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COURT OF APPEALS
STATE OF WASHINGTON

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

Petitioners/Appellants,

vs.

WASHINGTON STATE HEALTH CARE AUTHORITY and
Dorothy Frost Teeter, not individually, but solely in her official
capacity as Director of the WASHINGTON STATE HEALTH
CARE AUTHORITY,

Respondents/Appellees.

REPLY BRIEF OF PETITIONERS

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INTRODUCTION

This appeal may be distilled to one basic question: Did the Agency comply with the CMS Rule?¹ And, as to that, CMS has now spoken. On September 10, 2018, CMS issued a letter ruling stating in the plainest possible terms that the Agency’s professional dispensing fees for Washington pharmacies do not comply with the CMS Rule and violate federal law. *See* 9/11/18 Statement of Additional Authorities (the “CMS Denial Letter”).²

In its brief, the Agency argued that its dispensing fees complied with Section 30(A) of the Medicaid statute (42 U.S.C. § 1396a(a)(30)(A)) as well as the CMS Rule. But now, especially in light of the CMS Denial Letter, such an argument cannot stand. In fact, the CMS ruling tracks and agrees with the Pharmacies’ opening brief in this appeal. In particular, CMS states that the Agency’s dispensing fees do not comply with

¹The defined terms or abbreviations used in the Pharmacies’ Opening Brief are used in this Reply Brief.

² The Agency filed the CMS Denial Letter as an additional authority under RAP 10.8 on September 10, 2018—prior to the date of this reply. Consequently, this reply responds pursuant to RAP 10.3(c) to the issues raised by the Agency including the CMS Denial Letter, which directly relates to the issues in the briefing.

Section 30(A) and the CMS Rule because (a) the Agency’s dispensing fees must reflect actual costs and (b) the Agency has failed to provide adequate data to demonstrate how those dispensing fees complied with that requirement. CMS also points out that despite CMS requesting the Agency to provide such information, it failed to do so.

The Pharmacies’ opening brief demonstrated that the Agency failed to comply with the CMS Rule. The CMS Denial Letter now confirms that conclusion. This reply will discuss the CMS Denial Letter, why it is entitled to substantial deference, and why that ruling requires that the Agency’s decision setting dispensing fees be reversed. This Court should direct the Agency on remand to set dispensing fees that cover pharmacies’ costs retroactive to April 1, 2017—the compliance deadline set by the CMS Rule.

ARGUMENT

A. The CMS ruling confirms that the Agency’s dispensing fees fail to comply with federal law.

The Agency’s brief relies heavily on the general language from Section 30(A) of the Medicaid statute (42 U.S.C. § 1396a(a)(30)(A)) requiring that reimbursements be “consistent

with efficiency, economy, and quality of care” to ensure sufficient providers participate in a given geographic area. Respondents’ Br. at 18, 22, 26, 29-36. But the CMS Denial Letter states plainly that the Agency’s own rule setting dispensing fees “does *not* comply with [Section 30(A)] and the CMS Rule.” *See* CMS Denial Letter at 1 (emphasis supplied).

CMS’s letter also details why the Agency’s dispensing fees, and the reimbursement methodology on which they are based, fail to comply with the CMS Rule. Specifically, after quoting the CMS Rule defining “professional dispensing fees” (also referred to as “PDF”), CMS notes that when a state proposes changes to either ingredient cost reimbursement or dispensing fees, the state must consider both elements. *Id.* at 2.

CMS also explains that the Agency did not provide “adequate data” to demonstrate that Washington pharmacies have been reimbursed for dispensing costs consistent with the CMS Rule and Section 30(A), including that those fees fit within the definition of “professional dispensing fees in 42 CFR section 447.502.” *Id.* at 1-2. Additionally, CMS states that the Agency did not “present evidence of how it calculated its [professional

dispensing fee] or how the current dispensing fee methodology is consistent with the current definition of [professional dispensing fee].” *Id.* at 2.

