DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Washington State Health Care Authority,	*	**Reconsideration of Disapproval**
	*	
Petitioner	*	**Washington Medicaid State Plan Amendment No. 17-0002**
v.	*	
Centers for Medicare & Medicaid Services,	*	**Docket No. SPA 2019-01**
Respondent		

PROPOSED DECISION OF THE PRESIDING OFFICER

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I. ISSUES

Whether the Washington State Plan Amendment ("SPA") 17-0002 is inconsistent with the requirements of:

1) Section 1902(a)(30)(A) of the Social Security Act ("the Act" or "SSA") (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").

II. SUMMARY OF THE PROPOSED DECISION

As the State did not comply with the Centers for Medicare and Medicaid Services ("CMS") request to provide information regarding the actual cost to dispense prescriptions, it neither demonstrated that it met the substantive legal requirements of SSA § 1902(a) (30) (Issue 1) or the regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518 (Issue 2). The controlling procedural authority governing the Medicaid SPA submission and review process do not permit States to unilaterally determine that responding to a request for additional information is unnecessary (SSA § 1915(f)(2) (42 U.S.C. § 1396n(f)(2)) and 42 C.F.R. § 430.16). Accordingly, CMS' disapproval of the SPA was appropriate.

Moreover, the Presiding Officer finds that CMS' information request was appropriate. While the State justifies its refusal to provide the information by insisting that its aggregate reimbursement rates, comprised of ingredient and PDF component costs, are sufficient, the controlling regulations provide that cost based professional dispensing information is a core element in evaluating the aggregate rate.

III. PROCEDURAL LEGAL AUTHORITY – MEDICAID STATE PLAN REVIEW PROCESS

Medicaid 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. SSA § 1901 (42 U.S.C. § 1396-1). Medicaid is jointly financed by the Federal and State governments and is administered by the States.

States that choose to participate in the Medicaid program must submit to HHS / CMS a State plan to provide medical assistance. *Id.* The Medicaid statute provides that the HHS Secretary shall

approve any plan which meets the requirements as outlined in 42 U.S.C. § 1396a. The regulations at 42 C.F.R. §§ 430.00 through 430.104 implement the statute setting forth the State plan requirements, standards, procedures and conditions for obtaining Federal financial participation ("FFP"). The Secretary has the authority to issue regulations under the program and has delegated responsibility for approving State plans and State plan amendments to CMS, which is a component of HHS.[1]

The regulation at 42 C.F.R. § 430.10 indicates that a State plan must contain all necessary information for CMS to evaluate the plan and provide appropriate assurances as follows:

> The State plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and **giving assurance** that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances of the Department. The State plan **contains all information necessary** for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

(Emphasis added.)

The regulation at 42 C.F.R. § 430.12(c) dictates, in relevant part, that States have a continuing obligation to promptly update plans as follows:

> (c) *Plan amendments.*
> (1) The plan must provide that it will be amended whenever necessary to reflect –
> (i) Changes in Federal law, regulations, policy interpretations or court decisions; or
> (ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program . . . .
> (2) Prompt submittal of amendments is necessary –
> (i) So that CMS can determine whether the plan continues to meet the requirements for approval . . . .

Similarly, the regulation at 42 C.F.R. § 430.15 outlines, in relevant part, that the State plan is continually obligated to meet legal requirements:

> (a) *Basis for action.*
> (1) Determinations as to whether State plans (including plan amendments and administrative practice under the plans) originally meet or continue to meet the requirements for approval are based on relevant Federal statutes and regulations.
> (2) Guidelines are furnished to assist in the interpretation of the regulations.

[1] 42 C.F.R. §§ 430.1, 430.14 and 430.15.

