, RMR, CRR - Official Court Reporter—

(206) 370-8507 Barry_Fanning@WAWD.uscourts.gov
1717 Pacific Ave - Tacoma, WA 98402

Appendix B

02:02:13PM 1 Now, the threshold question is first presented in the
02:02:20PM 2 petitioners' motion for remand. The petitioners contend
02:02:24PM 3 that, while conceding there is no private right of action
02:02:27PM 4 under Title 19 of the federal Social Security Act of 1935,
02:02:33PM 5 they insist that they are not pursuing a private right of
02:02:37PM 6 action, because their claim alleges a violation of Title
02:02:40PM 7 19 as only an element of their state cause of action, and
02:02:44PM 8 does not state a claim arising then under federal law.

02:02:54PM 9 The absence of a federal private cause of action,
02:02:59PM 10 however, does not mean the court lacks federal
02:03:02PM 11 jurisdiction in this case. This is from *Grable & Sons*
02:03:11PM 12 *Metal Products*, the 2005 Supreme Court case. The quote
02:03:17PM 13 there is, "The question is, does a state-law claim
02:03:21PM 14 necessarily raise a stated federal issue, actually
02:03:26PM 15 disputed and substantial, which a federal forum may
02:03:30PM 16 entertain without disturbing any congressionally approved
02:03:34PM 17 balance of the federal and state judicial
02:03:37PM 18 responsibilities."

02:03:39PM 19 In this case, two of the three state law claims in
02:03:42PM 20 the petition for declaratory relief are based on
02:03:45PM 21 allegations that respondents violated federal rules.

02:03:50PM 22 Respondents argue that these claims are based on
02:03:53PM 23 substantial federal questions, which is a sufficient
02:03:55PM 24 allegation to establish jurisdiction at this time.

02:04:00PM 25 Although petitioners have challenged this allegation,

02:04:03PM 1 the record must be further developed for full
02:04:08PM 2 consideration of the issues in dispute.

02:04:11PM 3 The court is satisfied, for the purpose of this
02:04:15PM 4 hearing, and from the face of the complaint, and the
02:04:19PM 5 allegations in the notice of removal, that the court has
02:04:24PM 6 jurisdiction to hear the motion for temporary relief.

02:04:29PM 7 Now, I believe that the docket has it noted for
02:04:39PM 8 April 28th. The court wanted an accelerated response from
02:04:46PM 9 the state. But this is where I think further development
02:04:52PM 10 of this question of whether there is subject matter
02:04:56PM 11 jurisdiction needs to be fleshed out, looking at the rule
02:05:05PM 12 here in Grable & Sons Metal Products, because I think this
02:05:12PM 13 is still a very live question for the court. But, as I
02:05:18PM 14 said, there is sufficient information in the record for
02:05:22PM 15 the court to preliminarily conclude there would be subject
02:05:29PM 16 matter jurisdiction here.

02:05:34PM 17 That will then turn our attention to the actual
02:05:37PM 18 motion for temporary restraining order. The court has
02:05:41PM 19 read the pleadings filed. Although I have not dug deep
02:05:50PM 20 into the 286 pages of record yet. I will hear then from
02:05:59PM 21 Ms. Nicholson on your argument as to why the court should
02:06:07PM 22 grant the relief requested, temporarily.

02:06:11PM 23 MS. NICHOLSON: Thank you, your Honor. Your
02:06:17PM 24 Honor, we represent the National Association of Chain Drug
02:06:20PM 25 Stores, which are basic drug stores, pharmacies in mass

02:06:26PM 1 market -- excuse me, mass merchants with pharmacies. And
02:06:30PM 2 this is 332 pharmacies (sic), employing 72,000 people in
02:06:35PM 3 the state of Washington.

02:06:35PM 4 THE COURT: What portion, do you think, of all
02:06:38PM 5 pharmacies does that represent? Three hundred and how
02:06:42PM 6 many?

02:06:48PM 7 MS. NICHOLSON: Nine hundred and thirty-two
02:06:48PM 8 pharmacies, employing 72,000 people from this organization
02:06:51PM 9 alone in the state of Washington.

02:06:51PM 10 THE COURT: Nine hundred and thirty-two?

02:06:55PM 11 MS. NICHOLSON: Nine hundred and thirty-two.
02:06:56PM 12 This would include the Costcos and any mass merchants that
02:06:59PM 13 have pharmacies associated.

02:06:59PM 14 THE COURT: In the state of Washington?

15 MS. NICHOLSON: In the state of Washington.

02:07:00PM 16 THE COURT: Would you say that is a pretty
02:07:01PM 17 exhaustive list of pharmacies within the state? Are most
02:07:05PM 18 pharmacies members of your organization?

02:07:07PM 19 MS. NICHOLSON: I wouldn't say most, because
02:07:08PM 20 these are for the chains. We also represent the National
02:07:11PM 21 Community Pharmacies Association. They represent owners,
02:07:15PM 22 managers, technicians for independent community
02:07:19PM 23 pharmacies. They operate 324 stores. That wouldn't be
02:07:22PM 24 included in the other organization.

02:07:23PM 25 THE COURT: Again, all within the state of

02:07:25PM 1 Washington?

02:07:25PM 2 MS. NICHOLSON: All within the state of
02:07:26PM 3 Washington. Those stores dispense over 3 million
02:07:29PM 4 prescriptions to Medicaid patients.

02:07:32PM 5 We also represent the Washington State Pharmacy
02:07:36PM 6 Association. They represent pharmacists, technicians,
02:07:38PM 7 corporate members that provide care to Medicaid patients
02:07:42PM 8 throughout Washington's underserved communities. How many
02:07:45PM 9 of their members are members of the other two
02:07:47PM 10 organizations, I am not aware.

02:07:50PM 11 Again, your Honor, what brings us here is the
02:07:54PM 12 Healthcare Authority's -- I am going to say HCA -- new
02:07:58PM 13 rule regarding total reimbursements to
02:08:03PM 14 Medicaid-participating pharmacies in the state of
02:08:04PM 15 Washington.

02:08:04PM 16 The new rule is invalid and it is wrongful.
02:08:08PM 17 Implementation of the rule would immediately harm
02:08:10PM 18 Washington Medicaid participating pharmacies. They would
02:08:14PM 19 be reimbursed at over \$12 million below the cost of
02:08:18PM 20 actually providing the prescriptions to Medicaid patients.

02:08:21PM 21 THE COURT: Would that \$12 million be shared
02:08:24PM 22 among the -- that loss that you are talking about, among
02:08:27PM 23 the nearly 1,000 pharmacies?

02:08:30PM 24 MS. NICHOLSON: Yes, that is shared amongst all
02:08:32PM 25 the pharmacies. And that is a yearly figure.

02:08:34PM 1 THE COURT: My math would tell me that if it is
02:08:40PM 2 \$12 million estimated annually for the 1,000 pharmacies,
02:08:44PM 3 would be, roughly, a thousand dollars a month per
02:08:51PM 4 pharmacy.

02:08:52PM 5 MS. NICHOLSON: That is, roughly, correct, your
02:08:53PM 6 Honor. But you also have to take into account the size of
02:08:56PM 7 the pharmacies that we are dealing with, from very small
02:08:58PM 8 pharmacies in rural areas and underserved areas, to
02:09:01PM 9 big-chain pharmacies. There is a vast difference on how
02:09:04PM 10 that impact would affect --

02:09:06PM 11 THE COURT: Certainly. One would expect the
02:09:09PM 12 larger chain pharmacies that have larger volume would be
02:09:12PM 13 more than a thousand, but smaller pharmacies would be
02:09:15PM 14 less.

02:09:17PM 15 MS. NICHOLSON: That's correct. The impact on
02:09:19PM 16 the smaller pharmacies would absolutely be more.

02:09:21PM 17 THE COURT: I understand.

02:09:22PM 18 MS. NICHOLSON: Under the current rules, total
02:09:24PM 19 reimbursement for a Medicaid prescription has two
02:09:28PM 20 components: There is the ingredient cost and the
02:09:31PM 21 dispensing fee. These are considered together as the
02:09:33PM 22 total reimbursement.

02:09:36PM 23 Until March 31st, the total ingredient cost was an
02:09:40PM 24 estimated cost of acquiring the drug. The dispensing fee
02:09:46PM 25 was from \$4.24 to \$5.25, depending on the size of the

02:09:52PM 1 pharmacy, for a prescription. That range is set by the
02:09:56PM 2 HCA, and hasn't been changed since at least 2009.

02:09:59PM 3 THE COURT: I take it that this cost includes a
02:10:03PM 4 margin or profit. There must be some place in there that
02:10:09PM 5 there is a profit for the pharmacies.

02:10:11PM 6 MS. NICHOLSON: Well, you have to think about
02:10:13PM 7 this in tandem. This will help explain it: This cost of
02:10:18PM 8 the ingredient cost reimbursement, when it goes from an
02:10:22PM 9 estimated acquisition cost to the actual acquisition cost,
02:10:27PM 10 that's a \$6.4 million decrease in revenue for the
02:10:32PM 11 Washington pharmacies. So that's where that might be.

02:10:36PM 12 The dispensing fee should be, under the CMS rules,
02:10:39PM 13 the actual cost of dispensing. But there is a little bit
02:10:43PM 14 of play there -- or there was.

02:10:45PM 15 THE COURT: Again, there has to be a profit in
02:10:48PM 16 one of those two figures, or both --

02:10:51PM 17 MS. NICHOLSON: Correct.

02:10:52PM 18 THE COURT: -- in order for them to be able to
02:10:53PM 19 stay in business.

02:10:54PM 20 MS. NICHOLSON: What I'm saying, your Honor, on
02:10:56PM 21 the dispensing fee, that's low, and the ingredient cost
02:11:01PM 22 was higher. So there is a balance between the two for the
02:11:04PM 23 total reimbursement.

02:11:05PM 24 What this new rule does, your Honor, is it takes this
02:11:09PM 25 part of the fee, this ingredient cost, changes it from

02:11:12PM 1 estimated to actual, the \$6.4 million reduction in
02:11:16PM 2 revenue, and it holds this cost, the dispensing fee,
02:11:19PM 3 artificially low.

02:11:20PM 4 Now, what the rule requires is that this cost be the
02:11:23PM 5 actual cost. It has to be sufficient to cover the actual
02:11:26PM 6 cost of the ingredients.

02:11:28PM 7 And on the dispensing fee side, the new professional
02:11:31PM 8 dispensing fee, it is supposed to cover the actual cost of
02:11:35PM 9 dispensing the drug. That includes the operation of the
02:11:38PM 10 pharmacy, employing the pharmacists that serve the
02:11:41PM 11 Medicaid patients. It has to include the actual cost.

02:11:46PM 12 And just via a common sense argument, if that hasn't
02:11:49PM 13 moved since 2009, it is not covering the actual costs that
02:11:54PM 14 the pharmacies incur to dispense the drugs.

02:11:56PM 15 In fact, the OIC study -- I am getting ahead of
02:11:59PM 16 myself. But there is an OIC study that the legislature
02:12:03PM 17 directed the Office of Insurance Commissioner to conduct.
02:12:05PM 18 And they determined that the actual cost to dispense per
02:12:09PM 19 prescription is over \$10 in the state of Washington. So
02:12:15PM 20 it is the two.

02:12:17PM 21 So when they changed the ingredient costs -- actual
02:12:21PM 22 ingredient costs, and they hold down the professional
02:12:23PM 23 dispensing fee to below the cost of what it costs to
02:12:26PM 24 dispense, that's the over \$12 million figure that the
02:12:29PM 25 pharmacies will be -- they would be reimbursed over

02:12:33PM 1 \$12 million less than their actual cost.

02:12:41PM 2 THE COURT: Let's go back to the irreparable
02:12:44PM 3 harm. The \$12 million is the damage being caused
02:12:50PM 4 annually. I am still not convinced that equitable relief
02:12:55PM 5 is required where this is an economic measurable, and one
02:13:06PM 6 in which, it appears to me, is sustainable pending this
02:13:10PM 7 litigation by individual pharmacies.

02:13:15PM 8 In any case, I don't see enough in the record to show
02:13:18PM 9 how this would -- other than just the opinion itself that
02:13:22PM 10 it is \$12 million, how that would impact individual
02:13:25PM 11 pharmacies. That seems to be lacking in the record at
02:13:29PM 12 this point.

02:13:30PM 13 MS. NICHOLSON: Your Honor, what we would like is
02:13:32PM 14 to be able to provide that for you. We had very little
02:13:35PM 15 notice to get this together. We were not informed that
02:13:39PM 16 they intended to not -- to adjust that fee to actual costs
02:13:43PM 17 until March 2nd. That was a full 30 days after the
02:13:47PM 18 comment period had ended, and that was after they sent the
02:13:50PM 19 final rule to the code reviser. That's when the
02:13:53PM 20 pharmacies were notified. Those were some of the
02:13:56PM 21 procedural errors that I can go through. But we didn't
02:13:59PM 22 have the time to go through and build a full record before
02:14:03PM 23 this TRO hearing.

02:14:04PM 24 Your Honor, I would like to call attention to one
02:14:06PM 25 thing. In 2009, that is fully eight years ago, the same

02:14:09PM 1 exact thing occurred, where the HCA -- then it was DSHS,
02:14:15PM 2 wanted to move the ingredient cost to actual cost, and
02:14:18PM 3 leave the dispensing fee the same.

02:14:20PM 4 At that time we had three months. We had pharmacists
02:14:23PM 5 submit declarations, and on the record the court
02:14:26PM 6 determined that there was irreparable harm, because the
02:14:29PM 7 pharmacies can't sustain that level of loss per Medicaid
02:14:34PM 8 prescription, especially in the areas of rural and
02:14:37PM 9 underserved communities.

02:14:39PM 10 I would like to bring that opinion to your attention,
02:14:46PM 11 your Honor. I have copies of that. In that case the TRO
02:14:49PM 12 was granted. Here it is. May I approach the bench?

02:14:54PM 13 THE COURT: Yes.

02:15:08PM 14 MS. NICHOLSON: Your Honor, the court found --
02:15:11PM 15 This is a different -- It was a different time, it was
02:15:13PM 16 under a different request for relief, but the facts are
02:15:18PM 17 exactly the same. So under those exact same facts the
02:15:23PM 18 court found that the rate cut would harm Washington
02:15:29PM 19 Medicaid patients and would harm the pharmacies, and found
02:15:32PM 20 irreparable harm to grant the TRO.

