CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the matter of: **The Disapproval of the Washington State Plan Amendment 17-0002**	**Hearing Docket No. 2019-01**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), pursuant to 42 C.F.R. §430.102, for final agency review of the CMS disapproval of Washington State Plan Amendment (SPA) 17-0002. The CMS Presiding Officer's recommended decision was issued November 20, 2020. Exceptions were received from the State of Washington and CMS. Exceptions to the recommended decision were reviewed and included in the administrative record. The Administrator issued a decision on January 19, 2021 approving the Washington SPA 17-0002.

On April 29, 2021, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the Washington State Pharmacy Association (the Plaintiffs), filed a Complaint against Xavier Becerra, Secretary of United States Department of Health and Human Services (HHS), concerning the final decision on the approval of Washington State Plan Amendment 17-0002 in the United States District Court for the Western District of Washington at Seattle. *National Association of Chain Drug Stores v. Becerra*, Case No. 2:21-cv-00576-RSM.

The Plaintiffs stated that, after initially disapproving the SPA, the Administrator on reconsideration approved the SPA pursuant to a decision issued January 19, 2021. The Plaintiffs claimed that the Secretary's conduct was arbitrary and capricious because it completely ignored the years of prior and consistent agency communications that the State's reimbursement methodology violated Federal law because it did not fulfill the required standards. Moreover, the final administrative decision also wholly ignored the recommended decision by the CMS Presiding Officer who recommended that the SPA be denied. The decision also violated CMS' own statute and regulations governing the type of data needed to support an appropriate pharmacy reimbursement rate methodology.

The Secretary of HHS and the Plaintiffs filed a joint motion for voluntary remand and dismissal without prejudice. The joint motion set forth that the Plaintiffs sought judicial review pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 702 and stated that:

> Plaintiffs alleged that the Secretary's approval of the SPA, insofar as it pertains to the adequacy or amount of cost based professional dispensing fee reimbursement rates, is invalid under the APA and federal law because it is arbitrary and capricious because the data before the Secretary did not address the CMS Rule's own required elements for a cost-based professional dispensing fee. After a review of the administrative record, the Government agrees that record does not contain an

> adequate basis to sustain the agency's approval. Therefore, if the Court remands the matter to CMS, CMS will reconsider its decision approving the SPA and provide an adequate basis for its reconsidered decision.[1]

The Washington State Health Care Authority (HCA), the single-state agency that administers Medicaid on behalf of the State of Washington, filed a motion to intervene. While the State (HCA) was not a party to the matter at the time of the motion filing, the joint motion set forth in full the State's response opposing the motion to vacate and remand. The Court, in granting the joint motion, stated it had reviewed the Motion, as well as the documents on file, and was otherwise fully informed. The Court ordered**:**

> That the Parties' Motion For Voluntary Remand and Dismissal Without Prejudice is GRANTED.
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> IT IS FURTHER ORDERED that this matter is remanded back to the Centers for Medicare & Medicaid Services.
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> IT IS FURTHER ORDERED that this matter is dismissed without prejudice with the parties to bear their own costs and fees.[2]

Accordingly, pursuant to the foregoing order, the Administrator reconsiders the January 19, 2021 decision approving the SPA and provides an adequate basis for its reconsidered decision as set forth below.

Issues

The issues are whether Washington State Plan (SPA) 17-0002 is inconsistent with the requirements of:

1) Section 1902(a)(30)(A) of the Social Security Act (42 U.S.C. § 1396a(a)(30)(A)) which requires, in part, that States have a State plan that provides such methods and procedures 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 to the general population in the geographic area; and

2) Federal regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518, which provide that payments for drugs are to be based on the ingredient cost of the drug based on the Actual Acquisition Cost (AAC) and a Professional Dispensing Fee (PDF).

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[1] Joint Motion for Voluntary Remand and Dismissal Without Prejudice, Dated July 9, 2021, at 3.

[2] Order Granting Joint Motion for Voluntary Remand and Dismissal Without Prejudice, Dated July 12, 2021, at 2.

CMS Disapproval

By notice dated September 10, 2018, CMS disapproved the proposed Washington SPA 17-0002.[3] The SPA 17-0002 was received by CMS on June 26, 2017. The proposed effective date for Washington SPA 17-0002 was April 1, 2017. [4]The SPA proposed to bring Washington into compliance with the pharmacy reimbursement requirements in the Covered Outpatient Drugs final rule with comment period (CMS-2345-FC) (Final Rule), published at 81 Fed. Reg. 5170 (February 1, 2016). At the time of the submission, Washington's pharmacy reimbursement methodology reimbursed for ingredient costs based on Estimated Acquisition Cost (EAC), including a tiered dispensing fee (high-volume pharmacies $4.24/Rx, mid-volume pharmacies $4.56/Rx, low-volume pharmacies $5.25/Rx, and unit dose system $5.25/Rx.) The submitted SPA proposed to reimburse for ingredient cost based on Actual Acquisition Cost (AAC), using the National Average Drug Acquisition Cost (NADAC) without a change in the dispensing fee. In addition, this SPA included proposed changes to reimbursement for 340B drugs, physician administered drugs, clotting factor, Federal supply schedule, and drugs purchased at nominal price.

CMS disapproved the Washington SPA 17-0002, as submitted, because it did not comply with §1902(a)(30)(A) of the Social Security Act and the applicable Federal regulations. Section l902(a)(30)(A) of the Act requires, in part, that States have a State plan that provides such methods and procedures to assure that 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.

CMS explained that, under that authority, the Secretary has issued regulations to ensure that Medicaid pharmacy providers are reimbursed accordingly for covered outpatient drugs. The regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518 provide that payments for drugs are to be based on the ingredient cost of the drug based on AAC and a Professional Dispensing Fee or PDF. AAC is defined at 42 C.F.R. §447.502 as the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. The definition of PDF set forth at 42 C.F.R. §447.502 is the professional fee which:

> (1) Is 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;
> (2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs including but are not limited to, 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

[3] CMS Administrative Record (A.R.) at 0011. CMS provided an administrative record of the disapproval of SPA 17-0002.Certain documents are duplicated in the record.

[4] The effective date of a SPA is controlled by 42 C.F.R. §430.20.

> to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and (3) Does not include administrative costs incurred by the state in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

The regulation at 42 C.F.R. §447.518(d) specifically provides that, when a State proposes changes to either the ingredient cost reimbursement or PDF reimbursement, States are required to evaluate their proposed changes in accordance with the applicable regulations, and consider both the ingredient cost reimbursement and the PDF reimbursement when proposing changes to ensure that total reimbursement to the pharmacy provider is in accordance with § 1902(a)(30)(A) of the Act. The regulation at 42 C.F.R. §447.518(d) sets applicable data requirements, establishing that States must provide adequate data to support any proposed changes to either or both components of the pharmacy reimbursement methodology.