The regulation at 42 C.F.R. § 430.16 delineates that CMS may ask for additional information and addresses the timing with regard to denials of State plan submissions as follows:

> (a) *Timing.*
> (1) A State plan or plan amendment will be considered approved unless CMS, within 90 days after receipt of the plan or plan amendment in the regional office, sends the State –
> (i) Written notice of disapproval; or
> (ii) Written notice of any additional information it needs in order to make a final determination.
> (2) If CMS requests additional information, the 90-day period for CMS action on the plan or plan amendment begins on the day it receives that information.[2]

Section 1116(a)(2) of the Act (42 U.S.C. § 1316(a)(2)) and the implementing regulation at 42 C.F.R. § 430.18 provide that States dissatisfied with an adverse administrative decision relating to a SPA disapproval may request a review hearing. The regulation at 42 C.F.R. § 430.60(a) further provides that appeals involving the decision to disapprove a SPA are reviewed on the basis of whether the plan is "in compliance with Federal requirements." The regulations at 42 C.F.R. §§ 430.66 and 430.102 provide that the CMS Administrator may designate a presiding officer to conduct a hearing and issue a proposed decision. The Administrator also specifies the issues to be considered in the hearing notice. 42 C.F.R. §§ 430.70 and 430.74.

IV. SUBSTANTIVE LEGAL AUTHORITY – MEDICAID PAYMENT METHODOLOGY FOR PRESCRIPTION DRUGS

In setting appropriate payment levels, § 1902(a)(30)(A) of the Act broadly requires that State plans must:

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

State Medicaid programs may provide coverage for prescription drugs as an optional service under § 1905(a)(12) of the Act (42 U.S.C. § 1396d(a)(12)). Section 1903(a) of the Act (42 U.S.C. § 1396b(a)) provides for FFP in state expenditures for these drugs. Section 1927 (42 U.S.C. § 1396r-8) governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs ("CODs"), which are defined in § 1927(k) of the Act. For payment to be made available for CODs,

[2] Section 1915(f)(2) of the Act (42 U.S.C. § 1396n(f)(2)) also provides that the federal Medicaid program has the authority to request additional information from a state.

manufacturers and States must meet certain requirements. SSA § 1927; *see generally* 81 Fed. Reg. 5170 (Feb. 1, 2016).

On February 2, 2012, CMS issued a proposed rule to revise certain drug requirements, including payment related aspects. In moving towards a "more accurate reference price" for prescription drug reimbursement for ingredients based on the AAC, CMS also recognized the need 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. 77 Fed. Reg. 5317, 5320 (Feb. 2, 2012). Accordingly, without modifying the definition itself, 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 drug is transferred to a Medicaid beneficiary." *Id.* at 5326. As such, CMS proposed that as State Medicaid agencies adjusted their payment for ingredient cost, they must also reevaluate the dispensing fee. *Id.*

On February 1, 2016, CMS published the Covered Outpatient Drug final rule with comments (CMS 2345-FC) ("February 2016 final rule") that addressed these key changes for Medicaid reimbursement for CODs. 81 Fed Reg. 5170 (Feb. 1, 2016).[3] The new rule sought State Medicaid Agencies' compliance with the requirements of 42 C.F.R. §§ 447.512(b), 447.518(a) and 447.518(d), through submission of a SPA. CMS allowed a one-year implementation period, but 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. *Id.* at 5173-74. In its final rule, CMS also explained:

> 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.

Id. at 5201.

[3] *See also* CMS' Prehearing Brief at 3-4 and CMS' Post-Hearing Brief at 3-4 (providing additional historical background regarding Congressional and HHS concerns about Medicaid payment levels for prescription drugs costs).

> After evaluating [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.[4]

Accordingly, the regulation at 42 C.F.R. § 447.512(b) provides the following instruction relating to payment levels:

> (b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the following:
> (1) **AAC plus a professional dispensing fee** established by the agency; or
> (2) Providers' usual and customary charges to the general public.

(Emphasis added.)