02:15:35PM 21 THE COURT: The Medicaid patients would be harmed
02:15:38PM 22 because why?

02:15:39PM 23 MS. NICHOLSON: Your Honor, the pharmacies can't
02:15:41PM 24 sustain that type of loss per Medicaid prescription.

02:15:46PM 25 THE COURT: Over what period of time?

02:15:48PM 1 MS. NICHOLSON: I don't know the exact period of
02:15:50PM 2 time, your Honor. Certainly they are going to have to
02:15:52PM 3 immediately adjust, whether that is closing -- less hours,
02:15:56PM 4 whether that is laying off pharmacists, whether that is
02:15:59PM 5 closing up a smaller branch. All of those things have an
02:16:04PM 6 impact on every single Medicaid patient in this state, or
02:16:10PM 7 could. And that harm is significant.

02:16:14PM 8 Moreover, your Honor, when we are talking about
02:16:17PM 9 irreparable harm, if we are staying in federal court, this
02:16:21PM 10 \$12 million over the year, there is no way for our clients
02:16:25PM 11 to recoup that. They can't sustain a complaint for
02:16:28PM 12 damages in the state against their own state. So that's
02:16:32PM 13 an irreparable harm right there.

02:16:35PM 14 In addition --

02:16:44PM 15 THE COURT: I need that more developed. In other
02:16:47PM 16 words, if the reimbursement rate was arrived at
02:16:51PM 17 erroneously, and is therefore invalid, then wouldn't the
02:16:58PM 18 previous reimbursement rate remain in effect? And why
02:17:04PM 19 wouldn't the pharmacies be able to, once the rule is
02:17:11PM 20 declared invalid, indicate they have past due amounts
02:17:15PM 21 under the old rate, which is now the existing rate?

02:17:19PM 22 MS. NICHOLSON: Because they can't sue for
02:17:22PM 23 damages in this state under the Eleventh Amendment. So
02:17:24PM 24 they couldn't sue for the monetary damages.

02:17:26PM 25 THE COURT: Is that suing for damages, or is that

02:17:28PM 1 just making an administrative claim through the -- As
02:17:32PM 2 they are now -- they get reimbursed now through the Health
02:17:37PM 3 Care Authority.

02:17:37PM 4 MS. NICHOLSON: They do.

02:17:38PM 5 THE COURT: It seems to me -- Although I don't
02:17:40PM 6 know. It has not been briefed. It seems to me if this is
02:17:43PM 7 an invalid rule, it is just a matter of processing the
02:17:48PM 8 claim under the same rights that they have currently to
02:17:52PM 9 get reimbursement for their costs.

02:17:56PM 10 MS. NICHOLSON: There is a way that they can --
02:17:59PM 11 if CMS reviews the state plan and rejects it, then the
02:18:04PM 12 rates would return back to the normal rate.

02:18:06PM 13 THE COURT: Or if the court overturned it.

02:18:09PM 14 MS. NICHOLSON: Or if the court overturned it.
02:18:11PM 15 If the court overturned it, and it goes back to the same
02:18:13PM 16 rate, we still have that time period in which the
02:18:16PM 17 reimbursements were not proper.

02:18:18PM 18 THE COURT: Why wouldn't they be able to have
02:18:20PM 19 administrative claims processed under the now again
02:18:26PM 20 existing rate? Not the new rate. If they were reimbursed
02:18:31PM 21 only at 90 percent of their cost under the new rate, as
02:18:37PM 22 adopted by the HCA, why wouldn't they be able to process a
02:18:44PM 23 claim for the full reimbursement that they were entitled
02:18:48PM 24 to under the only rule that is valid?

02:18:52PM 25 MS. NICHOLSON: I am unaware of the process they

02:18:55PM 1 would go through to do that, your Honor. I would love the
02:18:58PM 2 opportunity to brief that.

02:18:59PM 3 THE COURT: You will get an opportunity, I think.

02:19:03PM 4 MS. NICHOLSON: I would like to mention another
02:19:05PM 5 element of irreparable harm. What happened here, your
02:19:08PM 6 Honor, is we were -- we brought state law claims. That is
02:19:12PM 7 the only claims that we can bring under the APA for an
02:19:15PM 8 improper rule that was unlawful. That's the way to
02:19:19PM 9 challenge it, you file a petition for declaratory relief.
02:19:23PM 10 Once that is filed, then you can file your emergency
02:19:26PM 11 motion for relief to stay.

02:19:28PM 12 So that's what our client did. We filed the
02:19:33PM 13 petition, we gave plenty of advance notice of what we were
02:19:36PM 14 doing with the emergency notice. At least we tried. We
02:19:40PM 15 gave them a draft copy of the emergency motion so that
02:19:42PM 16 they could be there when we were arguing this ex parte in
02:19:45PM 17 Thurston County Superior Court.

02:19:48PM 18 On the way there, when they knew I was in the car
02:19:50PM 19 driving to Olympia, they filed this notice for removal.
02:19:54PM 20 What that effectively did is it removed our relief -- any
02:19:56PM 21 chance of getting our relief prior to that rule being
02:19:59PM 22 adopted. That is irreparable harm, as well, your Honor.

02:20:03PM 23 THE COURT: I'm not sure if it is irreparable if
02:20:06PM 24 it is later determined to be invalid. Again, I'm not sure
02:20:12PM 25 what the ability is for your group members to recover the

02:20:20PM 1 proper reimbursement rate, assuming that this court or
02:20:30PM 2 Thurston County Superior Court makes invalid or renders
02:20:33PM 3 invalid the change.

02:20:35PM 4 MS. NICHOLSON: Your Honor, the fact is we are
02:20:37PM 5 here in federal court arguing under a higher standard,
02:20:41PM 6 because we are trying to overturn a rule rather than
02:20:44PM 7 prevent its adoption under the TRO standard.

02:20:47PM 8 THE COURT: You are really touching on the -- the
02:20:49PM 9 first issue, the threshold question now, the one on which
02:20:51PM 10 I think we are going to need to have the record developed
02:20:54PM 11 more to find out whether or not the court, in looking at
02:20:57PM 12 this and doing the balancing that it is required to do,
02:21:03PM 13 again, under the Grable & Sons Metal Products case and
02:21:07PM 14 progeny.

02:21:11PM 15 The court is not able at this point to make a
02:21:15PM 16 complete final decision. As I have said, for the purpose
02:21:20PM 17 of this hearing, the court is satisfied that there is a
02:21:25PM 18 sufficient basis for federal jurisdiction to at least
02:21:30PM 19 answer this question.

02:21:32PM 20 MS. NICHOLSON: Your Honor, we can't stipulate to
02:21:35PM 21 jurisdiction.

02:21:36PM 22 THE COURT: I am not asking you to.

02:21:38PM 23 MS. NICHOLSON: We brought state law claims, and
02:21:40PM 24 we asked for state law relief. We filed a motion for
02:21:44PM 25 remand on an emergency basis to try to get back in front

02:21:47PM 1 of that state court again, because that's where our relief
02:21:49PM 2 is.

02:21:50PM 3 If you determine that you have federal jurisdiction
02:21:52PM 4 over this, we have full confidence that you can provide
02:21:54PM 5 the same relief that we need to obtain. And we have no
02:21:57PM 6 objection to that.

02:21:59PM 7 Our question, though, is, we need emergency relief.
02:22:02PM 8 Right now the rule is in place, and we would like to get
02:22:06PM 9 some sort of temporary restraining order, at least if the
02:22:10PM 10 remand goes through, until that remand occurs; if you
02:22:15PM 11 decide to maintain jurisdiction, then until we can prove
02:22:18PM 12 our claims on the merits.

02:22:19PM 13 THE COURT: Do you have any knowledge of how the
02:22:25PM 14 CMS will -- if the court were to enter a restraining
02:22:33PM 15 order, what steps it takes to impose sanctions on the
02:22:39PM 16 state of Washington for not meeting the April 1st deadline
02:22:43PM 17 for establishing according to the new formula?

02:22:48PM 18 MS. NICHOLSON: I do not know what steps the CMS
02:22:51PM 19 would take on that. They did actually enter the rule on
02:22:54PM 20 April 1st, your Honor. We are trying to get it stayed
02:22:56PM 21 until we can get heard on the merits. But that rule was
02:23:01PM 22 entered. I don't know what that would mean to CMS.

02:23:03PM 23 To go through some of the procedural errors that
02:23:07PM 24 occurred with adoption of this rule, your Honor, again,
02:23:10PM 25 the notice to the pharmacies didn't occur until after --

02:23:15PM 1 like a month after the comment period had closed. That
02:23:18PM 2 was the main thing that happened.

02:23:20PM 3 The respondents are claiming that our clients knew
02:23:24PM 4 that they had every intention of reducing the ingredient
02:23:30PM 5 costs and keeping the dispensing fees artificially low.
02:23:33PM 6 They absolutely did not. Our clients had every reason to
02:23:36PM 7 believe that they would follow CMS requirements and state
02:23:39PM 8 and federal law. They had no idea that was coming. So
02:23:42PM 9 that was a surprise.

02:23:43PM 10 The other thing that -- There is quite a few things,
02:23:46PM 11 actually. They published their notice of proposed rule
02:23:51PM 12 making, and in that notice they are supposed to identify
02:23:54PM 13 any federal or state agencies that regulate the subject
02:23:58PM 14 matter of the rule, and then determine how they are going
02:24:00PM 15 to coordinate between those agencies. They listed only
02:24:03PM 16 CMS, even though the OIC had been tasked with producing a
02:24:07PM 17 study of the retail supply chain by the Washington
02:24:11PM 18 legislature.

02:24:12PM 19 THE COURT: Are those two different things,
02:24:14PM 20 though? I don't know. With respect to the Office of
02:24:21PM 21 Insurance Commissioner, they regulate private insurance
02:24:25PM 22 providers or carriers, right? That was their purpose in
02:24:30PM 23 doing the study?

02:24:32PM 24 MS. NICHOLSON: That was their purpose. But they
02:24:34PM 25 were also tasked by the legislature, in light of this CMS

02:24:38PM 1 rule, to produce that study. So they were involved in
02:24:41PM 2 this, your Honor.

02:24:41PM 3 THE COURT: That was directed by the legislature?

02:24:44PM 4 MS. NICHOLSON: Yes. Again, the concise
02:24:46PM 5 explanatory statement, which is to address the comments to
02:24:49PM 6 the rule, they addressed ten comments. Not one of them
02:24:53PM 7 had to do with the professional dispensing fee. That's
02:24:55PM 8 because nobody knew they were going to keep that on an
02:24:58PM 9 artificially low basis.

02:25:00PM 10 Again, that didn't allow the public or the pharmacies
02:25:03PM 11 to comment. It prevented them from meaningful
02:25:06PM 12 participation in the rule making. It didn't allow anyone
02:25:09PM 13 to question: Why isn't the information from the OIC study
02:25:13PM 14 included in the rule? Why are you not modifying the
02:25:19PM 15 ingredient cost and the professional dispensary fee in
02:25:23PM 16 tandem, as you are required to do under CMS?

02:25:26PM 17 Under the CMS rule, your Honor -- this is 42 CFR,
02:25:33PM 18 Section 447.158(d), requires the states to implement the
02:25:38PM 19 professional dispensing fee at the same time as the
02:25:40PM 20 ingredient costs reimbursement. In fact, any time you
02:25:44PM 21 change the calculation for the total reimbursement, you
02:25:47PM 22 are supposed to look at both sides.

02:25:49PM 23 In the Federal Register they make these two comments:
02:25:51PM 24 "States must review their current professional dispensing
02:25:55PM 25 fee whenever they propose to change their reimbursement

02:25:58PM 1 methodology, and CMS recognizes that the reimbursement for
02:26:11PM 2 drug ingredient cost and the professional dispensing fee,"
02:26:16PM 3 these two parts of the total, "must be adjusted in
02:26:19PM 4 tandem." That is in the 81 Federal Register at 5201.

02:26:27PM 5 So the rule that HCA proposed violated the CMS
02:26:32PM 6 requirements, and violated all these procedural
02:26:34PM 7 requirements. Our clients normally -- as they were -- the
02:26:39PM 8 only avenue that they had, filed the petition under the
02:26:44PM 9 APA, so under local and state law.

02:26:48PM 10 The CMS rule also requires them to provide adequate
02:26:51PM 11 data to support their decisions. That's where they really
02:26:54PM 12 fall down here, because they didn't cite the OIC study.
02:26:58PM 13 Instead, they cited two other studies that they say show
02:27:01PM 14 that this professional dispensing fee is actually more
02:27:06PM 15 than enough.

02:27:07PM 16 What they are comparing, your Honor -- In
02:27:12PM 17 particular, in the market check evaluation, mode of
02:27:16PM 18 health, the reports that they are reciting to support
02:27:19PM 19 their professional dispensing fee, make no representation
02:27:22PM 20 as to whether the payment rates cover the cost of retail
02:27:25PM 21 pharmacies. There is no representation whatsoever in
02:27:27PM 22 there. And the Milliman report, that is the same thing,
02:27:31PM 23 there is no representation that it is an actual cost of a
02:27:34PM 24 pharmacy to dispense. And in fact, it comes with a
02:27:37PM 25 caution: "Comparing the AWP discounts and dispensing fee

02:27:41PM 1 benchmarks to other markets should be done with caution
02:27:45PM 2 due to the difference in drug demographics within
02:27:48PM 3 populations."

02:27:49PM 4 One thing that they are comparing with, and this is
02:27:51PM 5 what -- another thing in the rule, they left in the
02:27:53PM 6 definition of "dispensing fee" under the WAC. They left
02:28:00PM 7 in there that they could compare with other third-party
02:28:04PM 8 payers, such as healthcare plans.

02:28:06PM 9 And that's in direct conflict with the CMS
02:28:08PM 10 requirement that it has to be -- the professional
02:28:11PM 11 dispensing fee has to be the actual cost of the pharmacies
02:28:14PM 12 to dispense. And they are comparing a dispensing fee from
02:28:16PM 13 a health plan, who is not held to the same standard of
02:28:20PM 14 making actual cost -- of ingredient costs. So they can
02:28:23PM 15 have an above-average ingredient cost and a below-average
02:28:26PM 16 dispensing fee. And they are comparing this dispensing
02:28:30PM 17 fee. It is not the same thing. It is not an
02:28:34PM 18 apples-to-apples comparison in the very least.