CMS found that the State had not documented that the proposed PDF is consistent with the statutory and regulatory requirements because the State did not submit adequate data that demonstrates pharmacy providers are reimbursed for their professional services consistent with the requirements of the final regulation, and thus, it has not assured that the State plan complies with §1902(a)(30)(A) of the Act. More specifically, the data requirements at 42 C.F.R. §447.518(d) require that: "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...."

CMS found that the State did not provide sufficient support to demonstrate that the proposed PDF is consistent with the definition of PDF at 42 C.F.R. §447.502, despite the documents submitted and arguments provided by the State under Washington SPA 17-0002. This is further evidenced by the fact that the State did not present evidence of how it calculated its PDF or how the current dispensing fee methodology is consistent with the current definition of PDF. CMS pointed out that pursuant to the Final Rule, States "must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access."[5]

Despite CMS' request for additional information to support the PDF, Washington did not provide documentation sufficient to justify its retention of its existing dispensing fee as satisfying the PDF requirements. However, CMS noted that should the State decide in the future to provide data and documentation in a SPA sufficient to support the requirements of the Final Rule with respect to the determination of the PDF, CMS would work with the State and review the data in the SPA. Based on the above, and after consultation with the Secretary, as required by Federal regulation at 42 C.F.R. §430.15(c)(2), the Washington SPA 17-0002 was disapproved.

CMS Presiding Officer's Recommended Decision

The Presiding Officer held that CMS' disapproval of SPA 2017-0002 was appropriate. The Presiding Officer concluded, regarding Issue 1, that the State of Washington did not meet the

[5] 81 Fed. Reg. 5170, 5201.

requirements of §1902(a)(30) of the Social Security Act. Regarding Issue 2, the CMS Presiding Officer found that the State of Washington did not meet the requirements of the regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518. While the State of Washington argued it was justified in its refusal to provide the information requested by CMS, the controlling procedural authority governing the Medicaid SPA submission and review process does not permit the State of Washington to unilaterally determine that responding to a request for additional information is unnecessary.

The Presiding Officer held that controlling regulations provide that cost-based professional dispensing information is a core element in evaluating the aggregate rate to ensure that total reimbursement to the pharmacy provider reflects actual costs and does not negatively impact access. As the State did not provide the requested information for CMS to evaluate the fees presented in SPA 17-0002, it did not properly provide CMS with requisite assurance that its payments are adequate in accordance with §1915(f) of the Act and 42 C.F.R. §430.16. CMS has a clear legal right to request information from the States under §1915(f)(2) of the Act. Accordingly, CMS' disapproval of SPA 17-0002 was appropriate.

Finally, with respect to whether CMS denial of SPA 17-0002 was arbitrary and capricious and violated the Administrative Procedure Act (APA), the Presiding Officer held that the issue was moot because the State of Washington failed to provide the required documentation to CMS. Moreover, even if otherwise reachable, such challenges are beyond the Presiding Officer's decision-making authority. The Presiding Officer's jurisdiction is confined to whether the State plan complied with Federal requirements and the issues specified in the hearing notice.[6]

Summary of Exceptions

The State of Washington submitted exceptions to the recommended decision by the CMS Presiding Officer, requesting that the Administrator reject the proposed decision and approve SPA 17-0002 because it complies with all applicable Federal law, including §1902(a)(30)(A) of the Act and amended rules, issued by CMS.

The State of Washington contended that it provided everything necessary to establish that SPA 17-0002 complies with all four of the factors listed in paragraph (A)—efficiency, economy, quality of care and access to care. If the pharmacies were not being reimbursed adequately for their costs, it would be reasonable to conclude that they would not continue to accept those rates. The State of Washington contended that there is no requirement for the State to pay more than is necessary to ensure that fee-for-service Medicaid clients have the same level of access to, and quality of care, as the non-Medicaid population.

The State of Washington also argued that CMS' denial of SPA 17-0002 is arbitrary and capricious and violates the Administrative Procedure Act (APA) by applying standards that were not part of its rule-making process. The State of Washington contended that CMS' denial is illogical because

[6] On January 8, 2019, pursuant to 42 C.F.R. § 430.76(b)(2), the National Association of Chain Drug Stores (NACDS), the National Community Pharmacy Association (NCPA) and the Washington State Pharmacy Association (WSPA) filed a petition to jointly participate as amici curiae. Amici supported CMS' disapproval of the SPA. The Presiding Officer granted joint amici curiae status and permitted them to jointly file a brief and provide a statement at the hearing.

for eight years (2009-2017), the State was determined to be compliant. Without any change in those laws, CMS has now determined the State to be noncompliant. The State of Washington contended that, because it was compliant in terms of dispensing fee levels in 2009, it remains compliant now. The only way that CMS can justify its position is by having brand-new interpretations of the exact same statute and, for all intents and purposes, the exact same regulation that have existed since 2009. CMS' new interpretations are not the result of notice-and-comment rule making under the APA, thus are arbitrary and capricious, and violate the APA.

CMS submitted exceptions noting that, in the Proposed Decision, under Section V.A. a typographical error existent and that the effective date for the proposed SPA was April 1, 2017, not August 1, 2017.

Discussion

In accordance with Joint Motion for Voluntary Remand and Dismissal Without Prejudice, dated July 9, 2021 and the Order Granting Joint Motion for Voluntary Remand and Dismissal Without Prejudice, dated July 12, 2021, the Administrator has reviewed the entire record, which was furnished by the CMS Presiding Officer, including all correspondence, position papers, transcripts, and exhibits. The Administrator has reviewed the CMS Presiding Officer's recommended decision. All exceptions submitted by the Parties that were received timely, are included in the record, and have been considered.[7]

The Medicaid Program was enacted in 1965 as Title XIX of the Act. Title XIX authorizes the Department of Health and Human Services (HHS) to make Federal funds available to assist States in providing medical assistance to persons whose income and resources are insufficient to meet the costs of necessary medical services.[8] Program regulations state that, "[w]ithin broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures."[9] Under Medicaid, the Federal Government shares a percentage of costs of providing medical assistance with the States, referred to as Federal financial participation.

