

In re:
Reconsideration of Disapproval of
Washington State Plan Amendment 17-0002

Docket No. 19-01

**JOINT PHARMACY AMICI BRIEF
IN SUPPORT OF CMS
DISAPPROVAL OF WASHINGTON
STATE PLAN AMENDMENT
17-0002**

I. Introduction and Summary of Argument

In 2016, CMS promulgated a rule that requires cost-based reimbursement for pharmacies in the Medicaid fee for service program (“CMS Rule”). 81 Fed. Reg. 5170 (Feb. 1, 2016), *codified at* 42 C.F.R. §§ 447.500 *et seq.* The CMS Rule requires States to adopt Professional Dispensing Fees (“PDFs”) that cover pharmacies’ costs of dispensing, as well as ingredient cost reimbursement for drugs that reflects pharmacy actual acquisition costs.

As detailed below, CMS has repeatedly made it crystal clear that PDFs should cover pharmacy costs of dispensing. The requirement to adopt cost-based PDFs is included in the language of the rule itself, the requirement is extensively explained in CMS’ formal preamble to the rule, and the requirement has been reiterated in subsequent guidance to States in general and to Washington in particular.

Over the past three years since the CMS Rule was promulgated, the vast majority of states have adopted cost-based PDFs, normally in the range of \$10-\$12. *See* “Medicaid Covered Outpatient Prescription Drug Reimbursement by State,” (Quarter Ending December 31, 2018) found at <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/drug-reimbursement-information/index.html>). Just last month, for example, California

became the latest state to implement cost-based PDFs of \$10.05 to \$13.20, retroactive to April 1, 2017 as required by the CMS Rule.¹

Unfortunately, the State of Washington has insisted on maintaining the same below-cost dispensing fees of \$4.24-\$5.25 that it adopted at least a decade ago. In a single paragraph at the end of its brief, the State argues that it need not “consider a pharmacy’s actual costs in determining dispensing fees.” Washington State Health Care Authority’s Prehearing Brief (“WA Brief”) at pp. 14-15. Washington is convinced that CMS does not understand its own rule, and Washington apparently also believes that all the other states adopted cost-based PDFs because they are similarly deluded about the CMS Rule.

Unlike CMS and every other state that has implemented the CMS Rule, Washington believes that the CMS Rule calls for PDFs based on “market” rates paid by “private” insurance companies and Medicare plans. WA Brief at p.7. The State does not cite any CMS regulation that calls for “market” based PDFs in the Medicaid fee for service program, because no such regulation exists. By rejecting cost-based reimbursement in favor of “market”-based reimbursement, Washington has apparently confused the Medicaid fee for service program with the Medicaid managed care program.²

In purported compliance with the CMS Rule, Washington cut pharmacy ingredient cost reimbursement to “actual acquisition cost” effective April 1, 2017, absent a cost-based PDF. *See* Washington State Plan Amendment (SPA) 17-0002 at CMS 0487, 0492; Decl. by Wendy Barcus

¹ See California, Department of Health Care Services, Jan. 28, 2019 Announcement, “Pharmacy Fee-for-Service Reimbursement Changes Beginning February 23, 2019,” found at http://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_27640.asp (accessed March 1, 2019) (noting increase for retail PDFs from \$7.25).

² See CMS’s Response To Petitioner’s First Interrogatories And Requests For Production (“CMS First Interrogatory Response”) at pp. 15-16 (pharmacy reimbursement rates paid by Medicaid managed care organizations and other payers “did not affect CMS’s review of the SPA” because the SPA “concerned pharmacy reimbursement for fee-for-service Medicaid.”).

at p. 4, ¶ 15 (CMS-0498). After more than three years of trying to work with Washington, CMS should require the State also to adopt cost-based PDFs effective April 1, 2017, as required by the CMS Rule.

For that reason, the National Association of Chain Drug Stores³ (NACDS), the National Community Pharmacists Association⁴ (NCPA) and the Washington State Pharmacy Association⁵ (WSPA) jointly submit this brief in strong support of CMS' disapproval of Washington State's SPA. Washington State's request for reconsideration of CMS' disapproval of the SPA should be denied and the disapproval upheld because its SPA fails to provide a cost-based PDF as required by the CMS Rule that implements Section 30(A). Further, once Washington establishes a compliant PDF, it should be applied retroactively to the April 1, 2017 effective date of the State's adoption of cost-based reimbursement.