Finally, CMS noted that the Agency failed to provide additional information to support its dispensing fees, and failed to justify why it never changed its existing dispensing fees. *Id.* at 2-3.

CMS’s analysis supports the analysis provided by the Pharmacies in their Opening Brief.

B. This Court must give “controlling weight” and defer to the CMS ruling.

CMS is a division of the U.S. Department of Health and Human Services, the federal agency charged with administering Medicaid payments to the states. Its ruling is therefore entitled to substantial deference under the Supreme Court’s landmark decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). In particular, courts defer to rulings by CMS, such as the one here, rejecting state plans dealing with Medicaid reimbursement. *See Alaska Dep’t of Health & Soc. Servs. v. Centers for Medicare & Medicaid Servs.*, 424 F.3d 931, 939 (9th Cir. 2005) (applying *Chevron* deference in

the context of the disapproval of a Medicaid state plan amendment); *Ohio Dep't of Medicaid v. Price*, 864 F.3d 469, 474 (6th Cir. 2017) (“we give the agency’s decision to disapprove the [state plan] amendment the benefit of *Chevron* deference.”)

In addition, courts take “special note of the tremendous complexity of the Medicare statute. That complexity adds to the deference due to the Secretary’s decision.” *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994). This heightened deference is “all the more warranted when, as here, the regulation concerns a complex and highly technical regulatory program.” *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

What is more, the CMS Rule has the force of law. *See Freedom Found. v. Wash. St. Dep't of Transp., Div. of Wash. St. Ferries*, 168 Wn. App. 278, 292 (Div. 2, 2012) (“federal regulation has the force of law”). When a federal agency interprets its own federal regulations, “considerable weight should be accorded” to that construction. *Id.*; *see also Alaska*, 424 F.3d at 942 (“We accord substantial deference to an agency’s interpretation of its own regulations.”); *Auer v. Robbins*, 519

U.S. 452, 461 (1997) (a court should give a federal agency’s interpretation of its own regulations “controlling” weight unless it is “plainly erroneous or inconsistent with the regulation.”). Therefore, without a showing that the CMS ruling is plainly erroneous or inconsistent with its regulation—and there is no indication of that here—this Court must give “controlling weight” to CMS’s conclusion that the Agency’s dispensing fees fail to comply with Section 30(A) of the Medicaid statute as well as the CMS Rule. Upon giving proper deference to the CMS ruling, this Court should invalidate the Agency’s dispensing fees.

C. No deference is owed to the Agency’s interpretation of Section 30(A) and the CMS Rule.

The Agency argues that because it has broad discretion as to some matters, its conduct here requires highly deferential review. Respondents’ Br. at 14-16. This is not so.

State agencies have broad discretion about many things, but when it comes to their interpretation of a federal statute or rule, the review is *de novo*. See *Jenkins v. Washington State Dept. of Social and Health Services*, 160 Wn.2d 287, 297 (2007). There is simply no authority to support the proposition that the

court should defer to a state agency's interpretation of a federal statute and rules, rather than defer to a federal agency's interpretation of its own rules and federal law. Indeed, "deference to an agency is inappropriate where the agency's interpretation conflicts with a statutory mandate." *Puget Soundkeeper All. v. State, Pollution Control Hearings Bd.*, 189 Wn. App. 127, 136 (2015). Moreover, "agency action that is in violation of a statute is, by definition, arbitrary and capricious, or contrary to law." *Skamania Cty. v. Columbia River Gorge Comm'n*, 144 Wn.2d 30, 57 (2001).

Additionally, agency action is arbitrary or capricious when the action is a "willful and unreasoning action in disregard of facts and circumstances." *Children's Hosp. & Med. Ctr. v. Washington State Dep't of Health*, 95 Wn. App. 858, 864 (1999). When applying this standard, courts consider, among other things, the evidence that an agency relied on in making its decision. *Id.* at 871. When an agency selects data favorable to a predetermined conclusion and ignores contrary data, then a decision based on such biased data is arbitrary and capricious. *See, e.g., Genuine Parts Co. v. Env'tl. Prot. Agency*, 890 F.3d

304, 313 (D.C. Cir. 2018) (“it was arbitrary and capricious for [the agency] to rely on portions of studies in the record that support its position, while ignoring cross sections in those studies that do not”).