States that choose to participate in the Medicaid program must submit to HHS a State plan to provide medical assistance.[10] The Secretary has the authority to issue regulations under the program. The regulations at 42 C.F.R. §430, *et seq*., implement the statute and set forth the State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation. Further, the Secretary has delegated responsibility for approving State plans and State plan amendments (SPAs) to CMS. The regulation at 42 C.F.R. § 430.10 requires that state plans must "contain [] all information necessary for CMS to determine whether the plan can be

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[7] The Amici submitted exceptions, dated December 18, 2020, in support of the recommended decision. The State submitted an opposition to the consideration of the exceptions based on the limitations placed on amici as not designated as a party pursuant to 42 CFR 430.76(c)(3) and because the exceptions were submitted late. The Administrator agrees with the State and the exceptions have not been considered during this review.
[7] 42 U.S.C. § 1396-1.
[8] 42 U.S.C. § 1396-1.
[9] 42 C.F.R. § 430.0.
[10] 42 U.S.C. § 1396-1.

approved..." 42 C.F.R. § 430.16 provides that, if needed, CMS may request additional information as part of the State plan and amendment review process.

The Medicaid statute provides that the HHS Secretary shall approve any plan which meets the requirements as outlined in §1902(a)(1) of the Act. Relevant to this case, §1902(a)(30)(A) of the Social Security Act provides that a State plan must 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."

With respect to the contents of a State plan to provide "medical assistance", §1905(a) of the Act states that the "term "medical assistance" means payment of part or all of the cost" of specified care and services for certain classes of individuals, including, under §1905(a)(12) of the Act, "prescribed drugs." Section 1927 sets forth the rules for the payment of covered outpatient drugs.

The regulations addressing payment methodology for prescription drugs are found, *inter alia*, at 42 Code of Federal Regulations, Part 447, Subpart I. The regulation at 42 C.F.R. § 447.500 (a)(5) explains that, among other things, this subpart implements "section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs." Further paragraph (b) explains that: "This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs."

For payment purposes, two components comprise the reimbursement paid to pharmacies for providing prescription drugs to Medicaid recipients: the ingredient cost of the drug and the professional dispensing fee. Generally, the regulations at 42 C.F.R. §§ 447.502, 447.512[11] and 447.518 provide that payments for drugs are to be based on the ingredient cost of the drug based on Actual Acquisition Cost (AAC) and Professional Dispensing Fee (PDF). The regulation at 42 C.F.R. §447.502 states that:

> Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

In addition, the regulation at 42 C.F.R. §447.502 states that the "professional dispensing fee" or "PDF" means:

> [T]he professional fee which:
>
> (1) Is 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;
> (2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient.

[11] 42 C.F.R. § 447.512 sets forth the rules for the "Aggregate Upper Limits of Payments" and also cross-references § 447.514.

> Pharmacy costs include, but are not limited to, 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; and
> (3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

The regulation at 42 C.F.R. §447.518 provides the rules for the "State plan requirements, findings, and assurances" for the payment for drugs. The States must evaluate and support proposed changes for prescription drug payment as follows:

> (a) State plan.
> (1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:
> (i) A covered entity described in section 1927(a)(5)(B) of the Act.
> (ii) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.
> (iii) An Indian Health Service, tribal and urban Indian pharmacy.
> (2) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.

Relevant to this matter, paragraphs (c) and (d) specify the record keeping and data requirements, stating that:

> (c) Recordkeeping. The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.
> (d) Data requirements. 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 this subpart, 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 the requirements of section 1902(a)(30)(A) of the Act. 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.

Relevant to this matter, in 2010, Congress enacted various legislation including the Patient Protection and Affordable Care Act (PPACA),[12] and the Health Care and Education Reconciliation Act of 2010 (HCERA)[13] collectively known as the Affordable Care Act or (ACA). Among other provisions, the ACA amended §1927 of the Act and mandated a number of revisions pertaining to Medicaid reimbursement for covered outpatient drugs.[14] In response to these statutory enactments, CMS on February 2, 2012, issued a Proposed Rule that would revise certain drug requirements, including key aspects of Medicaid coverage, payment, and the drug rebate program.[15] The "Medicaid Program; Covered Outpatient Drugs" proposed rule at 77 Fed. Reg. 5318 (February 2, 2012) with comment period, would implement other miscellaneous provisions pertaining to covered outpatient drugs.

CMS proposed to replace the term at 42 C.F.R. § 447.502, "estimated acquisition cost" (EAC) with "actual acquisition cost" (AAC) and to define AAC as the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.[16] As discussed in the proposed rule, CMS stated that this definition provides a more accurate estimate of the prices available in the marketplace, while assuring sufficient beneficiary access, consistent with § 1902(a)(30)(A) of the Act.[17]Significantly, in moving toward a "more accurate reference price" for prescription drug reimbursement based on "actual acquisition cost", CMS also recognized the need for States to evaluate both components of drug reimbursement: (1) the ingredient cost of a drug; and (2) a reasonable dispensing fee consistent with efficiency, economy, and quality of care.[18] Thus, the proposed rule replaced the prior definition of "estimated acquisition cost" with a new definition for "actual acquisition cost."[19] CMS further proposed replacing the term "dispensing fee" with "professional dispensing fee" to reinforce CMS' position that "once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary."[20]

CMS explained in the 2012 proposed rule regarding the professional dispensing fee, that:

> The definition of dispensing fee will remain unchanged as it already enumerates those costs to dispense a drug that the pharmacy incurs. However, we propose to replace the term "dispensing fee" with "professional dispensing fee" as drug ingredient cost is only one component of the two-part formula that States generally use to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries; and, we feel that this change from "dispensing fee" to "professional dispensing fee*" reinforces our position that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's*

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[12] See, Pub. L. 111-148.
[13] See, Pub. L. 111-152.
[14]See, PPACA §§ 2501 (Prescription Drug Rebates in Medicaid), 2503 (Providing Adequate Pharmacy Reimbursement in Medicaid), and 3301(d)(2) Medicare).
[15] 77 Fed. Reg. 5318 (Feb. 2, 2012) (Proposed Rule).
[16] 77 Fed. Reg. 5320, 5359.
[17] 77 Fed. Reg. 5320 through 5321.
[18] *Id.* at 5320.
[19] *Id.* at 5320-21.
[20] *Id.* at 5326.

> *professional services and costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary.* Therefore, as States change their payment for ingredient cost, we also propose to require States to reconsider the dispensing fee methodology consistent with the revised requirements.[21] (Emphasis added.)

On February 1, 2016, CMS published the Final Rule for the Covered Outpatient Drug with comment (CMS-2345-FC) that addressed these key changes to Medicaid reimbursement for covered outpatient drugs at 81 Fed. Reg. 5170 (February 1, 2016).[22] CMS again emphasized that:

> Professional Dispensing Fee
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> We proposed in §447.502 to replace the term "dispensing fee" with "professional dispensing fee" as the drug ingredient cost is only one component of the two-part formula used to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries (77 FR 5361). *We also proposed to require states to reconsider the dispensing fee methodology consistent with the revised requirements (discussed in more detail at 77 FR 5326.* [23]

In response to comments, CMS stated that:

> 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. In light of the issues raised in the comments, we have clarified the language in §447.518(d) of this final rule to indicate that when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to evaluate their proposed changes in accordance with this final rule, and states must consider the impacts of 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 the requirements of section 1902(a)(30)(A) of the Act. Further, states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement *which demonstrates that the change reflects actual costs and does not negatively impact access*. [24] (Emphasis added.)