02:28:37PM 19 So, again, your Honor, the irreparable harms, my
02:28:49PM 20 client is in a situation that is a little bit like the
02:28:52PM 21 Ralph's Grocery case, where they brought their claims in
02:28:55PM 22 state court, they were removed to federal court, and under
02:28:58PM 23 federal court they can't get the relief they request. And
02:29:01PM 24 that is pretty much in their response on the motion to
02:29:04PM 25 remand. They list all the federal statutes under which we

02:29:06PM 1 cannot get relief since the Armstrong case.

02:29:11PM 2 What relief -- Only if you find a federal question
02:29:14PM 3 and can provide the relief under state law, can we get the
02:29:17PM 4 relief that we requested.

02:29:20PM 5 Again, this is like history repeating itself, because
02:29:23PM 6 of the 2009 case, where they did exactly the same thing.
02:29:26PM 7 And in that case -- Here is the quote from that opinion
02:29:31PM 8 that I handed up, your Honor. "The April 1st, 2009 rate
02:29:35PM 9 cut well reduced quality of care delivered to Medicaid
02:29:38PM 10 beneficiaries in Washington, and as such violates state
02:29:41PM 11 law."

02:29:42PM 12 So when you take the balance of the hardships here,
02:29:45PM 13 we have a rule that will hurt the pharmacies, and it will
02:29:50PM 14 potentially reduce the consumer choice of Medicaid
02:29:54PM 15 patients. That is significant when you talk about rural
02:29:57PM 16 areas or underserved communities.

02:30:01PM 17 The balance of the harms favors the petitioners in
02:30:03PM 18 this matter, because instead of damages, when faced with a
02:30:08PM 19 conflict between financial concerns and the harm to
02:30:11PM 20 potential human suffering, the human suffering always wins
02:30:15PM 21 out. So the balance of the harm does favor the
02:30:18PM 22 petitioners, your Honor.

02:30:19PM 23 There is also an overriding public interest in having
02:30:22PM 24 the HCA follow the state and federal laws, and there is an
02:30:25PM 25 overriding public interest in having Medicaid patients be

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Appendix B

02:30:29PM 1 able to go to pharmacies and get their needed
02:30:31PM 2 prescriptions filled.

02:30:33PM 3 We would ask to also talk a little bit about the
02:30:37PM 4 bond, your Honor. Federal judges have discretion not to
02:30:40PM 5 order a bond for a TRO. In this case the risk of
02:30:44PM 6 noncompliance with federal and state law lies entirely
02:30:47PM 7 with the HCA and not with the petitioners. Considering
02:30:50PM 8 the likelihood of success on the merits, and that the
02:30:53PM 9 injunction simply requires the state to comply with
02:30:57PM 10 federal and state law, we would ask that no bond be
02:31:00PM 11 issued.

02:31:06PM 12 Again, your Honor, we feel that there is not federal
02:31:13PM 13 jurisdiction, and the removal was for -- was a procedural
02:31:18PM 14 maneuvering to ensure that we did not get the relief in
02:31:20PM 15 state court that we are entitled to ask for, simply by the
02:31:25PM 16 timing of it. And we ask that this court not condone such
02:31:29PM 17 procedural maneuvering. Thank you.

02:31:32PM 18 THE COURT: Thank you. I will hear from
02:31:41PM 19 Ms. Coats-McCarthy.

02:31:43PM 20 MS. COATS-McCARTHY: Yes, your Honor. May it
02:31:57PM 21 please the court, my name is Angela Coats-McCarthy,
02:32:00PM 22 representing the Washington State Health Care Authority
02:32:02PM 23 and Dorothy Frost-Teeter in her official role as director
02:32:06PM 24 of the Health Care Authority.

02:32:07PM 25 Washington state outpatient pharmacy rates are made

02:32:10PM 1 up of two different portions, the ingredient cost portion
02:32:13PM 2 and a professional dispensing fee. In compliance with the
02:32:18PM 3 federal regulations, HCA is moving from an estimated
02:32:23PM 4 acquisition cost to an actual acquisition cost. That's
02:32:27PM 5 the change that we are talking about here.

02:32:30PM 6 And what the federal regulations drove was, it
02:32:33PM 7 allowed HCA to have different methods of making that
02:32:38PM 8 actual acquisition cost.

02:32:39PM 9 I think it is important not to lose sight of the fact
02:32:42PM 10 that, in the end, both of these numbers for the ingredient
02:32:44PM 11 costs had the same end goal, and that was establishing the
02:32:48PM 12 acquisition cost. To the extent there was a big
02:32:52PM 13 separation in those numbers, that just shows that there
02:32:55PM 14 was a problem with the estimate.

02:32:57PM 15 The other issue here is --

02:32:59PM 16 THE COURT: Let's talk about irreparable harm.
02:33:02PM 17 You heard my questions, supposing the court denies the
02:33:09PM 18 restraining order. Is there a method -- And assuming
02:33:14PM 19 this court, or Thurston County, ultimately determines that
02:33:23PM 20 the new rule is invalid, has to be set aside and returned
02:33:29PM 21 to the preceding rule, is there a method for pharmacists
02:33:36PM 22 to recoup the difference from that which is being paid
02:33:40PM 23 under the new rule and the prior rule?

02:33:47PM 24 MS. COATS-McCARTHY: In terms of that
02:33:51PM 25 difference -- in terms of the remedy, CMS would have the

02:33:54PM 1 remedy. And I think we cited to this in our briefing,
02:33:58PM 2 where these rates -- we do have to show -- the state does
02:34:01PM 3 have to show to CMS that these rates meet the data
02:34:05PM 4 requirements and meet the sufficiency of federal law. And
02:34:08PM 5 the state has to assume financial risk if their
02:34:12PM 6 calculations are incorrect. So CMS has a hammer over --

02:34:17PM 7 THE COURT: I understand what you're saying, CMS
02:34:20PM 8 is not going to fully reimburse even if a court sets it
02:34:24PM 9 aside, because they didn't meet the April 1 deadline, so
02:34:27PM 10 they are still operating under the old rates. I am
02:34:30PM 11 asking, does the state of Washington then have an
02:34:33PM 12 obligation to pick up the difference in the reimbursement
02:34:40PM 13 rates if it is determined that the new rule was not in
02:34:46PM 14 compliance with the APA?

02:34:48PM 15 MS. COATS-McCARTHY: Your Honor, I think part of
02:34:50PM 16 it would depend on why CMS set aside the rates.

02:34:55PM 17 What the petitioners in this case are asking for is
02:34:57PM 18 not merely to go back to the previous rates, they are
02:35:01PM 19 actually asking for an increase in the dispensing fee, the
02:35:04PM 20 dispensing fee which did not change through this entire
02:35:07PM 21 process. They are asking for an increase in something
02:35:09PM 22 that didn't change.

02:35:12PM 23 I think that's part of the issue that you will see
02:35:14PM 24 when you go through the declarations. The numbers being
02:35:17PM 25 thrown around in this case are wildly different. Their

02:35:20PM 1 economist relied on national data, estimated \$12 million a
02:35:24PM 2 year. The Washington Health Care Authority estimates
02:35:28PM 3 \$1.12 million of impact, which they have actually made
02:35:33PM 4 moves to mitigate, because -- in terms of making
02:35:37PM 5 adjustments to smooth the implementation of it.

02:35:40PM 6 Because this was not done as some sort of cost-saving
02:35:43PM 7 mechanism. This was done to get closer to that actual
02:35:46PM 8 acquisition cost, which was always the goal, even with the
02:35:50PM 9 previous estimate.

02:35:53PM 10 So in terms of what the petitioners are asking for,
02:35:56PM 11 they are asking for something that is over and above even
02:35:58PM 12 what they have now. So it is difficult for me to see that
02:36:02PM 13 CMS would order the state to pay an exorbitantly higher
02:36:08PM 14 dispensing rate that never existed in the first place.
02:36:13PM 15 But it would depend on why the CMS rejected the rates and
02:36:16PM 16 then what CMS directed the state to do in order to
02:36:20PM 17 maintain federal funding.

02:36:21PM 18 THE COURT: What is your response to the
02:36:22PM 19 notice -- lack of adequate notice?

02:36:25PM 20 MS. COATS-McCARTHY: Your Honor, these rules were
02:36:27PM 21 in response to federal rules, which had been out since
02:36:32PM 22 February of 2016. The state rule-making process in this
02:36:35PM 23 case was open for nine months, from June 2016 to current,
02:36:42PM 24 with all of the proper notices and various phases.

02:36:46PM 25 One of the petitioners in this case actually

02:36:48PM 1 commented on the course of the rules. That's reflected in
02:36:53PM 2 Exhibits, I think, I and G of the declaration of Wendy
02:36:58PM 3 Barcus in the record. So there was actually participation
02:37:01PM 4 by one of the plaintiffs in the rule-making process.

02:37:04PM 5 What the petitioners are citing to was merely a
02:37:07PM 6 provider alert that was put out reminding people that the
02:37:12PM 7 new rates were going out. And it was always that the only
02:37:16PM 8 thing being adjusted was that ingredients cost component.

02:37:21PM 9 In terms of putting something out, that the
02:37:25PM 10 dispensing fee wasn't going to be adjusted, that was never
02:37:28PM 11 on the table to begin with. That was never a source of
02:37:31PM 12 the rule-making. And the rates themselves the petitioners
02:37:36PM 13 are complaining about aren't even in the text of the rules
02:37:40PM 14 that they are now seeking to enjoin.

02:37:42PM 15 This is why I say -- They are asking this court to
02:37:45PM 16 do something that is actually not even -- it doesn't sync
02:37:50PM 17 up. The rules themselves don't even have the dispensing
02:37:54PM 18 rate in them that they are seeking to block.

02:37:58PM 19 What they are seeking to block is the ingredient cost
02:38:00PM 20 component, which is being done directly -- in response to
02:38:03PM 21 the federal regulations. Again, there is wildly different
02:38:08PM 22 estimates about what that impact will be. But the goal of
02:38:10PM 23 that was always to get towards an actual acquisition cost
02:38:13PM 24 number.

02:38:14PM 25 THE COURT: What is your response to the

02:38:18PM 1 allegation that the OIC study wasn't considered?

02:38:25PM 2 MS. COATS-McCARTHY: Actually, the OIC -- And
02:38:27PM 3 you will see this in the declarations, your Honor, of Myra
02:38:29PM 4 Davis, the OIC study was considered in the course of
02:38:33PM 5 rate-making. What the OIC study does show is that the
02:38:36PM 6 Medicaid dispensing rates are actually significantly
02:38:39PM 7 higher than every other commercial payer in Washington
02:38:43PM 8 state.

02:38:44PM 9 OIC does not regulate Medicaid. They regulate
02:38:47PM 10 private insurance, as your Honor cited to. When you look
02:38:51PM 11 at the -- The legislature did direct a study of, I think,
02:38:55PM 12 chain of supply. But to my knowledge, it wasn't in
02:38:58PM 13 relationship to these federal regulations, because the
02:39:01PM 14 Office of Insurance Commissioner does not have bearing or
02:39:04PM 15 even regulatory authority on the Medicaid program in
02:39:08PM 16 Washington state.

02:39:08PM 17 In terms of what all the underlying features of that
02:39:11PM 18 study were, or what really the intent was of that study,
02:39:16PM 19 we would have to get the factual background of exactly
02:39:19PM 20 what was underlying that study.

02:39:21PM 21 What the study does show -- It references
02:39:24PM 22 cost-of-dispensing studies. But those
02:39:26PM 23 cost-of-dispensing -- The federal regulations, and in the
02:39:29PM 24 federal comments, they explicitly stated they were not
02:39:31PM 25 requiring the state to abide by any cost-of-dispensing

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02:40:08PM 11
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02:40:13PM 13
02:40:17PM 14
02:40:21PM 15
02:40:24PM 16
02:40:27PM 17
02:40:30PM 18
02:40:35PM 19
02:40:40PM 20
02:40:44PM 21
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02:40:58PM 25

study.

And if you look through the comments on the federal regulations, several commenters on the federal regulations made comments encouraging CMS to tie dispensing fees to cost-of-dispensing studies.

CMS declined to do that explicitly in their comments on the federal regulations. In fact, they repeatedly emphasized maintaining state flexibility in setting dispensing fees, stating that a state needs to do an evaluation of their ingredient costs and dispensing fees to make sure that it ensures economy, efficiency, and access.

And the state did that here. The state did revise its rules to change ingredient costs. It did revise the definition of "professional dispensing fee," which was not that different from how Washington already characterized its own dispensing fee. It just made it more uniform, because there is variation across the states. And then it did evaluate and look at studies and various research of its rates for the April 1st, 2017, rates.

And that evaluation is what CMS required, and what the regulations required, and that's what was done in this case.

I think saying that the federal regulations -- Particularly one of the quotes that petitioners rely on is

02:41:05PM 1 this quote about the rates have to be adjusted in tandem.
02:41:08PM 2 That is simply a mischaracterization of what is in the
02:41:12PM 3 Federal Register. I think the quote -- that particular
02:41:16PM 4 quote about being adjusted in tandem is actually what one
02:41:20PM 5 of the commenters wanted CMS to do, was have rates
02:41:24PM 6 adjusted in tandem. I am looking at 81 Federal Register
02:41:30PM 7 at Page 5201. That language is actually in the comment
02:41:34PM 8 portion.

02:41:35PM 9 The response that CMS did here was, you know, "We
02:41:41PM 10 agree that pharmacy providers should be reimbursed
02:41:43PM 11 adequately for their professional services within the
02:41:45PM 12 requirements of the final rule. While we are not
02:41:49PM 13 requiring states to update their professional dispensing
02:41:52PM 14 fees at specific intervals and frequencies, such as an
02:41:55PM 15 annual basis, they will be required to evaluate each
02:41:58PM 16 component when they propose change. We afford the states
02:42:02PM 17 the flexibility to adjust their professional dispensing
02:42:04PM 18 fee when necessary to assure sufficient access in
02:42:08PM 19 accordance with the requirements of Section 1902(a)(30)(a)
02:42:12PM 20 of the Act."

02:42:12PM 21 And that's what happened here. They have done that
02:42:14PM 22 evaluation. It just didn't come up to the result. These
02:42:18PM 23 regs didn't drive any particular result. They required
02:42:21PM 24 the state to do that evaluation and to present that
02:42:23PM 25 evaluation to CMS in the normal process.

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Appendix B

02:42:26PM 1 And that's consistent with why there is no longer any
02:42:30PM 2 private right of action on these types of rate
02:42:33PM 3 requirements in federal court, because the Supreme Court
02:42:36PM 4 dictated that CMS has that authority, CMS does that
02:42:40PM 5 review. And that's what we are relying on here.