The regulation at 42 C.F.R. § 447.502 defines the AAC and professional dispensing fees referenced in 42 C.F.R. § 447.512(b) as follows:

> *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.
>
> . . . .
>
> *Professional dispensing fee* means the professional fee which:

[4] To assist States in complying with the final rule, CMS issued sub-regulatory guidance in accordance with 42 C.F.R. § 430.15(a)(2), which detailed the need to re-evaluate both the ingredient cost *and* PDF independently, including the following:

- A State Medicaid Director ("SMD") Letter dated February 11, 2016 (CMS Exhibit 1 at 0864-70);
- Covered Outpatient Drugs Final Rule with Comment (CMS-2345-FC) Fact Sheet (*id.* at 1534-35); and
- Covered Outpatient Drugs Final Rule with Comment (CMS-2345-FC) Frequently Asked Questions ("FAQs") dated July 6, 2016 (*id.* at 1536-45). These FAQs noted that while States are not required to use a specific formula or methodology such as a cost study, the burden is on each State to ensure that pharmacy providers are reimbursed in accordance with the requirements of § 1902(a)(30)(A) of the Act (i*d.* at 1537).

> (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 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.

(Emphasis added.)

The regulation at 42 C.F.R. § 447.518 specifies that 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.
> (3) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.
>
> . . . .
>
> (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.

(Emphasis added.)

V. FACTUAL BACKGROUND[5]

A. SPA 17-002 SUBMISSION AND REVIEW PROCESS

As required, the pharmacy payment rate used by the Washington State Health Care Authority ("the Authority"; "the State"; or "Washington") is comprised of two components: an ingredient cost and a dispensing fee.[6] Until April 1, 2017, the Authority determined the ingredient cost for brand-name drugs by using an estimated acquisition cost method.[7] To comply with the February 2016 final rule, the Authority changed to an AAC method to determine ingredient cost as of August 1, 2017. Specifically, in its June 26, 2017 supporting documents,[8] the Authority chose to use the National Average Drug Acquisition Cost ("NADAC")[9] as the ingredient cost. Significantly, however, the proposed SPA did not modify the dispensing fee component of the rate, which ranged from $4.24 per prescription (for high volume pharmacies) to $5.25 per prescription (for low volume pharmacies and Unit Dose System).[10] The $4.24-$5.25 rate had been in place since at least 2009.[11]

After CMS reviewed the June 26, 2017 SPA, it communicated with the State and, on August 16, 2017, informally[12] sent the State questions. CMS posed the following question regarding how beneficiary access would be impacted given the dispensing fee level:

> CMS Question: Please discuss whether the proposed ingredient cost changes to providers, without an increase in your professional

[5] To provide context, the factual background section references testimony in which the parties reflected back upon their actions and communications through the submission and review process.
[6] *See* CMS Exhibit 1 at 1465 (Davis Decl. ¶ 3).
[7] *See id.* at 1465 (Davis Decl. ¶ 4).
[8] Washington Prehearing Brief at 5; CMS Prehearing Brief at 8.
[9] *See* CMS Exhibit 1 at 1465-66 (Davis Decl. ¶¶ 8-10). The State established a pricing override if the NADAC rate is less than the pharmacy's cost. Additionally, providers may request an adjustment if a payment does not cover costs. Washington Prehearing Brief at 5-6; CMS Exhibit 1 at 1466 (Davis Decl. ¶ 10).
[10] CMS Exhibit 1 at 0017-19, 0035-45. The SPA proposed other changes relating to reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price. *Id.* at 0017-19, 0049-53; CMS Prehearing Brief at 8 & n.4.
[11] Transcript ("Tr.") at 101-02, 290, 299; *see also* CMS Exhibit 1 at 0444.
[12] In addition to the "informal questions" given to Washington by CMS, the parties had informal phone calls to discuss the State's proposed SPA. Tr. at 213-15.