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[21] 77 Fed. Reg. at 5326.
[22] 81 Fed. Reg. 5170 (Feb 1, 2016) (Final Rule).
[23] 81 Fed. Reg. 5201,
[24] 81 Fed. Reg. 5201. *See, e.g.,* 81 Fed. Reg. 5176 ("Response: We appreciate the comments. We have revised § 447.518(d) to require states to consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either of these components of the reimbursement for Medicaid covered drugs. Additionally, we have addressed such implementation concerns by noting that states that need to revise their payment methodologies in accordance with this final rule must submit a SPA no later than 4 quarters from the effective date of this final rule to revise their payment methodology for CODs in accordance with the requirements of §§ 447.512(b) and 447.518(d).)

CMS also stated, in respond to commenters, that:

> We agree that pharmacy providers should be reimbursed adequately for their professional services within the requirements of this final rule. While we are not requiring states to update their professional dispensing fees at specific intervals or frequencies, such as on an annual basis, *they will be required to evaluate each component when they propose changes.* We afford the states the flexibility to adjust their professional dispensing fees when necessary to assure sufficient access in accordance with the requirements of section 1902(a)(30)(A) of the Act. (Emphasis added.) [25]

CMS also further addressed 42 C.F.R. §447.518(d), stating that:

> Furthermore, as discussed in the State Plan Requirements, Findings and Assurances section (section II.M.) of this final rule, we have revised § 447.518(d) of this final rule such that when states are proposing changes to either the ingredient cost reimbursement or the professional dispensing fee reimbursement, *they will be required to evaluate their proposed changes in accordance with the requirements of this final rule to ensure that total reimbursement to the pharmacy provider complies with the requirements of section 1902(a)(30)(A) of the Act*. States are responsible for providing adequate information to support any proposed changes to either or both of the components of the reimbursement methodology. (Emphasis added.)[26]

Finally, CMS responded that commenters "agreed with our proposal, and stated that they appreciate the policy to require states to reconsider their dispensing fee methodology as states change their payment for ingredient cost based on AAC. Several commenters stated that in the states where AAC is currently in use, CMS has required a comprehensive review and adjustment of dispensing fees, and commenters believed that this practice should continue."[27] Consequently, after consideration of the comments, CMS stated that "we are finalizing the definition of professional dispensing fee in § 447.502 as proposed (77 FR 5361)."[28] CMS allowed a one-year implementation period, by no later than June 30, 2017, for States to comply and to submit the SPA, with an effective date no later than April 1, 2017.[29]

The Administrator, after review of the law, regulations evidence of record, agrees with the Presiding Officer's findings that, regarding Issue 1, the State of Washington did not meet the requirements of §1902(a)(30)(A) of the Act, and regarding Issue 2, did not meet the requirements of the regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518.

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[25] 81 Fed. Reg. 5202.
[26] 81 Fed. Reg. 5175.
[27] 81 Fed. Reg. 5202.
[28] 81 Fed. Reg. 5175.
[29] *Id*. at 5173-74.

The Administrator finds that the State of Washington has not documented that its PDF is consistent with the statute and regulatory requirements. The State of Washington did not submit adequate data that demonstrates pharmacy providers are reimbursed for their professional services consistent with the requirements of the statute and regulations and, thus, it has not assured CMS that the SPA 17-0002 complies with §1902(a)(30)(A) of the Act. As CMS recognized, rather than establish cost-based PDFs in accordance with the Medicaid programs legal standards, Washington State adopted a market approach relying on Pharmacy Benefit Manger (PMB) survey of fees paid for PDFs. The State adopts the private marketplace lower dispensing fees, which as CMS witness found and the survey themselves reflect, do not demonstrate the cost. Washington State's approach to supporting its proposed rates for PDFs is inconsistent with Federal standards as the State fails to support its rates with data demonstrating the pharmacist's professional services and actual cost associated with ensuring the possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary.

The State responded to CMS' informal questions by electronic mail, dated September 8, 2017, with respect to supporting, among other things, the proposed professional dispensing fee.[30] The relevant Questions and Responses were as follows:

> Question: Please explain what is meant by "research and data" and why the state is opting this route as opposed to performing/or using a survey of pharmacy's cost to dispense a drug.
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> State Response:
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> a. Please see the materials submitted with the SPA package. The Agency undertook a careful examination of the ingredient cost and dispensing rates paid to, and accepted by, Washington pharmacy providers. The Agency used research, and data from other payers to compare to data from Washington Medicaid FFS pharmacy program. The Agency then made a determination of the rate that would be sufficient to maintain beneficiary access and provider participation.
> b. The state did not use a cost of dispensing study because pharmacy professional services are not purchased on that basis within Washington State. The guidance published with the rule specifically gives ".... the option to submit data, other than a survey, which demonstrates that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30(A) of the Act."[31]

The response also shows the evidence put forth by the State to support its dispensing fees as follows:

> Question: Washington's proposed professional dispensing fee is significantly lower than all other approved professional dispensing fees nationally, including your contiguous neighboring states. Prior to the formal WA SPA 17-0002 submission, the state provided 3 documents to support its decision to maintain its current dispensing fee, 1) the Mode Health-Market Check -Presentation, 2) Milliman

[30] CMS A.R. 0297.
[31] CMS A.R.0 298.

> Pharmacy Benchmark Report, and 3) HMA for Insurance Commissioner Pharmacy Supply Chain Study, please explain how these documents support the state's proposed professional dispensing fee to comply with the definition of professional dispensing fee at 42 CFR 447.502, and the State Medicaid Director's letter, SHO # 16-001. If there is any additional documentation that the state can provide to help justify the state's proposed professional dispensing fee, please submit those documents along with an explanation to support the state's proposal.
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> Response: The three documents submitted with the SPA establish that the aggregate ingredient cost and dispensing fee rates are sufficient to ensure that Washington FFS Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of 1902(a)(30)(A) of the Social Security Act.
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> The state relies on the submitted documents and on demonstrated sufficiency of the rates since April 1, 2017.[32]

As set forth in its responses, the record shows that during the SPA 17-0002 review process, the State of Washington submitted the three reports to support its PDF rate:

(1) 2015 "Market Check Evaluation" from the Burchfield Group for Moda Health and Northwest. Moda Health report);[33]
(2) Letter from Milliman to the Washington HCA, "Prescription Drug Reimbursement and Dispensing Fee Benchmarks," dated January 3, 2017. (Milliman report),[34] and;
(3) "Study of the Pharmacy Chin of Supply" from Health Management Associates for the Washington Office of Insurance Commission (OIC Report).[35]