02:42:42PM 6 Also, references to the previous case, actually
02:42:48PM 7 Mr. Stevens and I were counsel on that previous case eight
02:42:50PM 8 years ago, that was cited. That was a very different
02:42:53PM 9 time. That was a different legal theory. Also, there was
02:42:56PM 10 different evidence in the record that is not here.

02:42:59PM 11 Particularly, there is no evidence that there is an
02:43:01PM 12 access issue. There is no evidence that any Medicaid
02:43:04PM 13 individual is having difficulty getting drugs from
02:43:06PM 14 pharmacies. In fact, what the record shows is there is
02:43:10PM 15 extremely high participation in the Medicaid program.
02:43:15PM 16 That was with these exact same rates previously. And
02:43:18PM 17 there is no reason that the Authority knows that that
02:43:21PM 18 would not continue further.

02:43:23PM 19 Furthermore, that particular -- it is outside of a
02:43:29PM 20 different factual background and legal background. The
02:43:32PM 21 evidence -- there is no evidence in this record of any
02:43:36PM 22 access issue.

02:43:37PM 23 There is a statement of a cost-of-dispensing study,
02:43:41PM 24 which, like I said, CMS has explicitly stated in the
02:43:46PM 25 Federal Register, and we have quotes in our briefing, that

02:43:49PM 1 the state is not compelled to follow those surveys.

02:43:54PM 2 THE COURT: I think you have used up about all
02:43:56PM 3 the time I can give you. But I will hear a quick response
02:43:59PM 4 from Ms. Nicholson.

02:44:06PM 5 MS. NICHOLSON: First of all, I would like to
02:44:08PM 6 correct a mischaracterization of what we are seeking, your
02:44:11PM 7 Honor. We are not seeking, and never have, a particular
02:44:14PM 8 specific dispensing fee. That is not what we are seeking.
02:44:17PM 9 We are seeking the rule to go back to the way it was on
02:44:20PM 10 March 31st until we can prove that the dispensing fee
02:44:24PM 11 needs to be addressed. But we are not seeking any
02:44:27PM 12 specific dispensing fee.

02:44:28PM 13 We are simply pointing out that in every state that
02:44:30PM 14 has adopted the actual ingredient cost, that the
02:44:34PM 15 professional dispensing fee has been around \$10. And
02:44:37PM 16 that's exactly what the OIC found.

02:44:39PM 17 And I would like to highlight very briefly two
02:44:43PM 18 comments from that OIC study, your Honor. One is this,
02:44:46PM 19 "The CMS views an adequate reimbursement as a possible
02:44:49PM 20 violation of the federal statute that requires the states
02:44:52PM 21 to reimburse providers in a manner that is sufficient to
02:44:55PM 22 ensure provider participation and beneficiary access.
02:44:59PM 23 Accordingly, the states have adopted the actual
02:45:01PM 24 acquisition costs reimbursement, for ingredient costs have
02:45:06PM 25 dispensing fees that are generally in excess of \$10 per

02:45:09PM 1 prescription." That is from the OIC study. That is what
02:45:12PM 2 we are saying they ignored, your Honor.

02:45:14PM 3 Again, they talk about the difference in the --
02:45:17PM 4 There is a huge difference in the figures used here. And
02:45:20PM 5 we can't really follow where they are getting their
02:45:23PM 6 figures from, and apparently they can't follow where we
02:45:25PM 7 are getting ours from. We do know they are not comparing
02:45:29PM 8 apples to apples. They are comparing that dispensing fee
02:45:31PM 9 from a health plan and trying to pretend that is the same
02:45:35PM 10 as the professional dispensing fee that has to be based on
02:45:38PM 11 the actual cost of dispensing the prescription. It is not
02:45:41PM 12 the same thing. And that's where their figures are so
02:45:44PM 13 much wildly different than ours, it is my belief.

02:45:47PM 14 Their change of the definition of the professional
02:45:51PM 15 dispensing fee is a bit of form over substance. Again,
02:45:55PM 16 they left in that back door to compare the dispensing fee
02:45:58PM 17 with a third-party payer. That is contrary to the CMS
02:46:02PM 18 requirement that says it has to be an actual cost basis.

02:46:12PM 19 The problem is in the methodology that they used to
02:46:34PM 20 calculate the dispensing fee. It is not the fact that
02:46:37PM 21 they have this set dispensing fee, it is how they are
02:46:40PM 22 calculating that. They are calculating that based on an
02:46:43PM 23 improper comparison to health plan dispensing fees, your
02:46:47PM 24 Honor.

02:46:47PM 25 THE COURT: All right. Thank you. The court

02:47:01PM 1 concludes there is not sufficient evidence or persuasive
02:47:05PM 2 argument in the record, as it now exists, that petitioners
02:47:10PM 3 are likely to prevail. Neither is there sufficient
02:47:13PM 4 evidence that petitioners will suffer irreparable harm
02:47:17PM 5 that would require equitable relief.

02:47:21PM 6 As to the other two elements that must be considered
02:47:25PM 7 when weighing a request for a restraining order, the
02:47:28PM 8 balance of the equities and the public interest, the court
02:47:34PM 9 has difficulty weighing it, because there are balancing
02:47:41PM 10 interests on both sides on those two questions. So they
02:47:46PM 11 are at least neutral.

02:47:49PM 12 Therefore, the court finds that there is not a
02:47:52PM 13 sufficient basis to grant the temporary restraining order.

02:48:01PM 14 I noted that there was no motion for preliminary
02:48:03PM 15 injunction. It seems to me that that is certainly an
02:48:10PM 16 avenue that petitioners may want to seek to develop a more
02:48:20PM 17 complete record on the areas where the court is concerned
02:48:23PM 18 about, the lack of showing of irreparable harm here.

02:48:29PM 19 I don't know whose numbers are right, but whether it
02:48:33PM 20 is a million dollars a year or \$12 million a year, I still
02:48:38PM 21 don't have enough in the record that tells me that there
02:48:45PM 22 will be an access problem here. The numbers seem to
02:48:51PM 23 indicate just the opposite, that the amount is
02:48:54PM 24 sufficiently small as to not interfere with either the
02:49:03PM 25 large or small pharmacies.

APPENDIX C

A P P E A R A N C E S

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1 THE COURT: Good afternoon. Please be seated.

2 Well, we're present in the National Association of Chain
3 Drugstores, et al., versus State Healthcare Authority, et
4 al. This is cause number 17-2-1489-34. And before we get
5 started if I could have all of the attorneys put their
6 appearances on the record.

7 MR. BINA: Good morning, Your Honor. Mark Bina,
8 counsel on behalf of petitioners.

9 MS. NICHOLSON: Virginia Nicholson, counsel on
10 behalf of petitioners.

11 MR. STEPHENS: And Bill Stephens assistant attorney
12 general representing the Healthcare Authority.

13 MS. COATS MCCARTHY: Angela Coats McCarthy assistant
14 attorney general representing the Healthcare Authority.

15 THE COURT: Well, good afternoon to all of you.
16 Mr. Bina and Ms. Nicholson, how long do you anticipate you
17 will need for your arguments and how do you want to divide
18 up your time?

19 MS. COATS MCCARTHY: Mr. Bina will be doing
20 (indiscernible).

21 MR. BINA: Your Honor, we're certainly happy to
22 accommodate any questions the court would have. We would
23 estimate about 30 minutes for our presentation if that's
24 acceptable to the court.

25 THE COURT: Well, I'll just let you know that this

1 is the time slot for this type of a hearing. It's designed
2 to give you some time. So that's fine. And I'm not going
3 to hold you to a strict time, so that's fine, if you're in
4 the ballpark of about 30 minutes, and I imagine you'll want
5 some rebuttal time.

6 MR. BINA: Yes, Your Honor. Just in light of that
7 if you could estimate about 45 minutes and maybe reserve
8 five or ten for the rebuttal, that would be helpful.

9 THE COURT: Very well. Thank you.

10 And for Ms. Coats McCarthy and Mr. Stephens.

11 MR. STEPHENS: I would estimate 20 minutes.

12 THE COURT: And who's going to be arguing for the
13 Healthcare Authority?

14 MR. STEPHENS: I will.

15 THE COURT: All right. Well, I'll let you all know
16 that as you can see I appreciated your binders that you
17 submitted. They were very helpful to the court, and then I
18 went through the administrative record as well, which a lot
19 of it was duplicative, but there were certain portions of
20 it that were helpful to the court as well, but I think you
21 both did a good job of taking the most relevant pieces of
22 the administrative record and addressing them in your
23 briefing so that's appreciated by the court.

24 So with that, Mr. Bina, why don't we get started.

25 MR. BINA: Thank you, Your Honor. Just a moment to

1 get papers in order here, Your Honor.

2 Good afternoon, Your Honor. Mark Bina on behalf of the
3 petitioners. Before we get started I did want to call the
4 court's attention to our client who was able to join us
5 today, Dedi Little who is on behalf of the Washington State
6 Pharmacists Association, and the executive director Jeff
7 Rochon who is not here yet stuck in I-5 traffic right now.
8 But the reason I wanted to call it out to begin, Your
9 Honor, is because I think it sets the table about what this
10 dispute is really about. The Washington State Pharmacy
11 Association represents many of the thousands of pharmacists
12 who practice in community pharmacies, and many, if not
13 almost all of whom, participate in the state's Medicaid
14 program. The other petitioners, of course, are the
15 National Association of Independent Pharmacists and the
16 National Association of Chain Drugs. All told what we're
17 talking about is about 1200 pharmacies in the state of
18 Washington that are affected by the state's administrative
19 rule here, and of those, 324 of them are independent
20 pharmacies.

21 Your Honor, what the state's rule and why we're all here
22 today is because it has caused significant financial harm
23 to our clients. Because of the state's inability or
24 refusal to raise or adjust the dispensing fee to an
25 appropriate rate they are now reimbursing at a rate of

1 \$12.3 million per year below costs. And again, Your Honor,
2 we're not here because we're seeking a profit. Our clients
3 are not seeking a monetary windfall. We are simply looking
4 to obtain the costs associated with dispensing the drugs to
5 these most needy Medicaid beneficiaries. We're simply
6 seeking costs consistent with the CMS rule.

7 So Your Honor, as the court is well aware in the briefs,
8 I think it would be helpful to really look again at the way
9 these pharmacy reimbursements occur. There's two buckets
10 essentially, Your Honor. In this form you have the
11 ingredient cost side on the one hand and you have the
12 dispensing fee on the other hand. Now, historically those
13 dispensing fees and the ingredient cost were at a different
14 level before April 1st. The ingredient cost was an
15 estimated acquisition cost whereas now it is cost or actual
16 cost. The CMS rule, however, upended that formula. The
17 CMS rule instructed all states, all fifty of them, to
18 change the methodology by which both the ingredient cost
19 and the dispensing fee is adjusted. And of course the
20 problem here is the state -- we concede they changed the
21 ingredient cost consistent with the federal. We understand
22 that. But our real challenge here is with respect to the
23 inactivity or the way in which they did not adjust the
24 dispensing fee.

25 And Your Honor, again, just to set the stage here for

1 where the State of Washington is nationally, Washington is
2 now an outlier with respect to the dispensing fees that it
3 pays to pharmacies. In our reply brief we indicated that
4 the neighboring states are now two to three times higher on
5 the dispensing fee because, again, those states have used
6 cost dispensing and other reliable data. We're not
7 suggesting you have to do a cost of dispensing, but you do
8 have to look at data, reliable data, that is going to
9 instruct or inform how the dispensing fee is set up.

10 Again, Washington is -- we're -- we have not found any
11 state lower than where Washington is right now, and that's
12 in large part why we filed suit and why we're here today
13 because the Washington -- especially the independent
14 pharmacies in the rural areas are absolutely bearing the
15 brunt of these reduced reimbursements. Again, they're not
16 seeking a profit, Judge; they're simply seeking to get
17 costs of the services they're providing to Medicaid
18 beneficiaries.

19 One of the claims in our petition is that the specific
20 rule, the actual rule that was promulgated, permits the
21 state to rely on third-party payers such as private
22 healthcare plans in order to determine or calculate what
23 the appropriate dispensing fee is. And this is the
24 language specifically that conflicts with the CMS rule,
25 Your Honor. The CMS rule could not be more clear.

1 Although other parts of it may be a little difficult to
2 follow, I can say though that the pertinent section with
3 respect to the dispensing fees, how the states are to
4 determine that, could not be more clear. States are to
5 rely on reliable and adequate data that goes to the costs
6 it takes to reimburse a pharmacy for dispensing to a
7 Medicare beneficiary. Those are not costs takes to pay to
8 a private pay patient, which are different and we'll talk
9 about why that is later. But really it's supposed to be
10 the actual cost for operations, overhead and serving
11 Medicaid patients. There's also tension internally in the
12 regulation, Your Honor. On the one hand the rates have not
13 been changed, yet if you look elsewhere in the actual
14 definition of how "professional dispensing fee" is defined,
15 that does speak to costs, actual costs. So again, we're in
16 a situation where we understand if the state has done of
17 what they were supposed to do, but they -- they fell down
18 at the point where it mattered which is actually
19 determining what those dispensing fees are.

20 So as we mentioned in our brief, Your Honor, the rule is
21 invalid both substantively because it relied on erroneous
22 and unreliable data which suppressed the rates low, and
23 we'll talk in a little bit about I think some of the very
24 problematic nature that that occurred, and procedurally we
25 think it's defective as well.

1 Of course we're here on a motion for summary judgment.
2 The issue is are there undisputed facts that might support
3 a declaration of rules invalid. And I've not yet, of
4 course, heard what the state is going to say in response to
5 this, but as the court is conducting inquiry, I would focus
6 in on what facts are there here that are contested. I
7 don't think there are any that are contested. The state
8 admits in its e-mails that it does not want to pay or
9 conduct a cost-of-dispensing survey. The state doubles
10 down on its Milliman report. All these are undisputed
11 facts that would support granting the petition in our
12 favor.

13 So Your Honor, to jump right into the real problem that
14 we see in this case, we want to go back to the timeline of
15 how this whole dispensing fee came to light. Of course in
16 February 2016 the federal government through CMS issued a
17 final rule that's as we call it the CMS rule for shorthand.
18 That rule became effective on April 1st after the 90-day
19 publication, and it required states to modify that
20 reimbursement by April 1st the following year, April 1st
21 2017. The states had twelve months to comply so they had a
22 fairly decent period of time to study this issue, figure
23 out what they're going to do and then promulgate rules that
24 would enforce the federal law. Or carry it out I should
25 say.

