Date of Hearing: March 30, 2017
Time of Hearing: 1:00 PM
Calendar: Ex Parte

IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON

FOR THE COUNTY OF THURSTON

NATIONAL ASSOCIATION OF CHAIN DRUG STORES; WASHINGTON STATE PHARMACY ASSOCIATION; NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, Petitioners, vs. WASHINGTON STATE HEALTH CARE AUTHORITY; Dorothy Frost Teeter, not individually, but solely in her official capacity as Director of the WASHINGTON STATE HEALTH CARE AUTHORITY, Respondents.	No. 17-2-01489-34 [Clerk's Action Required] EMERGENCY MOTION FOR STAY

I. INTRODUCTION AND RELIEF REQUESTED

In less than 48 hours, Washington's Medicaid program will implement a new rule that unlawfully and significantly reduces the reimbursement it pays to pharmacies that serve the State's most vulnerable residents. Federal law requires the Washington Medicaid program to establish reimbursement rates that cover both pharmacies' costs to purchase prescription drugs ("ingredient cost reimbursement") and pharmacies' costs associated with dispensing those drugs to Medicaid patients ("professional dispensing fee"). States are not permitted to change ingredient cost reimbursement unless they simultaneously provide adequate data to ensure that the professional dispensing fee is sufficient to cover pharmacies' costs of providing medications

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to Medicaid patients. The purpose of these federal requirements is to ensure that pharmacies are able to participate in the Medicaid program and provide quality care to Medicaid patients. Nevertheless, Washington State's new rule decreases pharmacies' ingredient cost reimbursement without also increasing their professional dispensing fee to an amount that covers pharmacies' costs of dispensing drugs to Medicaid patients. As a result, total reimbursement to pharmacies will be more than $12 million below pharmacies' costs each year, threatening pharmacies' ability to participate in the Medicaid program. This Emergency Motion seeks to maintain the status quo by staying implementation of the new rule until such time that Petitioners' declaratory claims in its Petition can be considered on its merits.

The State's new rule is both substantively and procedurally flawed. First, it should be stayed because the State has exceeded its statutory authority by adopting an arbitrary and capricious rule that violates federal law. Second, it should be stayed because the State failed to follow the clear procedural directives that apply when amending a rule.

Washington's current dispensing fee ranges between $4.24 and $5.25 per drug that is dispensed. Last year, the federal government issued a new regulation requiring States to significantly change the way pharmacies are reimbursed in the federally-funded Medicaid program. This new federal regulation shifts Medicaid to *cost-based* reimbursement for pharmacies. As part of this change, each State Medicaid program must now establish a new "professional dispensing fee" that is sufficient to cover a pharmacy's overhead and other costs of dispensing drugs.

In response, Washington State issued Rule-Making Order WSR 17-07-001 (the "New Rule") that purports to comply with this federal regulation.[1] The New Rule amends the Medicaid reimbursement rate methodology for pharmacies as of April 1, 2017 by cutting the ingredient cost reimbursement paid to pharmacies by $6.4 million each year. In contravention of federal requirements, however, the State notified all pharmacies that it will not change the current

[1] *See* Declaration of Virginia Nicholson ("Nicholson Decl."), Ex. 4; *infra* fn **Error! Bookmark not defined.**.

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dispensing fees, which have not been updated since at least 2009,[2] even though those fees are woefully inadequate to cover pharmacies' costs of dispensing drugs to Medicaid patients. Moreover, the State notified pharmacies that the dispensing fee would not increase via a cursory e-mail sent *after* the comment period had concluded and *after* the State had adopted the New Rule, in violation of state law.

Petitioners seek to maintain the status quo and request an immediate stay of the New Rule pending the outcome on the merits of Petitioners' declaratory judgment action. The State has exceeded its statutory authority by adopting an arbitrary and capricious rule that conflicts with federal law. Moreover, the New Rule was adopted in violation of statutory rule-making procedures. Unless and until (i) the State increases the professional dispensing fee to cover the cost of dispensing, and (ii) provides adequate notice to allow for meaningful comment, the New Rule is unlawful and must be stayed. Petitioners do not ask the Court to order the State to pay pharmacies enough to make a profit. This Motion seeks to halt further reimbursement cuts until such time as the State properly implements Medicaid reimbursement rates that cover the actual costs that pharmacies incur when serving Medicaid patients, as required by law.

II. FACTS

A. Background on Petitioners

Petitioners are non-profit associations whose members include the many Washington pharmacies serving Medicaid patients that will be injured by the New Rule. The National Association of Chain Drug Stores ("NACDS") represents drug stores, supermarkets, and mass merchants with pharmacies. NACDS' members operate over 40,000 pharmacies and include regional chains and national companies. In Washington, NACDS' members operate 932 pharmacies and employ 72,000 people. The Washington State Pharmacy Association ("WSPA") represents pharmacists, technicians, and interns practicing within community pharmacies,

[2] Health and Recovery Services Administration (HRSA), *Prescription Drug Program: Billing Instructions*, Washington State Health Care Authority (October 20, 2008), https://www.hca.wa.gov/assets/billers-and-providers/prescription_drug_program_bi_01012010-05082010.pdf [hereinafter "Drug Billing Guide"].