The State set forth the rational to support the use of the studies and its rates in its response to CMS request for additional information.[36] In its brief, the State explained the evidence as follows:

> The first study was conducted for the Office of the Washington Insurance Commissioner. See CMS 0328, 1468 (Davis Decl. ¶ 16, Attach. B). The Commissioner examined data from pharmacy benefit managers ("PBMs") that serve nearly all of Washington's fully insured commercial market. See CMS 0330. The Commissioner found that PBMs were paying a weighted average dispensing fee of $0.66 to $1.88. See CMS 0386 (Ex. 44). The Authority's dispensing fees are much higher, at $4.24 to $5.25. See CMS 1469 (Davis Decl. ¶ 21).
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> The second study was conducted by the Burchfield Group on behalf of Moda Health. See CMS 1468, 1472-87 (Davis Decl. ¶ 16, Attach. C). The study showed that PBMs 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 16.83%. See CMS 1479. The Authority's fees were much higher, at $4.24 to $5.25.

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[32] CMS A.R. 0303-0304.
[33] CMS A.R. 0777-0791
[34] CMS A.R.0315-0327.
[35] CMS A.R. 0328-0434.
[36] CMS A.R. 0450-0464.

> See CMS 1469 (Davis Decl. ¶ 21). The Authority's ingredient cost payments were roughly the same, at the Average Wholesale Price minus 16%.
>
> The third study was conducted by Milliman, Inc., on behalf of the Authority. See CMS 1468, 1488-1501 (Davis Decl. ¶ 17, Attach. D). The study showed the median dispensing fees from Medicare and private companies were only $0.49 to $1.09 (see CMS 1496), compared to $4.24 to $5.25 from the Authority (see CMS 1469 (Davis Decl. ¶ 21)). With respect to ingredient costs, the Authority had been paying the Average Wholesale Price minus 16% for single-source drugs, while Medicare and commercial payors were paying roughly the same, at Average Wholesale Price minus 15.4% (CMS 1495).[37]

The State contended that Washington Medicaid currently pays tiered dispensing fees (based on pharmacy volume) ranging from $4.24 to $5.25 per prescription. The State contended that, pursuant to the State's evaluation of the proposed April I, 2017 pharmacy rates, the studies demonstrated that the (non-Medicaid) retail 30-day dispensing fees, paid and accepted in Washington, are significantly lower than the present Medicaid dispensing fees. The State maintained that non-Medicaid dispensing fees may be less than $1.00, and across all the studies' payers the dispensing fees are on average less than $1.88 per claim.[38]

After completing this analysis, the State consequently argued that its dispensing fee rates are much higher than other payers in Washington, operating with the same provider population, and with comparable ingredient cost rates. As such, the State contended that the State Medicaid pharmacy rates, that were to take effect on April 1, 2017, continued to be within the norms of well-accepted payment rates within the Washington pharmacy "marketplace." The State also argued that a high percentage of licensed Washington pharmacies choose to participate in the fee-for-service pharmacy network, confirming the sufficiency for access based on the existing rates. When CMS requested further documentation and justification for its rates, the State declined and submitted justification on why the additional information was not needed, including why the marketplace approach to pricing the dispensing fees was in conformity with the law and appropriate for Washington State.

CMS addressed the State evidence submitted during the pre-SPA technical assistance and the SPA review process in this matter as described below. The CMS listed those specific documents the State submitted to CMS:

> (1) A letter from Milliman to the Washington Dept. of Social & Health Services (DSHS), dated April 29, 2009, re: "DSHS Brand Name Prescription Drug Reimbursement Benchmarks" (CMS 0769-0775), and two letters from Milliman to the Washington Health Care Authority, each titled "Prescription Drug Reimbursement and Dispensing Fee Benchmarks" respectively dated August 5, 2016 (CMS 0309-0314), and January 3, 2017 (CMS 0315-0327) (Milliman Letters), and;

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[37] State Pre-Hearing Brief, 10-12.
[38] CMS A.R. 1468-69.

(2) A 2015 slide presentation titled "Market Check Evaluation" from The Burchfield Group for Moda Health and Northwest (CMS 0777-0791) and draft memo from Moda Health dated March 29, 2016 (CMS 0792-0798) (Moda Health Presentation);

(3) A "Study of the Pharmacy Chain of Supply from Health Management Associates for the Washington Office of the Insurance Commissioner (CMS 0328-0434) (CMS 0751-0763; CMS 0854-0856) (OIC Report).

However, CMS determined that these letters and studies, did not address the issues specific to the professional dispensing fee determination in Medicaid fee-for-service; that is, among other things, whether the proposed reimbursement met the criteria of §1902(a)(30) and, more specifically, whether the fees reasonably compensate for the reasonable costs of the pharmacist's time and costs and overhead as set forth in 42 C.F.R. §§ 447.502 and 447.518.

Instead of providing a State specific survey of professional dispensing costs, in response to CMS' request for "either a recent Washington state survey of pharmacy providers actual cost of dispensing or data from neighboring states' recent cost of dispensing studies to support the proposed rates," the State pointed to "the voluntary acceptance of the rates" by pharmacies servicing Medicaid Fee-For-Service (FFS) clients.[39] The State also argued that the regulation allows for alternatives to the use of "survey" data

The CMS Expert explained in his deposition that: "[T]he data were inadequate for me to determine whether the costs were being covered, and . . . based on everything we know about what it costs to dispense a prescription, both by the states in the region, the Northwest and nationally, [the State rates] would not seem to cover the average cost of dispensing." [40] Further, he noted that: "What we do know from the states that have submitted costs of dispensing studies and other national cost of dispensing studies is [that] it's hard-pressed for us to see how it costs about half the amount … for Washington to dispense a prescription than it does anywhere else in the country." [41] As CMS explained in the Prehearing Brief, the State's tiered dispensing fees are about one-half the amount of fees recently developed in neighboring States.[42] The lack of any data from the State showing pharmacy costs (as opposed to marketplace prices) for Washington resulted in the lack of documentation of the sufficiency of its proposed rates.[43]

Notably, CMS Expert testified that CMS held every State and the District of Columbia to the same standard, explaining that: "44 states are there and six are moving in that direction …."[44] Where CMS has approved a respective SPA, the State provided either a cost survey or related data to support the actual costs of dispensing a prescription drug within the State.[45] The CMS Expert explained that: "We don't treat any one state differently … [a]nd we would be treating [the State of Washington] to a different legal standard if we did not require you to pay the cost of dispensing

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[39] CMS A.R. 0458- 0459, CMS A.R. 0807-0808.
[40] Deposition of Dr. Coster, State Ex. 16, at 168-169.
[41] Deposition of Dr. Coster, State Ex. 16, at 170.
[42] CMS Brief at 13-14.
[43] Deposition of Dr. Coster, State Ex. 16, at 183-186.
[44] Transcript at 283-284, 287.
[45] Transcript at 311.

or submit reliable and accurate data to support that cost of dispensing."[46] Washington State is the only State in the current posture, the expert explained. In addition, on its face, these reports did not analyze the pharmacy cost of dispensing Medicaid fee-for-service drugs to beneficiaries in Washington and, thus, did not support the State's dispensing fees. CMS recognized that the studies, including the Moda Health presentation and Milliman Letters were highly focused on commercial pharmacy benefit manager (PBM) reimbursement methodologies and did not address the cost of dispensing in the Medicaid program. Pharmacy benefit manager or PBM generally means a third-party administrator that provide pharmacy benefits management on behalf of a health benefits plan that manages prescription drug coverage.