1 Now, two or three months after that initial rule came
2 out, the state is on notice that this is happening, the
3 state drafts a briefing paper, and this is contained, of
4 course, in our exhibits under the Virginia Nicholson
5 exhibit to our opening brief. The state's briefing paper
6 before it even begins the promulgation process, this is a
7 state agent in charge of the Medicaid program, writes, "We
8 must obtain external and a very credible report displaying
9 current market rates paid by private insurers for
10 point-of-sale pharmacy drugs and dispensing." End quote.
11 Quote, "We need this external report in order to avoid
12 being forced into higher rates that are not appropriate for
13 our market." End quote. The state wanted this report to,
14 quote, defend against the pressure to increase dispensing
15 fees. This is eleven months before the promulgation
16 process even began where the rule was even to go into
17 effect. The state, Your Honor, had already made up its
18 mind that it would not be adjusting rates to account for
19 costs that pharmacies bear.

20 Then June 2016, the state insurance commissioner reveals
21 a report after conducting various cost of dispensing and
22 other studies that dispensing fees are generally in excess
23 of \$10 per prescription. This is an example of what we
24 would deem reliable and adequate data. Now, it's not
25 specific, of course, to Medicaid, but it conducts a much

1 wider swath of research that would again fall in line with
2 what other states are doing. The state was well aware of
3 this and they ignored it.

4 June 29th, 2016, the state begins this promulgation
5 process and it sets February 7th, 2017, as the public
6 hearing deadline to submit comments on its proposed rule.
7 November 2016, within the promulgation process, the state
8 Medicaid program director e-mails internally to his
9 colleagues, quote, "CMS will be expecting the dispensing
10 fees to be raised and that Medicaid does not compare itself
11 to commercial payers. Instead the comparison should be to
12 other states." End quote. Again, Your Honor, nine months
13 before this rule is to go into effect the state is well
14 aware of the problem.

15 January 2017 Washington begins the process drafting the
16 specific language in the rule. The state Medicaid pricing
17 director, quote, in an e-mail, "CMS is on a mission to
18 raise fees. This is completely inappropriate for
19 Washington. We don't need to infuse money into pharmacy
20 rates." End quote. Your Honor, the standard in this case
21 is cost. It's not personal opinion.

22 March 2nd, 2017, a month after the comments close, they
23 send an e-mail. The state sends an e-mail to all
24 pharmacies letting us know for the very first time, the
25 public for the very first time, that dispensing fees, the

1 other part of that formula, will be unaffected by this
2 change to the ingredient cost. There was no data or
3 support anywhere in that indication. It was a summary
4 notice that went out. But the proposed rule, that
5 promulgation process, addressed the dispensing fee
6 definition, which again we think that tracked the language
7 appropriately under the federal rule. But they left in
8 there the notion that they could compare with other
9 third-party payers and private PBMs that in our view is
10 apples and oranges or apples and coconuts. They both look
11 like the same thing, but it's entirely different the way in
12 which private and Medicaid costs engage. The state's rule
13 is in direct conflict with the CMS rule.

14 So this rule is designated to become effective on April
15 1st. And Your Honor, I remember that very well, that
16 period of time. I remember Ms. Nicholson and I were
17 burning the midnight oil because we filed a -- our
18 petition. We filed an emergency motion before this court
19 on I believe it was March 30th or March 31st, and I recall
20 Your Honor receiving a call from Ms. Nicholson while she
21 was stuck on I-5 driving here, but the state removed this
22 matter to federal court on the eve of our hearing, filed an
23 emergency motion to stay this matter. All right. Well,
24 their ground there was because I guess our brief used the
25 word "Medicaid" which is technically a federal law, there

1 must be some federal jurisdiction here. Well, we dutifully
2 went to federal court, Your Honor. We briefed that and we
3 won. The matter was remanded. The problem is that took
4 time, it took time and money for us to make that fight, but
5 we're here. It took us nine months and we're back.

6 Your Honor, let's talk about the CMS rule because that's
7 where this case begins and ends as far as we're concerned.
8 The CMS rule is effectively a blueprint or instruction
9 manual for states to follow when they're changing or
10 modifying this actual cost determination. States are to
11 consider both the ingredient cost and the dispensing fee.
12 They must, again, review and provide adequate data.
13 That's, quote, adequate data such as a dispensing survey or
14 other reliable data if it's not a dispensing survey.

15 Now, the state in my research, and has had certainly
16 other litigation involving pharmacy rates, certainly has
17 done cost-of-dispensing surveys in the past. I've seen
18 that in the case law and I think the state would concede
19 that they've done -- I know they can do it. The issue
20 here, Judge, is why they didn't. Why did the state
21 Medicaid pricing director determine early on, months
22 before, that they didn't want to do this? Whether it's a
23 personal opinion or an agency opinion, the problem is
24 that's arbitrary and capricious agency action, Your Honor.

25 The data they did rely on to support their figure -- as

1 I mentioned, this is called the Milliman report, and then
2 the second report called Moda Health. This data is the
3 consummate definition of suspect data. It was a report
4 prepared at the direction of the state agent who had,
5 again, already determined months before that they wanted to
6 reach a certain outcome. We don't want rates to get raised
7 up because -- I'll paraphrase -- we think pharmacies are
8 getting paid enough. We think rates are fine the way they
9 are. And if you look at private insurance data, yes,
10 there's no question. Independent pharmacies, they get paid
11 a dollar fifty or so when you're dealing with a PBM. PBM,
12 of course, is a pharmacy benefits manager or certain
13 private insurance companies.

14 The difference there, Judge, is we talked about the
15 tandem weighing which these formulas work. In a private
16 insurance plan the ingredient cost is necessarily higher
17 because that allows you then to pay a lower dispensing fee
18 in a private insurance plan. The court may be aware some
19 insurance plans permit or require users to have mail order.
20 So for -- let's say if I'm taking a blood pressure
21 medication, which I hope I'm not ever, but those are often
22 provided in 90-day dosages and those are sent through the
23 mail. Now, mail order dispensing, you don't get a
24 dispensing fee. That's a goose egg, Your Honor. But yet
25 the reports that the state's relying on takes into account

1 those mail orders. So in other words, you've got some
2 dispensing fees that are skewed down. So yes, it might be
3 a dollar fifty on average, but that includes some of that
4 mail order data.

5 So again, separate and apart from the private, this is
6 not Medicaid data. This is not the cost it takes for
7 putting the lights on in a pharmacy, paying a pharmacist to
8 do drug utilization review and all the things necessary to
9 take care of a Medicaid beneficiary.

10 Now, the Milliman report is also problematic because it
11 admits it. The Milliman report is written -- like any good
12 accountant or lawyer would, they hedge their report. They
13 tell you exactly what data they relied on to draw this
14 conclusion. They relied on this private data. There's no
15 Medicaid data that they relied on at all. Now, our expert,
16 Your Honor, Dr. Miller, which is part of our opening brief,
17 ran the numbers and looked at the various issue, and we
18 show a \$10.55 mean cost of dispensing nationally, and
19 \$10.30 for Medicaid only. Now, in Washington it's slightly
20 off, \$10.48 for Washington Medicaid.

21 But the report doesn't even go there. The Milliman
22 report relies exclusively on commercial data, and it
23 actually cautions within the report because of this you
24 shouldn't compare this date to other markets such as
25 Medicaid. Why? For several reasons. One, the Medicaid

1 population is quite different than commercial or Medicare
2 markets. In other words, the drugs that a Medicare
3 beneficiary, let's say, who might be age 65 and above, is
4 taking a different drug than someone in Medicaid --
5 Medicaid typically would.

6 The Milliman report was also a national data set. It
7 was a vast aggregate average of national data all across
8 the country from Maine to Florida, California to
9 Washington, everywhere in between. And I mentioned earlier
10 about the mail order and some of this direct and indirect
11 remuneration, the way in which the ingredient costs for a
12 private plan are much different than Medicaid.

13 All together the Milliman report gave the state exactly
14 what it wanted, Your Honor. It gave the state cover. It
15 gave them something to stand behind to be able to say,
16 look, the dispensing rates are very low. It's a dollar, a
17 dollar fifty. Therefore, the 4.50 where we have been and
18 continue to be, this -- this is the state arguing of course
19 -- that 4.50 is far and above the dollar fifty that the
20 private plans get. Therefore why are the pharmacies
21 unhappy? They should be celebrating.

22 Your Honor, the CMS rule is clear. It must be a
23 dispensing fee that covers the costs of dispensing to a
24 Medicaid beneficiary, not a private-pay beneficiary.

25 Now, we raised an alternative argument in our brief as

1 well with respect to the state violating its own rule, and
2 that goes to the definition of what a dispensing fee is.
3 The dispensing fee definition in the state's rule -- I'll
4 hand it to them. It's spot on. It says that the state
5 shall -- or the dispensing fee is the actual cost of
6 dispensing to a Medicaid beneficiary. But by not adjusting
7 or relying on data to make that dispensing fee actually
8 account for costs, that violates its own rule internally as
9 inconsistent.

10 So Your Honor, I just want to check on how I'm doing on
11 time. I've probably got another five minutes or so, or
12 maybe ten minutes at the most. Thanks, Your Honor.

13 The remedy here, Your Honor, is we're seeking a motion
14 and a declaration that the rule is invalid under the
15 Administrative Procedure Act, that it exceeds the statutory
16 authority of the agency as arbitrary and capricious and was
17 adopted without compliance to proper procedure.

18 Now, the court's well aware that the state's arguments
19 were brought up and we rebutted those in our reply so I
20 won't spend too much time on that, but there were some
21 points I did want to raise because I think it's very
22 important. The state's chief argument seems to be, well,
23 Judge, all this might become moot if the federal CMS agency
24 approves our program. They might do that. It could happen
25 today. It could happen next week. It could happen in a

1 couple months. It could also happen five years from now.
2 We don't know what's going to happen.

3 Your Honor, we mentioned before that CMS has already
4 tipped its hand that it's not happy with the state's
5 submission. But regardless of what CMS does, and we
6 certainly think it will be rejected, the court nonetheless
7 has an independent duty and a jurisdiction to strike down
8 an unlawful regulation regardless of the CMS action. We
9 cited to some case law, although there's none on point
10 apparently in this state. I believe it was Kentucky,
11 Louisiana, and I think the third one may have been
12 California, but those are instances in which state courts
13 have found and have ruled on APA-type claims in the face of
14 CMS action. So there's no reason to delay that.

15 I mentioned earlier we've already suffered -- our
16 clients have already suffered a nine-month delay based on
17 the state's removal to federal court. We filed this before
18 the rule went into effect. We moved swimmingly to try to
19 prevent this damage. We've not been sitting on our hands.
20 It's also in the public interest to decide quickly.

21 Lastly, Your Honor, the federal agency, CMS, they do not
22 have the ability to cure any sort of procedural defects in
23 the state's action. The court has the sole authority to do
24 that, and to suggest otherwise I think would cause some
25 significant separation of powers concerns because

1 otherwise, the CMS can cure anything by making a decision.
2 That's just not the situation.

3 Your Honor, the CMS -- the other -- I'm sorry. The
4 state's other arguments that the CMS rule doesn't require a
5 certain outcome, that, hey, the petitioners are really just
6 asking you for us to raise rates and they're suggesting
7 that the CMS rule would mandate that. In fact, the state
8 goes so far as to say, "Well, in light of the Milliman
9 report we could actually cut rates if we wanted to. It's
10 supported. Look at this data." Well, that might be true.
11 Maybe the state could cut the 4.50, but the touchstone in
12 all this, Judge, is do they have adequate and reliable data
13 to justify such a cut. And if they don't, whether it goes
14 up or down, it's unlawful.

15 Judge, let's look at this a different way. Let's say
16 the state decided to make the dispensing fee \$450 per
17 prescription. Now, setting aside the fact that I would
18 probably become a pharmacist tomorrow and others may join
19 me, the point is there may be some interested party with
20 standing to come in and say, "That can't be right, Judge.
21 That's not the standard." The standard is what's the
22 actual cost. And if it's not the actual cost, it's
23 unlawful.

24 Your Honor, the state really has dug down, or doubled
25 down I should say, on the Milliman study. Their response

1 brief, "The Milliman report is fine. Because these
2 pharmacies already accept low dispensing fees from private
3 payers, that confirms our data's accurate." Your Honor,
4 CMS, the federal agency in charge of reviewing all this,
5 has already communicated to the state how absolutely wrong
6 they are. And this is cited in our reply brief on page
7 two. I'll quote it here because I think it's key. It
8 completely eliminates this argument. "The fact that
9 pharmacists are willing to 'accept' a dispensing fee paid
10 by managed care plans in the state in order to stay in the
11 Medicaid . . . service network does not negate the
12 regulatory requirement of professional dispensing fee as
13 defined in" the applicable regulation. The Milliman data
14 is skewed low because private payers pay a higher
15 ingredient cost.

16 And why is Washington the only state to be in this
17 situation? All of our neighbors have complied
18 appropriately. We indicated everyone else is between two
19 and 300 percent higher because they have looked at the
20 data. They looked at actual reliable and adequate data to
21 determine that the costs are in the ten to eleven to \$13
22 range.

23 I won't spend a lot of time on due process, Your Honor,
24 because I know my time is running short, but the state's
25 defense is essentially "Well, it was a five-step program

1 and we met every step so therefore we've complied." But
2 Your Honor, the standard is substantial compliance. Just
3 going through the motions is not enough. The notice only
4 informed the public that the ingredient cost would be
5 modified, that it was changing to comport with the federal
6 rule.

7 THE COURT: Can we go back? When you had
8 Dr. Miller's -- she cited to a number of reports. One of
9 those was the Myers and Stauffer survey of dispensing costs
10 of pharmaceuticals in the state of Idaho, and on page 24
11 through 26 of that report there is a list of the dispensing
12 fees and ingredient reimbursements by state.

13 MR. BINA: Yes, Your Honor. I see it.

14 THE COURT: How do those numbers fit with the
15 argument that you're making today? Because when I look at
16 those numbers, they're quite a bit different than the
17 summary that Dr. Miller gave in her declaration attributing
18 certain dispensing fees to the State of Idaho.

19 MR. BINA: It's a great question, Your Honor, and
20 I'm looking at the same page you are. You're right. The
21 numbers are different. I would direct the court though to
22 the very first page of that Iowa dispensing study which is
23 August 2011.