II. Washington State's Market-Based Dispensing Fees Fail to Meet CMS Requirements for *Cost-Based* PDFs

The CMS Rule requires each State Medicaid agency to establish a PDF that is sufficient to cover a long list of specified pharmacy costs associated with operating pharmacies and

³ NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Its nearly 100 chain member companies include regional chains with a minimum of four stores to national companies. Chains operate more than 40,000 pharmacies and employ a total of more than 3 million employees, including 152,000 pharmacists. They fill more than 3 billion prescriptions yearly and have annual sales of over \$750 billion. NACDS members operate over 850 pharmacies in Washington State, employing nearly 69,000, including over 3,300 pharmacists.

⁴ NCPA is a non-profit organization incorporated and based in Alexandria, Virginia. NCPA represents the interests of the owners, managers, and employees of more than 22,000 independent community pharmacies across the United States (hereinafter, "Independent Pharmacies"). Together, Independent Pharmacies employ over 250,000 individuals on a full or part-time basis and dispense nearly half of the nation's retail prescriptions. There are 286 Independent Pharmacies operating in Washington. Most of them participate in Washington's Medicaid program.

⁵ WSPA is a non-profit organization incorporated and established under the laws of the State of Washington. The WSPA represents pharmacists, technicians, and interns practicing within community pharmacies, as well as clinics, nursing homes, and hospitals. Many of WSPA's members participate in Washington's Medicaid program.

employing pharmacists to provide services to Medicaid patients. 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1). These costs include, at a minimum:

reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

42 C.F.R. § 447.502. As CMS has explained to Washington, this definition “details the specific factors that States must take into consideration when determining the PDF.” *See* CMS First Interrogatory Response at p. 19. States with approved SPAs followed this definition and adopted PDFs “within a consistent range,” in contrast to Washington’s dispensing fees which are an “anomaly.” *Id.*

The State argues at length that CMS adopted this regulatory requirement for cost-based PDFs prior to 2016. Of course, the fact that the requirement for cost-based PDFs has been in place for more than three years does not excuse Washington’s refusal to comply with that requirement. Moreover, the 2016 CMS Rule did add significant new requirements for states to demonstrate that their PDFs are sufficient to cover pharmacy costs of dispensing. Under the CMS Rule, States are obligated to issue findings and assurances that their PDFs are sufficient to cover pharmacy costs associated with dispensing drugs to Medicaid patients, 42 C.F.R. § 447.518(b), and to “**provide adequate data** such as a State or national survey of retail pharmacy providers or other reliable data other than a survey” in support of those findings and assurances. 42 C.F.R. § 447.518(d) (emphasis added).

The importance of each state's obligation to adopt cost-based PDFs, and to provide assurances and data demonstrating that its PDFs are sufficient to cover pharmacy costs, was made very clear by CMS in the preamble of the CMS Rule:

- “Our proposal to revise the term dispensing fee to professional dispensing fee is designed to reinforce our position that the dispensing fee should reflect the pharmacist’s professional services and costs to dispense the drug product to a Medicaid beneficiary.” 81 Fed. Reg. 5170, 5201 (Feb. 1, 2016).
- “States should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate [drug] is transferred to a Medicaid beneficiary.” *Id.* at p. 5294.
- “[T]he total reimbursement should consider not only the pharmacy’s cost to acquire the drug, but also the pharmacist’s professional services in dispensing the drug [S]tates are in the best position to establish fees based on data reflective of the cost of dispensing drugs in their state.” *Id.* at pp. 5310-11.
- “In accordance with the definition of professional dispensing fee that we are finalizing at § 447.502 ... states should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate [drug] is transferred to a Medicaid beneficiary.” *Id.* at p. 5338.