As the CMS Expert explained at the hearing, a problem with using PBM data, "the fees that are being paid by PBMs to pharmacies in the state might be lower than what [the State is] paying," but that "most PBMs are giving pharmacists more spread on the product."[47] Pursuant to the Deposition, the CMS Expert explained that these reports do not "show what it costs to dispense prescriptions in the state of Washington. All this is, is a comparison of rates for a Medicare program [and] commercial payers, which has no relevance to what the rules require with respect to payment to pharmacies under Medicaid."[48] The rates being paid by Medicare or commercial payers "really have nothing to do with the cost of dispensing prescriptions."[49] As summarized by CMS witness, the lack of any cost data from the State showing pharmacy/professional dispensing costs in Washington resulted in a failure to support the sufficiency of its proposed rates.[50] In the deposition, the CMS Expert explained that "the rates that they're taking from Medicare don't reflect – or commercial payers are not really reflecting their costs of dispensing.[51]

The CMS Expert also testified as to the significance of each of the surveys presented by the State in support of its proposed rates. The hearing testimony reflects, regarding the Milliman Letters, as follows:

> Ms. Freeman: Let's flip to the next tab. We've heard testimony about the Milliman report, and I'm referring to CMS page 315 through 327. Had you seen this Milliman report during the SPA review process?
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> The Witness: Yes.
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> Ms. Freeman: Did this report satisfy CMS that the professional dispensing fee requirements were met?
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> The Witness: No, it did not.
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> Ms. Freeman: Why not?

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[46] Deposition of Dr. Coster, State Ex. 16, at 85.
[47] Transcript at 319.
[48] Deposition at 158.
[49] Deposition of Dr. Coster, HCA Ex. 16, at 185-186.
[50] Deposition of Dr. Coster, HCA Ex. 16, at 183-186.
[51] Deposition of Dr. Coster, HCA 16, at 186.

> The Witness: Well, because as we had discussed, our data expectations were for the state to submit data, reliable, accurate data that reflected the cost of dispensing. As has been pointed out by the morning witnesses, this is a study on what pharmacies are accepting in terms of reimbursement. If I can also point out, the state doesn't say in its testimony that, yes, the fees that are being paid by PBMs to pharmacies in the state might be lower than what they're paying, b also -- most PBMs are giving pharmacists more spread on the product. I want to make sure that that is entered into the record that the state is not telling the full story regarding what these PBM rates are. If you look on page 315, you'll see for the discount off AWP, at least in this study it's about 15 percent off AWP and $1.09 dispensing fees. The pharmacies may be taking $1.09. but they're also getting some margin on the product side, which is now eliminated in Medicaid. Therefore, it's easy to point to these fees and say, look, pharmacies are taking these. What the state doesn't say is that there's also margin left on the product where under a NADAC reimbursement there's no margin left. [52]

Regarding the Moda Health/Burchfield Group Report, the CMS expert testified as follows:

> Ms. Freeman: Turning to the next tab, this has been referred to as the market tech evaluation, MODA Health, also called the Burchfield Group, which is at CMS page 777.
>
> The Witness: This report, by the time we received it, it was about two years old. Again, the Burchfield Group is really a PB consulting group. Again, like the previous report, it really didn't tell us much about what it costs to dispense prescriptions in the state. As I just pointed out about the previous report, the state only talks about half the data, the other half of the data in the report shows that, yes, the pharmacies may be accepting fees that are low, but there's also still margin left for the pharmacist on the product side, which helps to offset at least the lower fees that these PBMs are paying. The bottom line is that no other state, no other state submitted anything like this. Under our legal standard, this is not what we had expected the state to submit to us to approve their SPA. [53]

Finally, regarding the Office of Insurance Commissioner (OIC) Study, the CMS witness testified that:

> Ms. Freeman: Turning to the next tab, which is referred to as the Office of the Insurance Commissioner study of the pharmacy chain of supply at page CMS- 328, did this report have any impact on the CMS review of the professional dispensing fees?
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> The Witness: No. It did not because like the previous two studies, there was really nothing in here that told us what it cost the pharmacist to dispense a prescription in the State of Washington.

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[52] Transcript at 319-320.
[53] Transcript at 320-321.

> Ms. Freeman: Turning your attention to page 12 of that report, which is also numbered as the CMS page 33, what can you tell us about Footnote 3?
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> The Witness: So back in probably 2012, '13, the two national pharmacy associations commissioned -- in anticipation of the move to the more cost-based reimbursement system in Medicaid, the two big national pharmacy associations, National Association of Chain Drug Stores and NCPA commissioned a cost of dispensing study. This study, this report, whatever you want to call it footnotes that study, which apparently shows that the Washington State estimates range from $10 to $15 to dispense a prescription. We would not have relied on a pharmacy study like this to approve or disapprove for that matter a SPA. These are industry studies. We would not have relied on it, but I think -- I don't have any reason to doubt the validity of the study in terms of the numbers. It's basically a study that was done by the two big national pharmacy organizations in order to at least be informative about what the average cost of dispensing is in the various states.
>
> Ms. Freeman: So the dispensing cost in that footnote estimates a range from approximately $10 to $15 per prescription. Is that range consistent with what CMS has been generally finding nationwide?
>
> The Witness: The outer bounds are a little high. The $10 is probably more consistent with what the states have been finding.[54]

The reports themselves also demonstrate that the State's reliance on them is misplaced. For example, the Moda Health presentation sets forth as a caveat that:

> Information in this report is intended to assist Moda Health in evaluating and assessing pharmacy benefit management options in the marketplace. Other uses of this information may not be appropriate.[55]

The Milliman Report had similar caveats, stating that:

> Contracts between pharmacy benefit managers (PBMs) and pharmacies can be complex and are generally negotiated in totality. AWP discounts, dispensing fees, and rebates are common levers used to adjust overall contract terms. For example, as one lever is negotiated up, another may be negotiated down. Given this dynamic, it is unlikely that the most aggressive AWP discount will be paired with the most aggressive dispensing fee. Comparing AWP discounts and dispensing fee benchmarks to other markets should be done with caution due to differences in drug mix and demographics within the populations. It should be recognized that a Medicaid population will utilize a different drug mix than a commercial or Medicare population. It is also important to mention that the benchmark data provided utilizes information from national health plans and are not specific to one geographical area. One last item of importance is the nuances of each of these

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[54] Transcript at 322.
[55] CMS A. R. 1486.