24 THE COURT: I saw that there was a date issue. My
25 first question though was how that goes with the -- it was

1 page seven of Dr. Miller's declaration. And table one
2 where she indicates Idaho, year 2011, mean overall 12 19,
3 Medicaid mean, 12 29. And then there was table one,
4 estimated costs of dispensing for states near Washington.

5 MR. BINA: Your Honor, what I can -- what I can
6 imagine happened is Dr. Miller, who is I think an
7 econometrician and has probably taken the sum total of
8 these states and run the -- I guess she calls it an
9 estimated mean overall of Medicaid costs of dispensing. I
10 don't have an answer handy of why those numbers are
11 different other than saying I expect because it's from 2011
12 and it's before the period where, again, the cost angle
13 came into approach in 2016. Those are still showing AWP,
14 or average wholesale price reimbursements, where, again,
15 the -- that rate is higher than an actual acquisition cost.

16 THE COURT: That would be for the ingredient
17 reimbursement, correct?

18 MR. BINA: Correct.

19 THE COURT: That's not so much for the dispensing
20 fee.

21 MR. BINA: Correct. Correct. Yeah. So your
22 dispensing fees are also going to be low though because
23 again, if you're looking at a total reimbursement model and
24 this is higher, then your dispensing fees ought to be
25 lower.

1 THE COURT: Again though going back to her
2 declaration, is that -- because I understand the argument
3 you're making that this is a 2011 study there are
4 differences, I understand that, but what I'm saying is
5 Dr. Miller gives her figures based on that 2011 Idaho
6 report in that table. And I'm just asking how that matches
7 up to the actual Idaho report itself because just looking
8 through those numbers based on that report I'm not sure I
9 understand how she gets to that conclusion.

10 MR. BINA: Your Honor, I'll look at the next
11 paragraph there, paragraph 28, which she's saying you've
12 got that range between eight and \$14, and certainly Idaho
13 does come down. She's got it listed as \$12.19. Again, I
14 don't have the time to look through all of this, but I can
15 represent that she's, of course, carefully reviewed all
16 this and has done the necessary calculations to come up
17 with that figure. And it could very well be that the cost
18 of dispensing is not necessarily the same thing as the
19 dispensing fee itself. In other words, there is probably
20 some additional figures or calculations to go into that.
21 So it's one thing to have what that cost is; it's another
22 thing to then convert it into the fee because you have to
23 account for location and, again, pharmacy in Seattle versus
24 a county in a rural area. So again, I apologize if that
25 doesn't answer the court's question necessarily, but I

1 think that's where the answer lies.

2 THE COURT: And so I interrupted you. You were
3 talking about the compliance with the Administrative
4 Procedures Act in terms of the notice requirement when I
5 interrupted you.

6 MR. BINA: Thank you, Your Honor. And I'm almost
7 finished. Appreciate the court's indulgence on time here.
8 This is all detailed fairly well in our brief so I won't
9 spend too much time on it, but the concern I'm left with is
10 this predetermined outcome notion, that the state has made
11 up its mind months before the process, and we cited to the
12 *Mahoney* case, which again, full consideration of public
13 comment prior to agency action is both a statutory and
14 constitutional imperative, and quote, "rulemaking conducted
15 without substantial compliance with APA requirements is per
16 se invalid."

17 THE COURT: You're referring to *Mahoney versus*
18 *Shinpoch* which is found at 107 Wn.2d 679. That was
19 actually a case that was decided at the trial court level
20 by Judge Doran, but that dealt with a formal letter from
21 DSHS to the Social Security Administration as opposed to in
22 this particular case there would be e-mail internal
23 communications. Is your position that's the same as the
24 situation in *Mahoney*?

25 MR. BINA: No, Your Honor. I think we cited *Mahoney*

1 really for the proposition that it's a substantial
2 compliance which is key here, and if you miss one of those
3 levels, that's sufficient to strike down the rule alone. I
4 don't think we can draw too close of a comparison just
5 given the facts. It is obviously a different scenario, but
6 that's really the focus on that citation.

7 THE COURT: Thank you.

8 MR. BINA: So Your Honor, to conclude here, as I
9 said, we're looking for the court to order and declare that
10 the rule is invalid both substantively and for any of the
11 alternative reasons that we've given, and in light of that
12 order we would submit that the remedy here is to simply
13 strike down the rule, and the state then would need to
14 reimburse pharmacies and pay pharmacies at the pre-April
15 1st level until such time that they cure this rule and
16 comply with the CMS rule. I thank the court for its time,
17 and I'm certainly happy to answer any questions.

18 THE COURT: Thank you. I appreciate that.

19 MR. BINA: And if I could reserve maybe five minutes
20 for rebuttal.

21 THE COURT: I really don't have any issue. You used
22 your time well, and I'll give you at least ten minutes.
23 Don't worry about that.

24 MR. BINA: Thank you, Your Honor.

25 THE COURT: Mr. Stephens.

1 MR. STEPHENS: Good afternoon, Your Honor.

2 THE COURT: Good afternoon.

3 MR. STEPHENS: Bill Stephens representing the
4 Healthcare Authority. The Healthcare Authority asks the
5 court to deny the motion. We heard a little discussion
6 about what type of motion this is. Just to clear that up,
7 Counsel referred to this as a motion for summary judgment.
8 Technically speaking it's referred -- it's called a brief
9 for order invalidating rule and dispensing fees. So I'm
10 not going to get into a big technical argument about
11 whether there's a big difference here. The point from the
12 state is that the motion should be denied in any event, but
13 if it's a summary judgment motion, then they have to prove
14 that there's no genuine issue of material fact, and they
15 haven't argued that in their brief, and in any event, there
16 are some differences of opinion here, especially between
17 the experts and things as -- other examples would be what
18 did HCA staff do -- (court reporter interruption.)

19 THE COURT: And I will just tell the parties when I
20 prepared for this I did up my own sheet of acronyms because
21 it's a challenge, and I would just ask you all to be
22 thoughtful as to the court reporter because he can be your
23 best friend in terms of making sure to capture what you all
24 mean, and I know it's very easy to slip back into use of
25 acronyms, but at least to begin with you might want to give

1 out the whole number of words and then shift to an acronym.

2 MR. STEPHENS: Yes. I appreciate that. Of course
3 we've been on kind of a campaign not to use so many
4 acronyms in our brief. Sometimes though we slip up on
5 that. In any event, whatever the nature of the motion, it
6 should be denied.

7 The Healthcare Authority complied with all applicable
8 laws when it created the new state rules that took effect
9 on April 1, 2017. First of all, these rules were required
10 under the new federal rules which is why the state
11 undertook this action in the first place. New state rules
12 comply with the overall governing standards that's
13 applicable here, which counsel did not mention in his
14 arguments, which I refer to as section (30) (A). That's the
15 easy way to talk about this. Section (30) (A), the entire
16 citation -- it's a mouthful -- 42 USC 1396a(a) (30) (A). So
17 I refer to this as simply (30) (A) or section (30) (A).

18 So the rules -- the state rules that are required under
19 the new federal rules, the governing standard for the new
20 federal rules is section (30) (A). The state complies with
21 that standard. The new state rules adhere to the
22 substantive requirements of the new federal rules, and the
23 state adopted these new state rules in full accordance with
24 all of the procedural requirements of the Administrative
25 Procedure Act. So that's reason enough alone for the court

1 to rule in the state's favor and deny the motion.

2 The state also has pointed out that the court could
3 defer action until such time as CMS -- excuse me -- the
4 Centers for Medicare and Medicaid Services, which is the
5 federal oversight agency for the Medicaid program,
6 completed its action on the state plan amendment, or SPA,
7 that the state has submitted to CMS with regard to these
8 new state rules. So the new state rules, of course, are in
9 effect. They took effect April 1. But in order to receive
10 federal funding, the state needs to get approval from the
11 federal government for the content of these new state
12 rules.

13 So that process is going on right now. It's not
14 completed. The SPA was submitted several months ago. CMS,
15 as allowed by its own rules, submitted to the state a
16 so-called request for additional information, or RAI in
17 bureaucratic parlance, and the state had a 90-day deadline
18 for responding to that RAI. That response was just
19 submitted on the deadline which was Wednesday December 20.
20 And if the court would like, I brought copies of the entire
21 RAI answers that could be considered by the court today, or
22 as part of its overall consideration.

23 THE COURT: The court is only going to consider the
24 things that were properly filed.

25 MR. STEPHENS: It was just late-breaking news so I

1 just wanted to mention that the answers have been
2 submitted. In other words, the key thing here is that the
3 process is still going on. Contrary to what the
4 petitioners suggest, this is not a done deal. Yes, there
5 has been informal comments by midlevel CMS staff with
6 regards to the draft SPA that the state had put together
7 and then the final version that the state submitted a few
8 months ago, but that's not a final decision. This hasn't
9 reached the upper levels of CMS management. I would doubt
10 that the CMS lawyers who are the ones who look at the
11 content of the statutes and the regulations, I doubt that
12 they've been involved. So this is an ongoing process.

13 So one option would be for the court to wait to see what
14 the experts at CMS have to say about this and defer ruling
15 on the motion or deny the motion until such time as that
16 happens again because all roads in this case lead back to
17 these new federal rules, what do those rules mean, how do
18 they comport with the overall governing standards of
19 section (30) (A) and did the state comply with those new
20 federal rules and the governing standard when it created
21 the new state rules.

22 So let me talk about why the state complied with this
23 governing federal standard which I refer to as (30) (A).
24 Section (30) (A) tells the states when it devises payments
25 rates to pharmacies or any other medicaid provider that

1 those rates must be consistent with four things:
2 Efficiency, economy, quality of care and access to care.
3 Those are the four governing standards in section (30) (A),
4 and the federal rule -- the new federal rules themselves
5 make reference to the fact that the governing standard is
6 (30) (A). That's referenced at 42 CFR 447.518D, and it's
7 also referenced in the Federal Register entry that
8 introduced the new federal rule, so 81 Federal Register at
9 5310, and again also referenced in a formal letter that CMS
10 sent to the state Medicaid director explaining the new
11 federal rules and offering some guidance as to their
12 implementation, that letter dated February 11, 2016.
13 That's included as attachment A to the Myra Davis
14 declaration that we had submitted. So again, a clear
15 acknowledgment that the governing standards is section
16 (30) (A).

17 The petitioners had not introduced any evidence in this
18 case to suggest that the state is out of compliance with
19 section (30) (A). There's no evidence of any problem with
20 access to care. There's no evidence of any problem with
21 quality of care. There's no evidence that these rates are
22 anything -- that they're inefficient or not economic. In
23 fact, the only evidence in the case supports the state's
24 conclusions that the state is in compliance with (30) (A).
25 I refer to the Myra Davis declaration where she points out

1 that there's been no problems with access to care, that the
2 level of participation by the pharmacies in the Medicaid
3 program has remained constant, that the vast majority of
4 pharmacies do participate in the program. There's been no
5 evidence of a lack of quality of care. So the state is in
6 compliance with section (30) (A). The petitioners' own
7 studies in fact that were included with Dr. Miller's
8 declaration also support the conclusion that section
9 (30) (A) is the governing standard, and that's what we must
10 refer to when determining whether the rates comply with the
11 new federal rules and section (30) (A), and I refer in
12 particular to -- so it's Exhibit C to the Miller
13 declaration which is a California study done by Mercer on
14 page nine. There's a reference right there to the fact
15 that the state is responsible for insuring that pharmacy
16 reimbursement is consistent with the requirements of
17 section (30) (A) of the Social Security Act which specifies
18 that provider reimbursement rates should be "consistent
19 with efficiency, economy and quality of care" while
20 assuring sufficient Medicaid beneficiary access. That's
21 right there at the beginning of her own study, and that
22 tells us that that is the governing standard. That's what
23 California needed to meet. That, of course, is what
24 Washington needs to meet.

25 I'd also point to a study that Your Honor mentioned

1 earlier, the Idaho study which is Exhibit E to Miller's
2 declaration talking about factors that must be considered
3 and could be considered when the state -- when a state
4 comes up with pharmacy payments. I think these are very
5 interesting words from the petitioners' own expert as she
6 -- as she relies upon this herself, the Myers and Stauffer
7 study about the Idaho situation. And in this study it says
8 the following on page six: "There are several factors that
9 should be considered in determining an appropriate Medicaid
10 pharmacy reimbursement formula besides dispensing costs
11 incurred by pharmacies. These factors include drug
12 acquisition costs and market dynamics, for example the
13 rates accepted from commercial third-party payers balanced
14 with the need to maintain sufficient access to services for
15 Medicaid recipients throughout the state." We just heard
16 counsel -- end quote. We just heard counsel say a minute
17 ago the rates that a pharmacy might accept from a
18 commercial third-party payer aren't relevant and are not
19 important, yet that factor is cited right here in their own
20 expert reports. The Idaho report continues, quote,
21 "Perhaps the most important factor to consider is the need
22 to maintain sufficient patient access to pharmacy services
23 for Medicaid recipients throughout the state. Medicaid
24 pharmacy programs must be aware of the issue of
25 accessibility of services and ensure that reimbursement

1 levels are adequate to provide Medicaid recipients with
2 reasonable levels of access to pharmacy services." Again,
3 the key thing, access. There's no allegation here that
4 there's any problem at all of access to care for services.

5 THE COURT: Mr. Stephens.

6 MR. STEPHENS: Yes.

7 THE COURT: I'll ask you though, Mr. Bina talked
8 about there was a short-fall for his clients that I believe
9 he approximated a figure of 12.3 million. How do you
10 factor that in to this discussion?

11 MR. STEPHENS: Well, a couple of different ways.
12 First of all, there's no evidence in the record to support
13 any such conclusion. The Dr. Miller declaration which was
14 completed months ago does not address at all what has
15 happened in real life in the nine months since the rule
16 took effect. So there's no evidence in this record to
17 prove that pharmacies have suffered a \$12.3 million hit
18 economically. That's the first thing.

19 Second of all, the question of access to services.
20 These pharmacies are still participating in the program. I
21 mean, if they're really losing money on every prescription,
22 how is it that they even continue to participate in the
23 program? I mean, it just doesn't make sense.