> dispensing fees, will affect beneficiary access to pharmacy providers and if so, please discuss your plans to ensure access.[13]

Washington submitted its response on September 8, 2017, stating, in relevant part:

> State Response: Please see documents submitted with the SPA [Fee for Service Access Sufficiency, Washington Medicaid Fee-for-Service Pharmacy Access Review and Monitoring Plan, and Analysis of the Effects of Change on Access.][14] Prior to implementing the ingredient cost change the Agency researched payment levels accepted within the same pharmacy networks that serve the Medicaid FFS program. We determined that the aggregate of the ingredient cost rate and the current dispensing fee rates would be sufficient to maintain strong beneficiary access and meet the sufficiency requirements of 1902(a)(30)(A). The ingredient cost changes were implemented April 1, 2017. To the best of our knowledge there has been no adverse impact to beneficiary access.[15]

Through the administrative hearing filings and proceeding, the State provided additional context regarding its conclusion that the aggregate ingredient and dispensing rate was sufficient to meet the statutory access and sufficiency requirements. The State explained that it decided not to change the dispensing fee because if it increased fees it "would have essentially been paying more for services [they] were already receiving."16 The State witness explained that while pharmacy related trade groups now advocate for increasing fees though this administrative proceeding, individual pharmacies did not raise concerns regarding the rates prior to the hearing.17 The State reiterated that it had evaluated both ingredient costs and dispensing fees in reaching its conclusion that the proposed rate complied with CMS' rules and the overarching § 1902(a)(30)(A) requirement of efficiency, economy, quality of care, and access to care.18

Citing Washington's low dispensing rates in comparison to national and neighboring state rates,19

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[13] *See* CMS Exhibit 1 at 0059-63.

[14] During the SPA review process in this matter, the State submitted the following fee based studies to CMS: (1) a 2015 slide presentation titled "Market Check Evaluation for the Burchfield Group for Moda Health and Northwest" (CMS Exhibit 1 at 0777-91) and draft memo from Moda Health dated March 29, 2016 (*id.* at 0792-98); (2) a letter from Milliman of the Washington Department of Social & Health Services ("DSHS") dated April 29, 2009, regarding DSHS Brand Name Prescription Drug Reimbursement Benchmarks (*id.* at 0769-75), two letters from Milliman to the Washington Health Care Authority, each titled "Prescription Drug Reimbursement and Dispensing Fee Benchmarks" dated August 5, 2016 (*id.* at 0309-14) and January 3, 2017 (*id.* at 0315-27); and (3) a "Study of the Pharmacy Chain of Supply" from Health Management Associates for the Washington Office for the Insurance Commissioner (*id.* at 0328-0434).

[15] *Id.* at 0753. Substantially similar questions were formally issued by CMS on September 21, 2017 (*id.* at 0765-68) with similar responses by the State on December 20, 2017 (*id.* at 0452-64).

[16] Tr. at 199.

[17] *Id.* at 203, 206-07, 252-53.

[18] *See* 42 C.F.R. § 447.518(d); CMS Exhibit 1 at 1468 (Davis Decl. ¶¶ 14-17).

[19] *See* CMS Prehearing Brief at 13. Approved dispensing fees from neighboring state fees include Idaho ($11.51 to $15.11), Montana ($11.00 to $15.00) and Oregon ($9.68 to $14.01). With regard to other states, averages reside around $10. *See* Tr. at 366. The State also alleged that some states used dispensing fees to pay for unrelated items, such as disease management, and to offset ingredient costs. Washington indicated that because it did not use the

in its "informal questions" to the State, CMS asked for additional support that centered upon the actual cost to fill prescriptions beyond the previously submitted fee based studies to justify the State's proposed dispensing fee. The State reiterated that it was relying upon fee based studies and the demonstrated sufficiency of the rates to establish that the "aggregate ingredient cost and dispensing fee rates are sufficient to ensure that . . . providers are adequately reimbursed in accordance with the requirements of § 1902(a)(30)(A) of the Social Security Act."20

At the hearing, the State conceded that while it understood that CMS expected that the SPA package include support that centered upon the cost to fill a prescription,21 it declined to provide such material as it did not believe that it was legally required to do so.