> markets and how they may be similar or different to the Washington Medicaid market. [56]

The report concluded by further acknowledging that:

> Pharmacy pricing is complex process highly dependent on the types of pharmacy programs in place and mix of medications being dispensed. The contractual terms illustrate the types of pricing terms that are available in the marketplace. It should be noted that it is unlikely for any given entity to have aggressive pricing for all terms and that contracts typically have various trade-offs between items. [57]

CMS also pointed out that, for similar reasons, the Office of Insurance Commissioner (OIC) Report did not support the State's dispensing fee in tiered amounts of $4.25-$5.25. While CMS stated it would not rely on a cost study, commissioned by the industry, *to establish rates* for any particular State, [58]this evidence as used in the context of this SPA reconsideration fails to support the State's rates contrary to the State's contentions. The OIC Report, too, pertained to PBM organizations and the report states that:

> It should be noted that conducting dispensing and actual acquisition cost studies were out of scope for this project; therefore, industry benchmarks were used as proxies for Washington-specific drug acquisition cost and cost of dispensing.[59]

Further, the OIC Report shows estimates of dispensing costs that ranged from $10-$15, almost twice the amounts the State proposed in its SPA.[60] The OIC Report cited the "Cost of Dispensing Study: An Independent Comparative Analysis of U.S. Prescription Dispensing Cost" September 2015 when stating: "The Washington State estimates range from approximately $10 to $15 per prescription."[61] The OIC Report also cited the 2015 national cost of dispensing survey that was commissioned by the National Community Pharmacy Association (NCPA) and National Association of Chain Drug Stores (NACDS), two of the amici participating in this hearing in support of the SPA' s disapproval.[62] The OIC Report also acknowledged that:

> In adopting the AAC reimbursement, CMS has been adamant that states must reevaluate their allowed professional dispensing fee to ensure pharmacies are adequately being reimbursed for the services provided … Accordingly, the states

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[56] CMS A.R.1468, 1488-1501 (Davis Decl. ¶ 17, Attach. D). CMS A.R.1491, Davis Declaration D.)

[57] The expert's and the studies' observation, regarding PRM impact on "prices" are also found in public data. See, e.g., McGrail, Samantha, Pharma News Intel, "PBM Reimbursement Significantly Varies for Generic Drugs" https://pharmanewsintel.com/news/pbm-reimbursement-significantly-varies-for-generic-drugs ("Our analysis of the population of claims data in our study arrives at an average dispensing fee of just $0.70 per prescription. If this were the only source of revenue for pharmacies, this would mean they would generate a profit of just $0.70 on each claim filled for patients, a fraction of the ten [dollar] per claim required to cover operating costs," researchers highlighted. Consequently, these minuscule dispensing fees leaves ingredient cost, or MAC rates, as the primary source of pharmacy revenue.")

[58] Deposition of Dr. Coster Ex. 16, at 236-237.

[59] CMS A.R. 0330.

[60] CMS A.R. 0333, 339.

[61] CMS A.R.352.

[62] CMS A.R. 339, n.3.

> that have adopted the AAC reimbursement for ingredient cost have performed cost of dispensing surveys and currently have dispensing fees that are generally in excess of $10 per prescription.[63]

Washington State's own report found that PBMs' ingredient cost reimbursement rates are higher than the State's NADAC rates. The State's own analysis found that, when ingredient cost reimbursement and dispensing fees are considered together, the State pays significantly less than other payers. The report also observed that:

> In general, if the actual drug acquisition costs for Washington pharmacies had been equal to the national drug acquisition cost benchmarks used in this analysis, PBM reimbursements may not have been adequate to cover pharmacy costs, assuming a $10 [cost of dispensing] COD. If the actual COD was higher than $10, the shortfall would have been greater.[64]

CMS had advised the State that its proposed tiered dispensing fee was significantly lower than all other approved professional dispensing fees nationally, including states contiguous to the State of Washington. Those States' professional dispensing fees, which CMS was able to approve, included: Idaho with a tiered PDF ranging from $11.51 (>70,000 prescriptions per year) to $15.11 (<39,999 prescriptions per year); Montana with a tiered PDF ranging from $11.00 (>70,000 prescriptions per year) to $15.00 (<39,999 prescriptions per year), and; Oregon with a tiered PDF ranging from $9.68 (>50,000 prescriptions per year) to $14.01 (<30,000 prescriptions per year). (CMS 0765-0768.)

CMS acknowledged that the comparison of professional dispensing fees among the contiguous States is not a determinative factor in approving or disapproving a SPA, however, the comparison allows for better evaluation of the dispensing fee rates in a geographic area. The State did not provide any relevant or meaningful data to support Washington's professional dispensing fee within the revised regulatory scheme, and the submitted data did not explain the reason for the significant discrepancy between the State of Washington's rates and other neighboring State's rates. These reports do not address the professional costs of dispensing a covered drug in the fee-for-service Medicaid program in the State of Washington.[65]

The reports do not relate to findings on the professional dispensing fees for pharmacist in Washington State. Such findings should reflect, in accordance with 42 C.F.R. §447.518, the related dispensing fee costs including but are not limited to, 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

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[63] CMS A.R. 0360.

[64] CMS A.R. 384. *See also, e.g.*, CMS 382 of the Report showing "Exhibit 40: Rural and Urban Net Income as percent of Gross Income at $10 and $15 cost to dispense for Case Study Pharmacies."

[65] Transcript at 273, 319-328; see also Deposition of Dr. Coster, HCA Ex. 16, at 158, 171-178, 185-186.

After a review of the record and arguments, the Administrator finds that these reports do not addressed the professional costs of dispensing a covered drug in the fee-for-service Medicaid program in the State of Washington and, thus, does not support the State's dispensing fees.[66] These reports only show a comparison of rates for a Medicare program and commercial payers, which is not reflective of the payment rules to pharmacies under the Medicaid rules. Section 1902(a)(30)(A) and the implementing regulations require meaningful evaluation by the State of both components of its total reimbursement methodology within the revised regulatory scheme, and the submission to CMS of adequate data to support the proposed reimbursement methodology. 42 C.F.R. §447.5l8(d). To assure that payments meet the goals of §1902(a)(30)(A) of the Act, the Administrator finds that, CMS specifically adopted data requirements establishing the types of evidence a State must submit to support any proposed change to either or both components of the pharmacy reimbursement methodology. These data requirements are not optional, in that a State "must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access."[67] States are required to evaluate their proposed changes in accordance with the requirements of this subpart, 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 the requirements of §1902(a)(30) of the Act and the regulations.