In its communication with state Medicaid directors, CMS reiterated the requirement to establish PDFs based on pharmacy cost to dispense. *See* CMS Letter to State Medicaid Directors, Feb. 11, 2016, SHO#16-001, Affordable Care Act #37 (CMS 864-870) at p. 5 (CMS 0868) (noting that renaming “dispensing fee” to “professional dispensing fee” was “designed to reinforce [CMS’s] position that the dispensing fee should reflect the pharmacist’s professional services and costs to dispense a drug to a Medicaid beneficiary.”). States are required to do so “to ensure that pharmacy providers are reimbursed adequately for their professional services consistent with the requirements of the [CMS Rule].” *Id.* *See also* CMS, Covered Outpatient Drugs Final Rule with Comment (CMS-2345-FC) Fact Sheet (CMS 1535) (the CMS Rule

“[i]mplements the use of the term professional dispensing fee to ensure that the dispensing fee paid to pharmacies reflect the cost of the pharmacist’s professional services and cost to dispense the drug product to a Medicaid beneficiary.”); CMS, Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC), Frequently Asked Questions (CMS – 1537) (“The requirements [of the CMS Rule] are to more accurately reflect the pharmacy providers’ actual prices paid to acquire drugs and the professional services required to fill a prescription.”).

Moreover, after Washington submitted its SPA, CMS repeatedly reminded Washington of the requirement to adopt cost-based PDFs. *See, e.g.* CMS Request for Additional Information, September 21, 2017, at p. 2 (CMS 0447) (reminding Washington that data regarding market-based dispensing fees “does not negate the regulatory requirement of a professional dispensing fee,” and instead requesting data demonstrating that the State’s dispensing fees “reimburse pharmacies for their average cost of dispensing.”).

Unfortunately, although Washington immediately cut payments to pharmacies by adopting cost-based reimbursement for drugs based on “actual acquisition cost,” the State specifically refused to adopt cost-based PDFs. *See* Washington Response to CMS Request for Additional Information, December 20, 2017, at p. 6 (CMS 0457) (noting that Washington is “opting not to pay pharmacies based on an average cost of dispensing”). The state also refused to comply with CMS’ request, pursuant to section 447.518(d), for adequate data demonstrating that the State’s dispensing fees cover pharmacy dispensing costs. Instead, the only data Washington supplied to CMS in support of its inadequate dispensing fees included reports it commissioned solely to study market-based payment rates by private and Medicare plans. *Id.* at pp. 5-6 (CMS 0456-57). These reports focused on payment rates specifically to avoid generating cost-based reports that would have supported higher PDFs. *Id.* at p. 6 (CMS 0457) (refusing to

pay cost-based PDFs due to marketplace factors). Further, in its own pre-hearing brief, Washington concedes that its inadequate dispensing fees are not based on pharmacy cost data. *See* WA Brief at pp. 9-10 (noting reliance on studies that focused on pharmacy reimbursement in the “fully insured commercial market . . .,” by “PBMs for private businesses . . .,” and the “median dispensing free from Medicare and private companies . . .”). This market data is clearly inadequate under section 447.518(d) because it does not reflect the costs that must be covered by PDFs under section 447.502’s definition of PDF.

Finally, it should be noted that although the State asserts in its brief that its overall reimbursement rates are “comparable” to market rates, the State’s own economic analysis indicates that it actually reimburses pharmacies significantly below market rates. The State’s analysis compares its Medicaid fee for service reimbursement rates with private payer “market” rates, and concludes that the State pays pharmacies \$779,967.64 less each year than the “market” rates included in the Burchfield and HMA reports.⁶ Of course, even if the State did pay market rates it would not be in compliance with the CMS Rule, which requires PDFs to cover the cost of dispensing.

III. The CMS Rule’s Requirement for Cost-Based PDFs is Consistent With, and Actually Implements, Section 30(A)

42 U.S.C. § 1396a(a)(30(A) (“Section 30(A)”) requires state Medicaid plans to ensure that provider payment rates 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. One way to encourage pharmacies to participate in Medicaid is to ensure that the reimbursement they receive at least covers their costs of buying and dispensing covered drugs to

⁶ *See* “WA State FFS Medicaid Defense of Current Dispensing Fee” at CMS-0853.

Medicaid patients. Therefore, CMS adopted the CMS Rule's requirements for cost-based reimbursement to implement Section 30(A). See 42 C.F.R. § 447.500(a)(5) (noting that the CMS Rule "implements" Section 30(A)). CMS also has repeatedly explained that the requirement to adopt cost-based PDFs is consistent with, and actually implements, Section 30(A):

- "Reimbursing providers based on the ingredient cost representative of the cost of the drug alone and 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." 81 Fed. Reg. at 5307.
- "After evaluating all the [pharmacy costs listed in the definition of professional dispensing fee], the states are responsible for establishing, and if necessary, revising, their professional dispensing fee to ensure that the Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of section 1902(a)(30)(A) of the Act. We believe that this flexibility should allow states to establish sufficient fees to cover costs and ensure adequate participation." *Id.* at 5291.
- "[P]ayment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act, and we believe the total reimbursement should take into account the pharmacy's cost to acquire the drug and the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary." *Id.* at 5339.