> I concluded . . . that a cost study was not appropriate. We couldn't find the authority for it in the law, and we couldn't find the reasonableness of it in view of where money needs to go to other providers . . . . Later on . . . it became clear in a conversation that the only kind of study that would be accepted would be a study about cost, then it unfolded that there was a radically new interpretation of the dispensing fee requirement, that the reference to cost was to be all costs. The language in the dispensing fee in my personal history has always been limiting, that you're paying only for these things, and you can't -- this is permissive. You can include these elements, but this is all you can include.[22]

Regarding CMS' expectation to the actual dispensing fee level, Washington's witness recalled that CMS indicated that the State must increase their dispensing fees to between $10 and $15 and that CMS declined to provide such directive in writing.[23] In contrast, at the hearing, CMS clarified that it was not expecting states to "absolutely" increase their fees.[24] CMS also indicated that it did not expect a specific fee amount although it believed that "the average cost of dispensing a prescription is pretty uniform across the country" and should vary little depending on payor type.[25] CMS did, however, expect the State to submit a dispensing study to support the fee.[26] CMS, in responding to Washington's Interrogatories, had previously explained to Washington that the regulatory definition of dispensing fee "details the specific factors that States must take into consideration when determining the PDF."[27]

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dispensing fee in such manner, no adjustment to the dispensing fee was required. *See* CMS Exhibit 1 at 1467 (Davis Decl. ¶ 13).

[20] CMS Exhibit 1 at 0057, 0081-82.

[21] Tr. at 180, 205. The State witness added that it was unaware that a cost related study existed specific to the State of Washington and it would have been required to hire a contractor to conduct such a study. Tr. at 121-22. CMS indicated it would have accepted a cost related study from other states. *Id.* at 305-11.

[22] Tr. at 212-13.

[23] *Id.* at 215.

[24] *Id.* at 46.

[25] *Id.* at 299-305.

[26] *Id.* at 305-11.

[27] CMS Exhibit 13 at 19 (CMS' Response to Petitioner's First Interrogatories).

CMS later articulated its position as follows:

> While the comparison of [PDFs] among the contiguous States is not a determinative factor in approving or disapproving a SPA, such a comparison is informative to CMS in better evaluating the dispensing fee rates in a geographic area. This comparison is further amplified by the absence of any meaningful data to support Washington's dispensing fee within the revised regulatory scheme. Without adequate data from the Petitioner, CMS had no basis to understand why the State's tiered PDFs ($4.24, $4.56, and $5.25) were significantly lower in comparison to the dispensing fees in the neighboring States.[28]

Moreover, the record contains additional details on CMS' concerns as it reviewed Washington's proposed SPA. In CMS' responses to the State's Interrogatories, the CMS witness specified that:[29]

- During the SPA review, CMS examined Washington's proposed rates against other rates that had been established and approved in neighboring states to better understand the Medicaid rates within a common geographical area;
- Washington's rates were less than one-half the rates being paid in neighboring states, and the state did not provide adequate data to support that its 8-year old rates supported the current costs to dispense prescriptions;
- As a result, CMS could not be assured that Washington's proposed rates reflected the current pharmacists' cost to dispense a prescription, and with the reduction in payment to pharmacies for drug products . . . by moving to the NADAC without a change in the dispensing fee, [CMS could not be assured this] would ensure access to care and, thus, adequate quality of care;
- CMS could not be assured that Washington's low professional dispensing fees were sufficient to enlist or sustain enough pharmacy providers over time to provide care to Medicaid clients;
- Without any corresponding change in the professional dispensing fee, a drop in the state's reimbursement rate for branded drug products can have a significant financial impact on access to covered outpatient drugs, especially in rural areas that are dominant in Washington;

[28] CMS Prehearing Brief at 13-14. CMS testified that the Authority's dispensing fees being about one-half the amount of fees of other states, coupled with the lack of cost data, called into question the sufficiency of the proposed rates. *See* Tr. at 305-11; CMS Post-Hearing Brief at 12 (citing the Authority's Exhibit 16 at 170) & 16 (citing the Authority's Exhibit 14 at 6).