D. The CMS Rule does much more than add the word “professional” to dispensing fees by including terms that require reimbursement of costs of dispensing.

The Agency argues that the CMS Rule’s treatment of dispensing fees is little more than a minor semantic refinement. It contends that the rule only changed the term “dispensing fee” to “professional dispensing fee.” Respondents’ Br. at 10, 20. CMS disagrees. In fact, the CMS Denial Letter says the exact opposite: the new rule now requires that actual costs of dispensing be reimbursed. In its letter ruling, CMS quotes the full definition of professional dispensing fees that specifically refers to “pharmacy costs” that include costs “incurred at the point of sale or service and pays for *costs* in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed” and “[i]ncludes only pharmacy *costs* associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid

beneficiary.” CMS Denial Letter at 2, citing 42 CFR § 447.502, § 447.518(d) (emphasis added). CMS interprets its own rule to require, as part of the “professional dispensing fee,” the reimbursement of actual pharmacy costs incurred in dispensing.

Further, the CMS Rule does *not* authorize the Agency to consider factors other than pharmacy costs. *See* 42 CFR § 447.502 (definition of professional dispensing fee “includes *only* pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary”) (emphasis added). Neither this definition nor any other provision of the CMS Rule suggests that “market rate” dispensing fees, such as those in Milliman and Moda reports, are acceptable. In fact, other factors beyond pharmacy costs are excluded. *Id.* Accordingly, the Agency has misread the CMS Rule.

Moreover, the CMS Rule added new data standards designed to enforce the requirement that dispensing fees must cover pharmacy costs. Specifically, the CMS Rule now requires each state to submit proof to CMS that its dispensing fees cover such pharmacy costs. *See* 42 CFR § 447.518(d). This section

further strengthens and enforces the definition of professional dispensing fees as covering “pharmacy costs.” The first sentence of Section 447.518(d) requires a state to ensure that its dispensing fee satisfies the “requirements of this subpart.” That statement necessarily requires dispensing fees to cover the “pharmacy costs” specified in Section 447.502 of the CMS Rule. *See Filo Foods, LLC v. City of SeaTac*, 183 Wn.2d 770, 792 (2015) (courts read statutes together to achieve “a harmonious total statutory scheme ... which maintains the integrity of the respective statutes.”).

The second sentence of that new Section 447.518(d) provides, “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.” *Id.* (emphasis supplied). Section 447.502 requires dispensing fees to cover “pharmacy costs,” so the data required by Section 447.518(d) is *pharmacy cost* data. The preamble to the CMS Rule explains that Sections 447.502 and 447.518(d) require states to submit data demonstrating that professional

dispensing fees cover pharmacy costs of dispensing. *See, e.g.*, 81 Fed. Reg. 5170, 5201 (Feb. 1, 2016) (“states must provide information supporting any proposed change to either ingredient or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access.”). The Agency’s failure to comply with the CMS Rule constitutes arbitrary and capricious agency action that is contrary to law and is grounds for reversal.

E. The Agency concedes that its dispensing fees are two to three times lower than those of any other state.

The Agency does not dispute the accuracy of the graphs in the Pharmacies’ opening brief showing that Washington has the lowest dispensing fees in the nation—in fact, two to three times lower than any other state. Further, the Agency offers no explanation as to why dispensing fees for Washington pharmacies are so much lower than those of any other state. The answer, of course, is that unlike other states, the Agency did

not base its dispensing fees on actual pharmacy costs as required by the CMS Rule.³

The Agency also does not contest that the Milliman and Moda studies relied exclusively on non-cost data from private insurance companies paying for Medicare (*not* Medicaid) patients. Such data skews the results. Reliance on these skewed studies led CMS to conclude in its letter ruling that the Agency “did not submit adequate data that demonstrates pharmacy providers are reimbursed for their professional services consistent with the requirements of the final regulation.” CMS Denial Letter at 2.