Washington tries to argue that it has complied with Section 30(A), but ignores the fact the CMS Rule's requirements for cost-based reimbursement, including PDFs, actually implement Section 30(A). As a result, Washington takes the illogical position that compliance with Section 30(A) somehow exempts the State from compliance with the cost of dispensing evaluation and PDF requirements of the CMS Rule. See WA Brief at pp.12-13. Consequently, the methodology adopted by Washington to maintain its allegedly market-based dispensing fees relies upon inapplicable rates paid by commercial health care plans, employer-sponsored insurance, Medicare Part D plans, and other government or commercial payers. Indeed, under its own rule, Washington may adjust pharmacy dispensing fees based on factors such as "legislative

appropriations for vendor rates” and “dispensing fees paid by other third-party payers including, but not limited to, health care plans ...” WAC 182-530-7050(3)(a), (d).

Washington has provided no “adequate data” – indeed, the State has produced no data at all – that health plan dispensing fees or legislative appropriations are adequate to cover the pharmacy costs that are required to be evaluated for PDFs under the CMS Rule implementing Section 30(A).⁷ Unlike State Medicaid programs, health plans are not legally required to reimburse pharmacies for costs of dispensing. In fact, the State’s own report found that dispensing fees paid by health plans are *not* sufficient to cover the costs incurred by pharmacies:

According to a survey of plan sponsors, the average dispensing fees for retail pharmacies in 2015 ranged from \$1.56 to \$2.17. This range, however, is likely reflective of the average dispensing fee level in the contract between the PBM and health plan and not the amount actually provided to network pharmacies. According to pharmacies surveyed, their reimbursed dispensing fees were significantly lower, around the \$1 mark, and they were seeing more prescriptions being reimbursed with no (i.e. zero) dispensing fee. According to cost to dispense surveys performed by various states and pharmacy organizations, the actual cost to dispense a prescription is in excess of \$10. Washington pharmacies indicated their dispensing costs were in the \$13 to \$16 range.

Washington Office of the Insurance Commissioner’s Study of the Pharmacy Chain of Supply (“OIC Study”) (CMS-0328 *et seq.*) at p. 30 (CMS-0357); *see also id.* at p. 60 (CMS-0387), p. 69 (CMS-0396) (citing \$11.65 as the average actual cost to dispense for Washington pharmacies). Dispensing fees paid by health plans clearly do not reflect pharmacy costs, as plans are able to offset their below-cost dispensing fees with above-cost ingredient cost reimbursement,⁸ whereas under the CMS Final Rule, State Medicaid programs must set both their PDFs and their ingredient cost reimbursement based on pharmacy costs. *See* 42 C.F.R. § 447.518(d).

⁷ *See* 42 C.F.R. § 447.518(d) (*requiring states to evaluate both ingredient cost reimbursement and the cost-based PDF when moving to cost-based reimbursement “to ensure that total reimbursement to the pharmacy provider is in accordance with” Section 30(A)*) (emphasis added).

⁸ *See* OIC Study at p. 41 (CMS-0368).

The State argues at length that it is not required to conduct a cost of dispensing study. WA Brief at pp. 11-12. And while it is true that the CMS Rule gives States options for providing pharmacy cost data, “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 demonstrate that the State has complied with the CMS Rule’s cost-based definition of PDF. 42 C.F.R. § 447.518(d). Here, the State never provided any “other reliable data” to support its position that cutting the reimbursement rate for ingredient costs without establishing a cost-based PDF complies with the CMS Final Rule’s requirement that reimbursement to pharmacies must cover pharmacy costs. Instead, the State provided reports by firms that evaluated non-Medicaid reimbursement rates, not pharmacy costs. *See* WA Brief at p. 7 (describing one as a study “analyzing rates in Washington’s retail pharmacy market” and another as a “survey of retail pharmacy reimbursement and dispensing fees from private insurance companies and the Medicare program.”).