[29] CMS Post-Hearing Brief at 16-17 (quoting the Authority's Exhibit 14 at 6-7).

- If payment rates to pharmacies are too low, without adequate data or justification to support the low rates, then such payment rates would not be consistent with efficiency and economy as required by Section 1902(a)(30)(A); and
- Further, changes in reimbursement rates can have impacts on the ability of pharmacy providers to enlist or remain in the Medicaid program and deliver care to Medicaid clients.

The Authority submitted access review reports to bolster its argument that beneficiary access has not been an issue with regard to dispensing fees.[30] CMS explained that such reports are informative, but not determinative, of what CMS needs before it can approve a SPA. Beneficiary access is just one component to be considered in conjunction with § 1902(a)(30)(A) of the Act, and CMS argues that "[w]ithout an updated, adequately-supported rate, the state could not realistically measure beneficiary access at any one point in time, and certainly not before an adequately-supported rate has gone into effect[,]" and that "[i]t often takes time for pharmacy providers, who are not reimbursed adequately, to decide to leave the Medicaid program or to close their business."[31]

On September 10, 2018, CMS disapproved Washington SPA 17-0002.[32] In short, CMS noted that the regulation at 42 C.F.R. § 447.518(d) dictates that when a State proposes change to either the ingredient or dispensing reimbursement to pharmacies, it must consider both costs to ensure that "total reimbursement to the pharmacy provider is in accordance with section § 1902(a)(30)(A) of the Act." CMS also quoted the final rule, which states that "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."[33]

B. APPEAL REQUEST

On November 5, 2018, the State filed a request for reconsideration.[34] The State explained that it complied with the February 2016 final rule, which "required the State to examine both the ingredient cost and dispensing fee components when changing the rates for either of those components."[35] Regarding CMS' assertion that the State provided inadequate data to demonstrate compliance with § 1902(a)(30)(A), Washington noted that the February 2016 final rule did not change the long standing statutory language. Accordingly, although the State changed ingredient reimbursement, it believed it was not required to also increase dispensing rates.

Through a letter dated December 3, 2018 (published in the Federal Register at 83 Fed. Reg. 62869 (Dec. 6, 2018)), the CMS Administrator scheduled the subject hearing in response to the Authority's request for reconsideration.[36]

[30] CMS Exhibit 1 at 0090-0115, 0256-91; *see also* Tr. at 62-64, 84, 195-95.
[31] CMS Post-Hearing Brief at 18 (quoting the Authority's Exhibits 14 and 16).
[32] CMS Exhibit 1 at 0008-13 (CMS Disapproval Letter).
[33] *Id.* at 0012 (quoting 81 Fed. Reg. at 5201).
[34] *Id.* at 0005-07.
[35] *Id.* at 0006.
[36] *Id.* at 0001.

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 parties did not oppose the petition (although the State generally contested the amici portrayal of the issues and whether amici would contribute materially to the disposition of the issues). The Presiding Officer granted joint amici curiae status and permitted them to jointly file a brief and provide a statement at the hearing.

A hearing was held on June 18, 2019. William T. Stephens and Michael C. Bradley of the Washington State Office of the Attorney General represented Washington Health Care Authority. Janet L. Freeman of the Office of the General Counsel, Department of Health and Human Services, represented CMS at the hearing. Brenda D. Thew attended on the panel with the undersigned.