24 The other thing -- I'm going to jump ahead a little bit
25 here. Counsel said that the remedy they're seeking is

1 invalidation of the new state rules. Well, even if the
2 court were to rule that, that would have no effect at all
3 on the level of dispensing fees. The dispensing fees are
4 contained in the billing guides. The methodology is in the
5 rule in full compliance with the APA. But invalidation of
6 the rule would not in and of itself lead magically to the
7 ten or eleven million dollar dispensing fee that the
8 petitioners are asking for. That wouldn't necessarily
9 result at all. Because as counsel points out, if the state
10 were to dramatically increase its fee, it would then have
11 to go back to CMS and say here's why we're doubling or
12 tripling our fee, so we would be in the reverse situation
13 of trying to get the federal government to pay between 50
14 and 70 percent more for a fee that might not be justified
15 based on market factors and other things cited by the
16 plaintiffs' own experts.

17 The last one that I wanted to point out was the Oregon
18 study which is Exhibit G to Dr. Miller's declaration on
19 page five, similar to the conclusion in the Idaho report
20 talking about the fact that rates from commercial third-
21 party payers and the need to maintain sufficient access are
22 factors that a state should consider when looking at its
23 pharmacy rates.

24 THE COURT: I believe that language is the Myers and
25 Stauffer language that they generally have included in all

1 their reports.

2 MR. STEPHENS: Yes. They're almost exactly the
3 same. But then at the end of this one on page five of this
4 report it says, quote, "One way to evaluate accessibility
5 to services" -- I don't think this is an exact quote from
6 the previous one. "One way to evaluate accessibility to
7 services is to -- (Reporter interrupts.) Quote, "One way
8 to evaluate accessibility to services is to analyze
9 pharmacy participation levels as well as any additional
10 data sources available for tracking complaints about
11 recipient access to services. A high level of pharmacy
12 participation and low levels of complaints about access
13 might suggest that there are not any problems regarding
14 access to services under the current Oregon health plan
15 reimbursement levels." Close quote.

16 The reason I mention that is because the only evidence
17 in the record in this case is that there is a very high
18 level of pharmacy participation in Washington's Medicaid
19 program and an extremely low level of complaints about
20 access to services to -- in the program. And in fact, as
21 far as complaints, since the state implemented the new
22 state rules on April 1, as far as complaints from
23 pharmacies themselves, not Medicaid beneficiaries, there
24 have been, as Myra Davis points out in her declaration, a
25 grand total of two phone calls to the state's hotline

1 regarding the pharmacy rule, two. One was just a question
2 about whether the rule was in effect or not, and the other
3 one was a question -- kind of an obscure question not
4 directly related to the level of the reimbursement.

5 So the studies that the plaintiffs themselves cite
6 support the state's position in this case. Similarly,
7 there's no evidence from any Medicaid client about a
8 problem with access to services or quality of care. If
9 there was a problem, then the plaintiffs should have
10 brought forth declarations from Medicaid clients about
11 problems they were having. There's no evidence in that
12 way. So there's compliance by the state with the
13 requirements of (30) (A) of efficiency, economy and quality
14 of care and access to care, and there's no evidence to the
15 contrary.

16 With regard to the new federal rules themselves, as
17 counsel has pointed out, one change was to the ingredient
18 cost side, and then of course to the dispensing fee side.
19 The plaintiffs are not complaining about the change the
20 state made to the ingredient cost side. Now, as far as the
21 dispensing fee side, the plaintiffs have -- petitioners.
22 Excuse me -- have suggested that the state was required to
23 do a cost-of-dispensing study before finalizing the new
24 state rules. There's nothing in the plain language of the
25 new federal rules that requires any such study. There's

1 certainly nothing in the governing standard of section
2 (30) (A) that requires it either. And in fact, there are
3 multiple instances in the Federal Register where CMS
4 introduced the new federal rules where the idea of the
5 requirements of a cost-of-dispensing study was explicitly
6 rejected.

7 THE COURT: I took from petitioners, and I'm sure
8 they'll correct me if I'm mistaken, but not so much to say
9 that a study had to be done, but that there had to be some
10 data that the state was relying on when it looked at
11 professional dispensing fees for Medicaid beneficiaries.
12 And I think that was the point of that particular attack on
13 the process the state employed in this case.

14 MR. STEPHENS: But then they conclude by saying that
15 you have to do a full-blown cost-of-dispensing study
16 similar to what some of these other states have done. But
17 in any event, the state relied upon the studies that Myra
18 Davis cited to in her declaration and including what the
19 pharmacies are accepting from other payers. It is reliable
20 data to support that these rates are consistent with the
21 section (30) (A) standards.

22 THE COURT: How do you respond -- and I know you
23 responded in some way in the briefing, but regarding the
24 fact that there are different approaches taken by different
25 states which looked at in a favorable light to the

1 petitioners certainly support their premise that dispensing
2 fees in those other nearby states are at quite a higher
3 rate than Washington is using, how do you respond to that?

4 MR. STEPHENS: Well, we don't know what all the
5 factors are that went into the conclusions by those states
6 as to why the dispensing fees would be at a certain level,
7 what the market forces are in those states, what the costs
8 might be that those pharmacies incur as compared to
9 Washington pharmacies, what -- like I say, what they're
10 accepting from other payers.

11 THE COURT: Did the state look at those other
12 reports, the experts within the Healthcare Authority look
13 at these other reports that are cited to by petitioners?

14 MR. STEPHENS: I don't know that they look in
15 particular at these studies that Dr. Miller has cited. In
16 the context of the litigation they did, but whether they
17 did before the new state rules were finalized I don't know.

18 But in any event, again, the guiding standard being
19 section (30) (A) and what (30) (A) requires, the state, you
20 know, got the information from Milliman and the other
21 studies and made its conclusions, and you know, kept the
22 dispensing fees where they had been.

23 THE COURT: And the petitioners make points that CMS
24 employees put a number of questions and some could say they
25 had a critical edge to them about the approach that the

1 State of Washington is taking. And have you how do you
2 respond to that?

3 MR. STEPHENS: I would agree there's been some
4 tension between what I would refer to as the midlevel CMS
5 staff and the midlevel Healthcare Authority staff with
6 regard to what the new federal rules do or don't require in
7 terms of the dispensing fee. The fact is the literal
8 language of the new federal rules in terms of dispensing
9 fee did not change. The only two changes were to add the
10 word "professional" in front of "dispensing fee" and to
11 change the word "recipient" to "beneficiary." But as far
12 as the substance of the rule as to what the methodology is,
13 that did not change at all. So --

14 THE COURT: I had noticed that as well. But isn't
15 it then the interplay of how the reimbursement for the
16 ingredients is and how that effects the dispensing fees?

17 MR. STEPHENS: Yes. You're right. The new federal
18 rules require that you have to look at both sides of the
19 coin when you're going to change anything or if you're
20 contemplating changing anything. So here when the state
21 was required to adopt this new actual acquisition cost
22 method on the ingredient cost side, it was required to look
23 at the overall reimbursement rate that would result, the
24 combination of the dispensing fee plus the ingredient cost.
25 And the state -- the state did do that. The change in

1 Washington on the ingredient cost side was very minimal
2 compared to some other states as Myra Davis explained in
3 her declaration. So this was different from some other
4 states where the methodology -- you know, there's an old
5 joke among Medicaid lawyers like me. If you've seen one
6 Medicaid program, you've seen one Medicaid program, meaning
7 that they're all different. There's the over-arching
8 federal standards of course, but every state is so
9 different, and including how they pay pharmacies. Some of
10 these studies point that out.

11 THE COURT: Thank you.

12 MR. STEPHENS: So I was talking about the federal
13 register and the cost of dispensing, that it's not a
14 requirement to do such a study. I would just point out
15 there's a couple of places where on page eleven of their
16 original motion the petitioners cite to two of those
17 Federal Register entries, but they don't read to you or
18 give to you the complete sentence, and I think it's
19 important to do so. So for example, I'm talking about
20 attachment I to Ms. Nicholson's declaration. So which is
21 -- the Federal Register entry I'm talking about is page 53
22 ten. And the part that they highlight is -- says, quote,
23 "We agree" -- meaning we at Centers for Medicare and
24 Medicaid Services. "We agree that the total reimbursement
25 should consider not only the pharmacy's cost to acquire the

1 drug but also the pharmacist's professional services in
2 dispensing the drug." That's what they cite to, but they
3 don't cite the remaining part of the sentence. "However,
4 we do not agree that states must conduct surveys to revise
5 dispensing fees. Rather, they have the option to submit
6 data other than a survey which demonstrates that the total
7 reimbursement to the pharmacy provider is in accordance
8 with the requirements of section (30) (A)."

9 So again, it's going to the point that CMS doesn't
10 require certain steps to be taken. It leaves great
11 flexibility to the states as to how they're going to get to
12 the end result, and we pointed out some of the other
13 Federal Register entries that get into that, and the same
14 thing in that state Medicaid director letter that was
15 attached to Myra Davis's declaration.

16 I want to get on to the state APA arguments. Again, the
17 state did everything it was supposed to do under the APA
18 when it created these new states rules. We've pointed out
19 the five steps a state agency must take when it creates,
20 amends or repeals a rule. You have to file a proposed
21 notice of inquiry, a CR 101 as we call it. The state did
22 that. You have to file the text of the proposed rule, a CR
23 102. The state did that. You have to hold a public
24 hearing. The state did that. Then you have to file the
25 final draft of the rule, the CR 103. The state did that.

1 Then you have to prepare the concise explanatory statement.
2 The state did that. All those steps were complied with.
3 The petitioners were fully aware of what the state was
4 doing. The petitioners submitted comments to the state.
5 This is included in the Wendy Barcus declaration attachment
6 E, a letter from the National Association of Chain
7 Drugstores dated December 12, 2016. This was even before
8 the text of the draft rule, the 102, was completed because
9 the association had been notified by the Healthcare
10 Authority of the possibility of amendments to the pharmacy
11 rules.

12 And so then the state's response a month later is also
13 provided in the Barcus declaration attachment F, again
14 before the public hearing. In the letter HCA stated that
15 the studies that Ms. Davis has cited to in her declaration,
16 quote, "document the sufficiency of the current fees,"
17 close quote. And the state also assured the association
18 that the Healthcare Authority was, quote, "not proposing to
19 lower dispensing fees," close quote. In fact, the claims
20 made by the association in that December 12, 2016, letter
21 are really the crux of their claims in this lawsuit. It's
22 simply not credible for the petitioners to suggest that
23 they had no idea until March of 2017 what was going on with
24 these rules or what the dispensing fees might be. They
25 knew that the fees were not going to be increased because

1 they had been told in the letter from the Healthcare
2 Authority that the studies that they were looking at and
3 document the sufficiency of the current fees. So the
4 petitioners claim that there's some sort of violation of
5 the APA because they weren't told until after the entire
6 process was over with that the fees were not going to be
7 changed, and that's not true. Plus they of course had the
8 right to attend the public hearing even after this exchange
9 of correspondence, and they did not.

10 I want to get into this -- there was a discussion of the
11 *Mahoney* case. To me the key factors as to why the *Mahoney*
12 case is not applicable, two things. In that case the
13 defendant agency, the Department of Social and Health
14 Services, argued in the first instance that the APA didn't
15 even apply to the situation, and of course we're not in
16 that situation at all. The Healthcare Authority concedes
17 that the APA applies, which of course is why the HCA went
18 ahead and followed all those steps that I outlined with
19 regard to the APA. The second, DSHS then conceded that it
20 had violated the APA, which of course is why DSHS was
21 trying to argue that the APA didn't apply in the first
22 place because it had made a concession to the trial court
23 that it was in violation of the APA. We, of course, make
24 no such concession. And the entire premise of that *Mahoney*
25 case doesn't apply to our situation.

1 Their final argument was with regard to the concise
2 explanatory statement. There was a suggestion in there --
3 by the way, this argument was about the CES or concise
4 explanatory statement was made for the first time in the
5 reply brief, and that's well settled that you can't do
6 that. I would give you a case citation for that, *Cowiche*
7 *Canyon Conservancy versus Bosley*, 118 Wn.2d at 801. But in
8 any event, the state did everything it was supposed to do
9 with regard to the concise explanatory statement. The
10 requirement is to prepare the CES. You don't have to file
11 it with the code reviser. The CES was prepared and it is
12 part of the rulemaking file.

13 Then there was a suggestion about that it wasn't
14 completed in time or something like that, but there's -- we
15 have -- and again, I realize the court is not going to
16 likely accept this, but we do have a declaration from Wendy
17 Barcus which was done in response to the reply brief where
18 she outlines the timeframe of the CES. And there's just --
19 there's no evidence to support the allegation that the CES
20 was not completed in time.

21 And finally, I would just, again, point out the
22 practical realities. First of all, after we get through
23 the point that the state has complied with section (30) (A),
24 the state has complied with the new federal rules, the
25 state has complied with the APA, we get down to what I --

1 again what I'm calling the practical realities. We've been
2 here for nine months under the new state rules. Where is
3 the harm? There's no proof of any harm. The pharmacies
4 are still in business. They're still providing care to
5 Medicaid clients. And there's still a very high level of
6 participation, no allegations of a lack of access to care
7 or a lack of quality care. So the practical realities are
8 another reason for the court to deny their motion.

9 And that's our arguments. This is where we ask you to
10 deny the motion. Thank you.

11 THE COURT: Thank you, Mr. Stephens.

12 MR. BINA: Your Honor, I'll conclude here in five to
13 ten minutes, and if I go long, please just let me know.
14 Sometimes I get a little carried away.

15 THE COURT: I realize this is an important issue to
16 both parties, and so like I said, I'm fine. You're fine
17 with time.

18 MR. BINA: Thank you, Your Honor.

19 THE COURT: I'd rather get everything out. Let's
20 hear it.

21 MR. BINA: Your Honor, the state's response there
22 was interesting for several reasons, and I'll go point by
23 point here in some of my notes. But they again push this
24 idea that the court ought to delay decision until CMS takes
25 some action while the SPA or state plan amendment is still

1 pending. And I was a little troubled by the late-breaking
2 news that they apparently have sitting on the table to my
3 direct right whatever submission they had the other day,
4 and I've been in this case *pro hac* for at least two or
5 three months, and co-counsel has been certainly with this
6 case for the past nine months. My e-mail and phone number
7 and counsel's number -- I would appreciate knowing that
8 before I walked in here this morning, and that's just
9 troubling me. But look, it doesn't change the fact,
10 whatever they submit, does not detract from this court's
11 independent jurisdiction, ability, and we would submit
12 duty, to strike down a rule that has taken place in this
13 matter.