These factors support the conclusion that the Agency rule conflicts with the law and is arbitrary and capricious.

³ Since the filing of the Opening Brief, yet another state has raised its dispensing fees significantly to cover pharmacy costs. On July 30, 2018, CMS approved the Pennsylvania State Plan Amendment (SPA) for a professional dispensing fee of \$10.00 effective retroactive to April 1, 2017. *See* Medicaid.gov at <https://goo.gl/SPHR7S>.

F. The Agency’s demonstrated bias against raising dispensing fees is relevant to the arbitrary and capricious analysis.

The Agency concedes that its Director of Pharmacy Rates sent emails maintaining that pharmacy rates should not be increased, helping to establish the Pharmacies’ argument of arbitrary and capricious rule-making. The Agency simultaneously contends that any possible bias by its staff against raising dispensing fees is irrelevant and this Court “should not probe the mental processes of administrative officials in making decisions.” Respondents’ Br. at 39. It cites *Nationscapital Mortg. Corp. v. State Dept. of Fin.*, 133 Wn. App. 723, 762 (2006) in support. This case is distinguishable. In *Nationscapital*, the court stated that “a party invoking the appearance of fairness doctrine must come forth with evidence of actual or potential bias,” and there the court found no evidence of bias. *Id.*

In contrast, here there is ample evidence of bias. Even before the rule-making, the Agency had already decided that pharmacies were being paid enough in dispensing fees. *See* Opening Br. 12-13. The emails contained in the record

demonstrate that the Agency had already made up its mind before undertaking the rate-setting process required by the CMS Rule. *See* CP 276, 279, 269. Here, based on the Agency’s admission, there is no factual dispute that the Agency had already determined the outcome before it began any rule-making and then relied only on data that would corroborate that outcome. As the Pharmacies explained in their Opening Brief, such predetermined decision-making is arbitrary and capricious. *See, e.g., Lead Indus. Ass’n, Inc. v. Env’tl. Prot. Agency*, 647 F.2d 1130, 1179 (D.C. Cir. 1980) (noting agency decision maker’s “single-minded commitment” to a particular position “makes him or her totally incapable of giving fair consideration to the issues that are presented for decision.”).

G. Merely because the CMS Rule does not mandate a cost-of-dispensing study, does not excuse using non-cost “market” data.

The Agency argues that the CMS Rule does not mandate cost-of-dispensing studies. Respondents’ Br. 21-22. That is true, but it is also beside the point. The CMS Rule still recognizes that a cost-of-dispensing study is just one form of such “adequate” or “reliable” cost data for setting compliant

dispensing fees. *See* 42 CFR § 447.518(d) (noting that adequate data is required, “*such as* a cost of dispensing study,” but in the alternative, “*other reliable data* other than a survey” may be used) (emphasis supplied). Whether or not the Agency conducts a formal cost-of-dispensing “study,” the CMS Rule requires the Agency to adopt dispensing fees that cover pharmacy costs. *See* 81 Fed. Reg. at 5291 (“the total reimbursement should take into account the pharmacy’s ... costs to dispense the drug product to a Medicaid beneficiary.”) and 5138 (“[r]eimbursing providers based on ... a dispensing fee representative of the cost to dispense the drug to the patient is in keeping with section 1902(a)(30)(A) of the Act.”).

Not being required to prepare a cost-of-dispensing study is no excuse for using unreliable data that does not reflect pharmacy costs. The CMS Denial Letter makes that plain: the Agency “did *not* submit adequate data that demonstrates pharmacy providers are reimbursed for their professional services consistent with the requirements of the [CMS Rule]....” CMS Denial Letter at 2 (emphasis added). The CMS Denial Letter is dispositive in describing how the Agency’s actions fail

to comply with federal law. Such a failure to comply with federal law supports reversal of the Agency's dispensing fees decision. *See Skamania*, 144 Wn.2d at 57 (2001) (“[A]gency action that is in violation of a statute is, by definition, arbitrary and capricious, or contrary to law.”).