VI. DISCUSSION: FINDING OF FACTS AND CONCLUSIONS OF LAW

A. ISSUE 1 ANALYSIS

The first issue presented is:

> Whether Washington SPA 17-0002 is inconsistent with the requirements of § 1902(a)(30)(A) 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 Presiding Officer finds the State did not demonstrate that the SPA meets the requirements of § 1902(a)(30) of the Act. As the State did not comply with CMS' request to provide information regarding the actual cost to dispense prescriptions, it did not properly provide CMS with the requisite assurance that its payments are adequate pursuant to SSA § 1915(f)(2) and 42 C.F.R. § 430.16. CMS' explanation that it was unable to ascertain whether the overall payment rates were consistent with efficiency, economy, and quality of care was reasonable.

Section 1915(f)(2) of the Act and 42 C.F.R. § 430.16 grant CMS the authority to request additional information from a State so that ultimately CMS may ensure that a proposed SPA meets Federal requirements. 42 C.F.R. §§ 430.12(c) and 430.15.[37] While the State concedes that it understood CMS requested supporting documentation relating to dispensing costs, the State nevertheless elected to rely upon its documentation relating to pharmacy fees.[38]

In summary, the State justifies its refusal to provide cost information by insisting that its fee based studies establish that the aggregate ingredient cost and dispensing fee rates are sufficient to ensure providers are adequately reimbursed in accordance with the requirements of § 1902(a)(30)(A).

[37] In fact, CMS is required to make a timely decision to either approve or deny the SPA after receiving the requisite information. *See* 42 C.F.R. § 430.16(a).
[38] *See, e.g.*, Tr. 121-22, 180.

The State explains that the fee studies are evidence regarding what commercial payers or pharmacies might accept in the Medicare program, and that access was not impacted.[39] The State also represents that while it did not provide the requested dispensing information, it internally considered dispensing fee levels in its evaluation of the aggregate payment level.[40]

Regardless of whether a State intends to change the dispensing fees, the PDF data is a relevant and important factor in establishing payment rates. The 1902(a)(30) criteria in isolation is not the only controlling authority which a State must meet and for which it is obligated to provide documentation. First, as noted above, CMS has a clear legal right to request information from the States under § 1915(f)(2) of the Act. The regulation at 42 C.F.R. § 430.10 indicates that a State plan must contain **all** necessary information and assurances for CMS to evaluate the plan. The regulation at 42 C.F.R. § 430.12(c) dictates that "[p]rompt submittal of amendments is necessary so that CMS can determine whether the plan continues to meet the requirements for approval." The regulation at 42 C.F.R. § 430.16 provides that CMS may ask for additional information and it imposes time limits on CMS to take action after receiving the information. In this case, while CMS asked for cost based studies to support the PDF, the State determined that it was unnecessary to provide the dispensing cost materials that CMS requested. Instead, the State relied upon a fee based study. As the State did not provide the requested information for CMS to evaluate the fees presented in the SPA, it did not properly provide CMS with the requisite assurance that its payments are adequate in accordance with § 1915(f)(2) of the Act and 42 C.F.R. § 430.16.[41] Accordingly, CMS' disapproval of the SPA was appropriate.

The Presiding Officer notes that the statute and regulations do not permit States to unilaterally determine that responding to a specific CMS request is unnecessary. Nevertheless, the Presiding Officer also finds that CMS' request that Washington provide a dispensing cost study[42] is most reasonable. For example, 42 C.F.R. § 447.512 provides the following instruction relating to establishing sufficient payment levels, noting that the PDF must be considered:

> (b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 must not exceed, in the aggregate,

[39] *See* Washington Post-Hearing Brief at 8.

[40] *Id.* at 5-6; Tr. at 118-19, 192.

[41] Moreover, with regards to prescription drug reimbursement, the regulation at 42 C.F.R. § 447.518 specifies that States evaluate and support proposed changes for prescription drug payments, must make satisfactory "assurances" to CMS, and make available "upon request" pertinent records and information to support the finding and assurances.

> (a) *State plan.*
> (1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs . . . .
>
> . . . .
>
> (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.

[42] *See, e.g.*, Tr. at 88-89.