Finally, the State of Washington arguments that CMS' denial of SPA 17-0002 is arbitrary and capricious and violates the APA by applying standards that were not part of its rule-making process, is not supported by the record. The *Federal Register* publications of the proposed and final rules shows that CMS engaged in notice-and-comment rulemaking concerning the reimbursement rate methodology (comprised of both the ingredient cost and professional dispensing fee) for prescription drugs in the Medicaid program, issuing its proposed rules on February 2, 2012[68] and finalized those rules on February 1, 2016.[69] The regulation and preamble defined professional dispensing fees and specifically addressed the need to evaluate both the ingredient costs and professional dispensing fees in conjunction when evaluating whether the rates meet the criteria of §1902(a)(30)(A) of the Act. The notice of rulemaking specified that 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 the requirements of §1902(a)(30)(A) of the Act.

CMS followed proper notice and comment rulemaking with respect to the rules being applied in this review. The CMS disapproval_was based on the State's failure to demonstrate "how it calculated its PDF or how the current dispensing fee methodology in its state plan is consistent with the current definition of PDF." The State's approach does not adopt the cost finding approach used by neighboring States in their approved State plan rates to support the PDF rate. As documented in the record, the State's market approach shows a significant discrepancy between its rate and cost finding method that CMS has accepted. The record shows that this discrepancy

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[66] *See*, CMS' Post Hearing Brief at 10.
[67] 81 Fed. Reg. 5170, 5201 (Feb. 1, 2016).
[68] 77 Fed. Reg. 5318 (Feb. 2, 2012).
[69] 81 Fed. Reg. 5170, 5173 (Feb. 1, 2016).

was due to the differences in the PBM contracting methodology that does not rely upon traditional cost finding for pricing, but is impacted by upon market forces and drug mark-ups on the pharmacy dispensing fee pricing used by PBMs.

In using an alternative method to determine the PDF rate, the State's market approach fails to show how the dispensing fees paid by PBMs relate to the State's proposed PDF rates in conformity with the rules. While the regulation at 42 C.F.R. §447.518 allows for the use of "other reliable data other than a survey", this does not negate the need to identify the pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to the Medicaid beneficiary. CMS specifies and defines "costs" in the customary way the term is used in the Medicaid and Medicare program. CMS specifies pharmacy costs, include but are not limited to the "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." The State has not pointed to authority as to another definition of "reasonable cost." The regulation also specifies that when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to evaluate their proposed changes in accordance with this final rule, and states must consider the impacts of 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 the requirements of section 1902(a)(30)(A) of the Act, which is not reflected in the "data" provided by the State.

The State's proposed rates range from $4.24 to $5.25 per prescription and the market surveys upon which it relies show PBM contracted fees are on average less than $1.88 per claim. As CMS stated in its disapproval, the State did not show how it calculated the PDF or how the current rates are consistent with the PDF rule. The proposed rates are not supported by a cost finding methodology. The State does not show how the market approach conforms to the requirements set out in the regulation in effectuating the statute. Critically, the reports do not demonstrate that the State is proposing a dispensing fee reflective of the actual pharmacy *costs* associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient."

The State does not demonstrate that it considered 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 the requirements of §1902(a)(30)(A) of the Act. Consequently, the State has failed to demonstrate that, as required under § l902(a)(30)(A) of the Act, the State has provided such methods and procedures to assure that State's 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.

The State of Washington also contended that CMS' denial is illogical because for 8 years, (2009-2017) it was incompliance and all of a sudden without any change in those laws, it is now noncompliant. The State of Washington argued that, if in compliance in terms of dispensing fee

levels in 2009, it remains so now. However, the State's contention choses to ignore the changes made to both the ingredient costs and professional dispensing fees pursuant to the proposed and final rule. While the State maintained CMS' rule change to the definition of dispensing fess was insignificant, the CMS significant revision of the definitions at 42 C.F.R. §447.512(b) and the documentation requirements of 42 C.F.R. §447.518(d), repeatedly highlighted that the changes to the definition and payment of ingredient costs was inextricably linked and impacted the determination of professional dispensing fees. The rule change was made with the specific regulatory recognition that the components must be evaluated, with respect to costs, together, and not in isolation.[70]

Pursuant to the notice and comment rulemaking, CMS directed States that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. The State did not demonstrate that evaluation occurred here. In addition, the CMS expert testified, which the State did not rebut, that CMS has consistently applied these standards nationally in evaluating State plan changes in light of the final rule. Accordingly, the Administrator finds that the State of Washington's argument, that CMS' denial of SPA 17-0002 is arbitrary and capricious and inconsistent with the law, is not supported by the history, application, and rulemaking of these requirements.

The controlling procedural authority governing the Medicaid SPA submission and review process also does not permit States to unilaterally determine that responding to a request for additional information is unnecessary under 42 C.F.R. §430.16. The State also failed to comply with data production requirements of 42 C.F.R. §430.518. Consequently, the State improperly declined to provide the needed data in the form required for evaluation and CMS, therefore, properly disapproved the SPA. As the Presiding Officer properly found and as articulated by CMS, "the result required by [§1902(a)(30)(A)] and the implementing regulations is clear: there must be a meaningful evaluation by the State of both components of its total reimbursement submission to CMS of adequate data to support the proposed reimbursement methodology."

Consequently, the Administrator finds that the Washington SPA 17-002 is inconsistent with the requirements of §1902(a)(30) of the Social Security Act which requires, in part, that States have a State plan that provides such methods and procedures 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 to the general population in the geographic area. The Administrator also finds that Washington SPA 17-002 is inconsistent with the requirements of the Federal regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518, which provide that payments for drugs are to be based on combined examination of the ingredient cost of the drug and a PDF as those terms are defined and based on documentation of the pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to the Medicaid beneficiary. Consequently, the Washington SPA 17-0002 is disapproved.

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[70] 42 C.F.R. §447.512(b)(1); 42 C.F.R. §447.518(d); 81 Fed. Reg. 5310, 5201.

Decision

In accordance with the Court's Order Granting Joint Motion for Voluntary Remand and Dismissal Without Prejudice, the Administrator has reconsidered the decision of January 19, 2020. As set forth in the foregoing opinion, the Washington State Plan Amendment SPA-17-0002 is disapproved.

THIS CONSTITUTES THE FINAL ADMINISTRATIVIE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: June 24, 2022

Jonathan Blum
Principal Deputy Administrator
Centers for Medicare & Medicaid Services