14 Counsel made -- spent a lot of time talking about
15 section (30) (A) of the Medicaid Act, and the reason we
16 didn't address this in oral argument, Your Honor, is
17 because this is not a section (30) (A) case. Section
18 (30) (A) case, of course, would be the classic fact pattern
19 where I represent let's say a Medicaid beneficiary or one
20 of these independent pharmacies who I've got
21 representatives here today, we would run into federal court
22 and say, Your "Honor, we're going out of business," or
23 "Mrs. Jones can't get her blood pressure medication and the
24 reason is the state's not paying us enough." We're not
25 making that claim, and we never have. Our papers never

1 raised that issue. One reason is because the Supreme Court
2 in 2014 I believe in the *Armstrong* case made it very clear
3 that section (30) (A) is not an independent -- does not vest
4 jurisdiction on parties any more so that quieted down the
5 section 30 claims at least on the beneficiary side.

6 But that's not why we're here today. But what I would
7 submit, Your Honor, is we understand certainly how the
8 statutes and regulations interplay both at the state and
9 federal level. Section 30 is the ultimate in vagueness. I
10 know my colleague who's a Medicaid expert can understand.
11 There's been reams of decisions talking about how vague
12 Medicaid law is. But I would submit, Your Honor, that the
13 CMS regulation, what we call the CMS rule here, that is the
14 agency speaking. That is the agency using what I would
15 call chevron deference to understand really where the
16 agency is coming down. So on the one hand you have section
17 30 with congress telling the states you need to make sure
18 you pay sufficient monies to attract enough pharmacies to
19 take care of beneficiaries, and we're not going to tell you
20 how to do that. Absolutely agree with the idea that
21 there's no set methodology. But Your Honor, when he was
22 talking about that -- and we cited this in our brief. This
23 is the *Hoag Memorial Hospital versus Price* case, 866 F.3d
24 1072. That's a Ninth Circuit case that came down this
25 year. There's a line in there that struck me, and I began

1 circling it vigorously when counsel said that. And I'm
2 going to quote here, and this is on page 1079. "Although
3 section (30) (A) grants states considerable latitude in
4 selecting a method for calculating reimbursement rates and
5 does not impose any particular method or process for
6 meeting its substantive requirements, that latitude is not
7 limitless."

8 So Your Honor, they can't just pick a figure out of thin
9 air or decide, as we had in this scenario, months before
10 the date the methodology was to occur. There needs to be
11 some guide rails, and the CMS rule is that guide rail that
12 tells us, the blueprint I mentioned earlier, of how these
13 actual costs are to be determined. There needs to be
14 adequate and reliable data. We just do not have that.

15 Your Honor, counsel then turned to some of the exhibits
16 and Dr. Miller's report and he talked about California and
17 Idaho and how those studies apparently in the contents says
18 it's okay to rely on third-party private payers, that it's
19 fine. Your Honor, the Idaho and California report are from
20 2011. It precedes the CMS rule by five years. So while
21 that may have been the law five years ago, as of April 1st,
22 2017, the CMS rule doesn't address private pay anywhere.
23 It addressed, again, in the blueprint you will get adequate
24 and reliable data, and in this scenario that adequate and
25 reliable data CMS says you can do that by doing a

1 cost-of-dispensing study if you like, but you don't have
2 to, but if you don't do a cost-of-dispensing study, find
3 some other adequate and reliable data. Again, it's
4 frustrating to hear the state take some of these positions.

5 THE COURT: So Mr. Bina, I asked the state about the
6 interplay of the ingredient reimbursement in the dispensing
7 fee, but the state correctly pointed out that the
8 definition of dispensing fee to professional dispensing fee
9 was near verbatim.

10 MR. BINA: Right.

11 THE COURT: How does that factor into your analysis
12 and your argument?

13 MR. BINA: It's an excellent question, Judge, and
14 one that frankly when we were constructing this lawsuit we
15 scratched our heads. And the best I'm left with is, again,
16 the state only did about half of what they were supposed to
17 do. They did correctly change the definition of
18 "professional dispensing fee." And if we look at that it
19 -- I'm happy to quote it if it's helpful, but it
20 essentially says -- I'm paraphrasing -- that you are to pay
21 the actual costs, again parrots the CMS rule. The problem
22 though, Judge, is elsewhere in that regulation when they
23 have the dispensing fee section and it talks about what
24 they can rely on when calculating that dispensing fee, that
25 regulation continues to have in it what it had five, ten,

1 fifteen years ago, the language that allows it to look at
2 third-party payer data. So we would submit, Your Honor,
3 the state erred by not eliminating that section of its
4 regulation, and its improper. In other words, they didn't
5 edit it properly. So while the definition appears to be
6 fine and tracks the language, elsewhere in the rule there's
7 that internal tension, and that goes to our alternative
8 argument that they violated their own rule.

9 So Your Honor, this is not a section (30)(A) case.
10 We're not here for that reason. This has from day one been
11 a state APA case. I don't want to spend too much time on
12 that. Counsel also said well, if the court were to strike
13 down this rule somehow there must be some *sue sponte*
14 calculation for jacking up the dispensing fee. We're not
15 asking for that, Judge. What we're asking for is to strike
16 down the rule. Let's put us back in the same place we were
17 on March 31st, the same relief we were going to ask for you
18 on an emergency basis. Let's stay all of this until we can
19 figure out what's going on. Now we're into a scenario
20 where the rule is already into effect. The relief we're
21 seeking is simply strike down the rule, go back to that old
22 ingredient cost until the state can then re-promulgate and
23 do whatever it needs to do. Again, we're not going to
24 force the methodology. We just simply want the right and
25 adequate data to be used.

1 Now, Your Honor, counsel mentioned also that the record
2 is very clear that there is high participation in
3 Washington Medicaid among pharmacies and low complaints.
4 No one's calling into the state's office about this issue.
5 Now, I don't think the state knows or we know standing here
6 today what the participation rate is. I don't know that it
7 matters necessarily because it's not a section (30) (A)
8 case. So I think that's all outside the record and
9 speculative.

10 But as to the complaints, Judge, the reason no one's
11 calling to complain is because they called me to file this
12 lawsuit. That's what we've been working on. That's why
13 the phones aren't ringing off the hook. Now, if there's
14 access problems, counsel's suggesting we should come in
15 this with affidavits from these pharmacy owners and others.
16 Again, this is not a section 30 case. It's an APA claim.

17 Counsel mentioned you see one Medicaid problem, you've
18 seen one, which I think I agree with. There is some
19 diversity there, and I appreciate that comment. And while
20 every program is different, every state is different, and
21 that's the beauty of this country. The one thing that is
22 consistent that binds us, and this is the essence of
23 federalism, is that CMS rule. The states, from Maine to
24 Florida to Washington, however you want to do it, as long
25 as you follow our blueprint, and that blueprint, the

1 touchstone of that is costs, and that's what the state is
2 not paying today, and that is why this rule needs to be
3 struck down.

4 I believe that would conclude my remarks, Your Honor,
5 unless there's any questions.

6 THE COURT: No. I think you've answered them.
7 Thank you.

8 Well, what I plan to do is we're going to take our
9 midafternoon recess, and then when we come back from that
10 I'll give my ruling. It is 2:47 now. I'll come back out
11 on the bench at 3:15. Thank you.

12 (A recess was taken.)

13
14 THE COURT: Please be seated.

15 Well, I realized when I got back there that, of course,
16 there was a question that I wanted to hear from Mr. Bina
17 about. So I apologize. But before we get to a ruling, I
18 wanted to hear -- Mr. Stephens had brought up the standards
19 in this case because obviously the three counts that were
20 alleged initially in the petition for declaratory relief
21 and emergency stay all fell under RCW 34.05.570. But then
22 there was a discussion of the standards for summary
23 judgment, and so what was your position, Mr. Bina, on the
24 standard the court's to look to in deciding the case?

25 MR. BINA: Your Honor, I appreciate the comments. I

1 will say that the governing standard is certainly the RCW
2 standard that we cited in the petition and also cited in
3 the motion. The reason that we went for summary
4 judgment -- and I'll just lay it out in the record here.
5 We went back and forth on that. The reason we added in the
6 summary judgment is because we found that in some of the
7 other case law that some of the -- for example the *Failor*
8 case I believe that was granted. That was on a summary
9 judgment situation as well as *McGee*, and other cases, not
10 just involving healthcare cases. So frankly, Judge, I
11 didn't want to get too hung up on that when we were
12 drafting our brief. But certainly the actual standard of
13 review would be RCW 34.05.570. As to, again, violating the
14 statutory authority of the agency, the rule's adopted
15 without compliance. The summary judgment was more of a
16 mechanism to empower the court to make that declaration,
17 and again, part of that confusion was counsel and I were
18 figuring out how to title this. In the lower left-hand
19 corner of the brief we determined to call it the motion in
20 support of striking down the rule. And that was more
21 consistent with that citation I just read to you, whereas
22 the motion for summary judgment we were covering our bases
23 because we thought if that is an alternative way in which
24 to get that relief, and again based on the other case law,
25 it was frankly a little unclear under an APA case how those

1 are to be brought before the court, and that's why we
2 decided to call it both.

3 I know it's a long explanation on a procedural point,
4 but it's one that I don't think changes the ultimate
5 relief, and we would agree -- or we would submit that we
6 think both standards have been met. Certainly the state
7 has to concede that they've -- again, this is -- this is a
8 case that can be decided on summary judgment because the
9 rule is out there. We know that that's what it says. The
10 e-mails that are in the record are out there. There's no
11 dispute on that. The CMS rule is out there. So we think
12 that could be one alternative way in which the court could
13 rule. But given the APA and its peculiar way of giving the
14 court the ability to enter declaratory injunction, that
15 could be an alternative path to granting that, Your Honor.

16 THE COURT: Thank you.

17 MR. BINA: Thank you.

18 THE COURT: And Mr. Stephens, not an invitation to
19 get back into necessary argument, but based on Mr. Bina's
20 explanation of petitioners' view of the standards does the
21 state or does the Healthcare Authority add or make any
22 additional record on that point?

23 MR. STEPHENS: Well, I guess just briefly I would
24 say the explanation was a little confusing to me. So I'm
25 still not sure where they're coming from, but if it's an

1 APA case, then the standard is error of law or arbitrary
2 and capricious action or violation of the constitution,
3 those things. If it's summary judgment, then it's are
4 there any genuine issues of material fact and are they
5 entitled to summary judgment as a matter of law. So I'm
6 still not totally sure where they're coming from. I think
7 he's trying to give you alternate paths to go down, but
8 they haven't briefed those. They simply didn't brief the
9 summary judgment so I'm a little unclear where they're
10 coming from. Naturally I'm going to conclude that the
11 motion should be denied whatever it's called because I
12 don't think they met either standard.

13 THE COURT: Well, I think Mr. Bina would say it
14 should be granted under either theory.

15 MR. STEPHENS: Yes. Well, I certainly agree with
16 that. But if it's summary judgment, then either -- if the
17 state had moved for summary judgment, then I could see
18 granting summary judgment because there would be no genuine
19 issues of material fact that would preclude that. But from
20 the way they're arguing, all these comments about what the
21 CMS staff has said or what they haven't said, what the
22 experts are saying, what the experts are not saying, I
23 think those present genuine issues of material fact so
24 certainly summary judgment should not be granted in their
25 favor.

1 THE COURT: Thank you.

2 Well, it's an interesting case. I've spent a lot of
3 time thinking about it. I found both your arguments to be
4 helpful. Briefing was helpful. This is certainly a
5 complicated area of law I think everyone would agree.

6 For me, I look back to the initial petition that was
7 filed by the petitioners which alleged three separate
8 counts, one of those being an alternative count, but the
9 first count was declaratory judgment under the Washington
10 Administrative Procedure Act regarding the ingredient cost,
11 reimbursement. And the way this was initially premised was
12 everything falling under RCW 34.05.570 that the petitioners
13 requested that the court find that the rule exceeded the
14 statutory authority of the agency, that the rule was
15 arbitrary and capricious and/or that the rule was adopted
16 without compliance with the statutory rulemaking
17 procedures.

18 I take it you'd agree with that, Mr. Bina.

19 MR. BINA: Yes, Your Honor.

20 THE COURT: Count two was declaratory judgment under
21 the Washington Administrative Procedure Act regarding the
22 professional dispensing fee, and then in the alternative
23 count three, another declaratory judgment under the
24 Washington Administrative Procedure Act regarding the
25 professional dispensing fee. And those are laid out in the

1 petitioners' original petition.

2 The court would state and rule that the rule here was
3 adopted with the correct rulemaking procedures, and so I'm
4 denying a basis of relief for the petitioners which alleges
5 that the rulemaking procedures were not followed. I don't
6 believe they have carried their burden in showing that.

7 The arguments that the Healthcare Authority exceeded
8 their statutory authority and/or were arbitrary and
9 capricious when adopting the rule are certainly more
10 interesting to the court. But when the court goes through
11 the record, the declarations, the case law cited, the
12 briefing of the parties, I don't find that the petitioners
13 have carried that burden. So said in another way, I don't
14 think the burden has been carried to show that the
15 Healthcare Authority was arbitrary and capricious, and I
16 don't find the petitioners have shown that the Healthcare
17 Authority has exceeded its statutory authority, and so I am
18 denying the relief sought by the petitioners.

19 I clearly have not adopted the state's position that the
20 court should somehow defer and wait. I don't believe
21 that's appropriate for the reasons, Mr. Bina, that you put
22 forth. I think a ruling needs to be made, and this court
23 is well aware that a higher court may weigh in on this
24 issue. But when the court goes through and looks at what
25 the state did in this case based upon direction from the

1 CMS, which in another way the Federal Centers for Medicare
2 and Medicaid Services, and looks at how the state
3 implemented their state process by going through the APA,
4 while one could argue that the state could have done things
5 differently, I don't find that the petitioners have
6 satisfied their burden as laid out in RCW 34.05.570 and the
7 progeny of cases that have interpreted those standards.

8 So I'll turn to you, Mr. Stephens. Do you have any
9 clarifying questions?

10 MR. STEPHENS: No, Your Honor, I do not.

11 THE COURT: Mr. Bina, do you?

12 MR. BINA: No, Your Honor.

13 THE COURT: Very well. Well, if the parties are
14 able to formulate an appropriate order that can be agreed,
15 that could certainly be presented through the court's *ex*
16 *parte* process, or if they cannot, can be put on for
17 presentation. But again, I want to thank all of you for a
18 very interesting and I think well-researched and well-
19 argued case.

20 And with that, I'll wish you all a good holiday and the
21 court will be in recess.

22 (A recess was taken.)
23
24
25

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Dated this 29th day of December, 2017

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