> payment levels that the agency has determined by applying the lower of the following:
>
> (1) AAC plus a **professional dispensing fee** established by the agency; or
> (2) Providers' usual and customary charges to the general public.

(Emphasis added.)

Likewise, given that the PDF definition found at 42 C.F.R. § 447.502 includes very specific elements regarding the reasonable costs associated with a pharmacist's time, it follows that States should expect that CMS would require PDF information to evaluate a change to aggregate rates.

The State also argues that CMS was arbitrary and capricious for requesting data as it alleges that CMS "knew" that that the fee should not be $4-5, but rather be $10-$11.[43] Additionally, the State alleges that CMS violated the Administrative Procedure Act ("APA") by applying standards that were outside of the rulemaking process. It contends that Washington's SPA was effective since 2009 and CMS did not previously raise that the State's methodology or the level of fees violated § 1902(a)(30)(A) of the Act. The statute has remained unchanged since 2009 and CMS' 2016 rulemaking did not substantively change the dispensing fee definition. Accordingly, the State argues that if the SPA complied in terms of the dispensing fee level in 2009, it remains compliant in 2019. CMS did not give notice and comment about its brand new interpretation of § 1902(a)(30)(A) and its own rules.[44] Similarly, the State argues that CMS violated *Allina*[45] for an alleged failure to follow notice and comment rulemaking as the State believes that CMS now expects States to increase their dispensing fees.[46]

The Presiding Officer finds that because the State failed to provide the required documentation to CMS, the State's allegations regarding whether CMS' actions were arbitrary and capricious or violated the APA in light of *Allina* are moot. 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 complies with Federal requirements and the issues specified in the hearing notice. 42 C.F.R. §§ 430.60 and 430.70.[47]

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[43] Washington Post-Hearing Brief at 8-9.

[44] *Id.* at 10-13.

[45] *Azar v. Allina Health Servs.*, 587 U.S. ___, 139 S. Ct. 1804 (2019). Washington Post-Hearing Brief at 12; Tr. at 18-19, 37-39.

[46] The Hearing Officer notes that CMS indicated it was not looking for a specific amount (Tr. at 299-305), but that the State did not provide sufficient PDF documentation for evaluation.

[47] Nevertheless, as far as the State's factual representations, CMS clarified that the $4-$5 PDFs were in such contrast to other states that it raised questions. CMS also indicated that it was willing to consider these PDFs once it received reliable data that would allow CMS to properly evaluate their reasonableness. The controlling authorities have always supported the right for CMS to request any information it needs to evaluate any aspect of a SPA, including dispensing fees. Finally, CMS continues that the February 2016 final rule was intended to reinforce that when State Medicaid agencies adjust their payment for ingredient cost throughout the implementation period, CMS requires they also concurrently re-evaluate the professional dispensing fee. In short, the Presiding Officer agrees with CMS that "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 methodology . . . and the submission to CMS of adequate data to support the proposed reimbursement methodology." CMS Prehearing Brief at 14.

B. ISSUE 2 ANALYSIS

The second issue presented is:

> Whether Washington SPA 17-0002 is inconsistent with the requirements of 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 AAC and a PDF.

As the State did not demonstrate that the SPA meets the requirements of § 1902(a)(30) of the Act, the SPA, as a whole, is not approvable. Additionally, incorporating the same rationale in the Issue 1 Analysis section above, as the State did not comply with CMS' request to provide information regarding the actual cost to dispense prescriptions, it did not properly provide CMS with the information needed to ensure that the SPA meets the requirements of 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 AAC and a PDF. Section 1915(f)(2) of the Act and 42 C.F.R. § 430.16.

VII. PROPOSED DECISION

CMS' disapproval of SPA 17-0002 is upheld. The State did not demonstrate that the SPA meets the requirements § 1902(a)(30)(A) of the Social Security Act and the regulations at 42 C.F.R. §§ 447.502, 447.512 and 447.518.

Benjamin R. Cohen, Esq.
Presiding Officer

Dated: July 31, 2020