Nothing in the CMS Rule, its preamble, or CMS guidance suggests that market-based dispensing fees are appropriate or intended for fee-for-service Medicaid, much less satisfy CMS Rule requirements. At some level, it appears that Washington understands that. *See* Washington Response to CMS Request for Additional Information, December 20, 2017, at p. 6 (CMS 0457) (admitting that Washington “understands the long-term objective [of Medicaid] to pay more for the professional services provided by pharmacists and reduce the revenue stream attached to drugs being dispensed”). But Washington rejects it, apparently, based upon its cost concerns. *See id.* (wanting to avoid what it views as “a much higher dispensing fee unnecessary in the marketplace just for the Medicaid [fee for service] program.”).

IV. Washington State Must Adopt a Cost-Based PDF Retroactive to April 1, 2017

While the CMS Rule does not require Washington to adopt a particular PDF dollar amount, the record supports the adoption of a cost-based PDF in Washington that is significantly higher than the current dispensing fee range of \$4.24-\$5.25. First, an independent cost-of-dispensing study shows that the cost to dispense to Medicaid beneficiaries in Washington, as of a few years ago, was \$10.48. *See* Miller Declaration at p. 6 (CMS-0920) at ¶26 (identifying the mean estimate for the state). Second, the state's own data, submitted to CMS in support of its SPA, cites studies referring to an average cost to dispense for Washington pharmacies as \$11.65. OIC Study at p. 60 (CMS-0387). Third, Washington's neighbors' PDFs offer some insight into what might be an appropriate PDF for Washington to adopt. For example, Idaho's PDF ranges from \$11.51-\$15.11; Montana's PDF ranges from \$11-\$15; and Oregon's PDF ranges from \$9.68-\$14.01. *See* CMS Request for Additional Information, September 21, 2017 (CMS 0444-449), at pp. 2-3 (CMS 0447-48).⁹

Once Washington has adopted a PDF that complies with the CMS Rule, the State will need to ensure that the new PDF is implemented retroactively to April 1, 2017. This effective date is required by the CMS Rule itself. *See* 81 Fed. Reg. 5170, 5170 (Feb. 1, 2016) (referring to the June 2017 deadline for state plan amendments which are "to be effective no later than April 1, 2017."). Additionally, since Washington implemented its change to product reimbursement pursuant to the CMS Rule on April 1, 2017, and the CMS Rule says the PDF calculation must occur at the same time to "ensure that total reimbursement to the pharmacy provider is in

⁹ Washington argues that other State's cost of dispensing studies are irrelevant. As CMS has explained to the State, however, States with approved PDFs have properly relied on "a neighboring state's survey" of pharmacy costs, which can satisfy the CMS Rule's "reliable data" requirement by providing "documentation on how the reimbursement methodology was established and how such methodology comports with the definition of professional dispensing fee." CMS First Interrogatory Response at p. 19.

accordance with the requirements of [S]ection [30(A)],” once CMS has approved the State’s new PDF, it too must be made effective as of April 1, 2017 .

This obligation is well-recognized. In fact, Washington acknowledges the mandatory April 1, 2017, effective date. WA Brief at p. 4 (“States needed to comply by April 1, 2017.”). Additionally, other states implementing the PDF after the April 1, 2017 deadline apply it retroactively back to April 1, 2017 for full compliance. For example, just this past month, California announced that it is implementing its CMS-approved, cost-based reimbursement required under the CMS Rule, including PDFs of \$10.05-\$13.25, to include retroactive adjustments to covered claims as far back as April 1, 2017. *See* California, Department of Health Care Services, Jan. 28, 2019 Announcement, “Pharmacy Fee-for-Service Reimbursement Changes Beginning February 23, 2019,” found at http://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_27640.asp (accessed March 1, 2019) (noting increase for retail dispensing fee from \$7.25). Washington State will need to do the same once it has adopted a CMS Rule-compliant PDF.

V. Conclusion

For the above reasons, NACDS, NCPA and WSPA support CMS' disapproval of Washington State's SPA and denial of Washington State's request for reconsideration, as well as a declaration that any PDF, adopted by Washington State and approved by CMS as compliant with the CMS Final Rule, must be retroactive to April 1, 2017.

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