H. The two new cases cited by the Agency do not apply, especially in light of the CMS Denial Letter.

After filing its brief, the Agency cited two new cases in another supplemental authorities filing. *See* 8/7/18 Statement of Add. Auth. at 1-2, citing *Santa Rosa Memorial Hospital, Inc. v. Kent*, 25 Cal. App. 5th 811, 814, 236 Cal. Rptr. 3d 199, 201 (Cal. Ct App. 2018) and *Tulare Local Health Care Dist. v. Cal. Dep't of Health Care Serv.*, 2018 WL 3496321 (N.D. Cal. 2018).⁴ Neither case applies here, for two critical and independent reasons.

First, both cases involved state Medicaid reimbursement rates that were *approved* by CMS, whereas the reimbursement rates in the present case have been *rejected* by CMS. Second, both cases involved unsuccessful attempts to assert a private

⁴ The *Tulare* case is currently on appeal to the Ninth Circuit, No. 18-16384.

right of action to enforce Section 30(A), whereas the Pharmacies in this case have filed suit under Washington's APA, which is why the federal court remanded the case to state court for lack of federal jurisdiction.⁵

I. The CMS Denial Letter does not make this case moot.

This Court should defer to the CMS Denial Letter as controlling. That letter is reason enough to reverse the Agency's decision on dispensing fees. But that letter does not make this appeal moot. The Agency may petition CMS to reconsider its decision, and may appeal to the federal district court or eventually to the Ninth Circuit, which could take years to resolve.

⁵ The Agency's discussion of procedural history before the federal court is immaterial and improper. On pages 13 and 33-34 of Respondents' Brief, the Agency notes the Pharmacies sought a TRO in federal court immediately after the Agency removed the state Petition there. This jurisdictional detour has no bearing on any issue before this Court and should be ignored for two reasons: First, because that federal court made no substantive finding on the merits of this litigation or the Pharmacies' claims given the emergency nature of the relief sought; second, because it is entirely outside of the record. The Agency's citation and appendage of this information violates RAP 10.3(a)(8) and should be ignored.

In the meantime, pharmacies across the State of Washington, large and small, have been losing millions of dollars as a result of the Agency's refusal to properly reimburse them for the costs of serving Medicaid patients. Now that CMS has ruled that the Agency's reimbursement rates do not comply with federal law, action by this Court is still needed to reverse the Agency's decision not to fulfill its legal obligation for cost-based dispensing fees and remand for the Agency to reset those fees to comply with the CMS requirements. Because judicial action is still necessary to implement that remedy, this appeal is not moot. *See City of Sequim v. Malkasian*, 157 Wn.2d 251, 258–59 (2006) (An “issue is not moot if a court can provide any effective relief.”).

CONCLUSION

This appeal has become quite simple. The central issue is whether the Agency complied with the CMS Rule. CMS has now ruled that it did not. This Court should reach the same conclusion.

The CMS ruling reinforces all the reasons provided by the Pharmacies in their opening brief to invalidate the Agency rule.

This Court should reverse the Agency's decision to use below-cost dispensing fees as arbitrary, capricious, and contrary to federal law. The case should be remanded to the Agency to set rates consistent with the CMS Rule, which would include providing for proper reimbursements retroactive to April 1, 2017, as the CMS Rule requires.

Dated: September 20, 2018

Respectfully submitted,

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The undersigned declares under penalty of perjury, under the laws of the State of Washington, that the following is true and correct:

That on the 20th day of September, 2018, I served the foregoing **REPLY BRIEF OF PETITIONERS** on the following parties and/or counsel of record via *Electronic Court E-Service* as follows:

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