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clinics, nursing homes, and hospitals. WSPA members provide care to Medicaid patients throughout Washington's urban, rural and underserved communities. The National Community Pharmacists Association ("NCPA") represents the pharmacist owners, managers, and employees of more than 22,000 independent community pharmacies nation-wide. In Washington, NCPA members operate 325 stores and dispense in excess of 3,000,000 prescriptions per year to Medicaid patients.

Collectively, Petitioners are the foremost stakeholders with regard to any proposed changes to the Medicaid reimbursement methodology in Washington. Each of the Petitioners have members that participate in the State's Medicaid program that will be injured by the April 1st reimbursement cut; therefore, each of the Petitioners have associational standing to bring this action on behalf of their members. RCW § 34.05.530; *Int'l Ass'n of Firefighters, Local 1789 v. Spokane Airports*, 146 Wn.2d 207, 213–14, 50 P.3d 618 (2002) *amended on denial of reconsideration, citing Hunt v. Wash. State Apple Adver. Comm'n,* 432 U.S. 333, 343 (1977) ("An association has standing to bring suit on behalf of its members when: (1) the members of the organization would otherwise have standing to sue in their own right; (2) the interests that the organization seeks to protect are germane to its purpose; and (3) neither claim asserted nor relief requested requires the participation of the organization's individual members.").

B. Background on the State's Medicaid Program

Medicaid is a joint federal and state program that provides health care to indigent and otherwise disadvantaged Washington citizens. Washington, like other states, administers its own Medicaid program, and the Washington Supreme Court has determined that "[a]s a voluntary participant in the federal Medicaid program, Washington State must comply with Medicaid statutes and related regulations." *Samantha A. v. Dep't of Soc. & Health Servs.*, 171 Wn.2d 623, 630, 256 P.3d 1138 (2011).

The State's Health Care Authority ("HCA") develops and administers the Medicaid programs in Washington State. RCW §§ 74.04.050, 74.09.500. The Washington Medicaid Plan

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is HCA's official written statement that describes the nature and scope of the State Medicaid program and gives assurances that HCA will administer the State Plan in conformity with the requirements of the Social Security Act. 42 C.F.R. § 447.518(a). In particular, Washington's Medicaid program must comply with Section 1902(a)(30)(A) of the Social Security Act, which provides, in relevant part:

> A State plan for medical assistance 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.

42 U.S.C.§ 1396a(30)(A).

Medicaid reimbursement to pharmacies includes two basic components: (1) "ingredient cost" reimbursement to pay for the drug; and (2) a "dispensing fee" to cover the costs of dispensing. 77 Fed. Reg. 5318, 5326 (2012). Washington's current regulatory standards regarding Medicaid reimbursement are codified at WAC 182-530-1000, *et seq.* (the "Current Rule"). Under the Current Rule, Washington's ingredient cost reimbursement is based on pharmacies' "estimated acquisition cost" to purchase drugs that are dispensed to Medicaid patients. *See* WAC 182-530-7000; WAC 182-530-8000. In addition, pursuant to the Current Rule, dispensing fees ranging from $4.24 to $5.25 have been in effect since at least 2009.[3] *See also* WAC 182-530-1050; WAC 182-530-7050.

C. CMS Rule

In February 2016, the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS") promulgated a new regulation that significantly changes the way States reimburse pharmacies. *See* 81 Fed. Reg. 5170 (2016) (the "CMS Rule"). The CMS Rule requires states to adopt reimbursement rates that cover the costs incurred by

[3] Drug Billing Guide at p. 83; Medicaid Covered Outpatient Drug Reimbursement Information by State (2016), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf, at 9 [hereinafter "Drug Reimbursement Chart"].

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pharmacies as they purchase and dispense drugs to Medicaid patients. *Id.* at 5291. With regard to ingredient cost reimbursement, the CMS Rule requires States to move from reimbursement based on "estimated acquisition cost" to "actual acquisition cost" ("AAC"). 42 C.F.R. §§ 447.502 (definition of actual acquisition cost), 447.512(b), 447.518(a)(2). The CMS Rule further requires each State Medicaid Agency to establish a new "professional dispensing fee" that is sufficient to cover a long list of specified "pharmacy costs" associated with operating pharmacies and employing pharmacists. 42 C.F.R. §§ 447.502 (definition of professional dispensing fee), 447.512(b), 447.514(b)(1). The CMS Rule requires States to issue findings and assurances that their ingredient cost reimbursement is sufficient to cover pharmacy costs to purchase drugs, and their new "professional dispensing fee" is sufficient to cover pharmacy costs associated with dispensing drugs to Medicaid patients. 42 C.F.R. § 447.518(b).

The CMS Rule further provides that States are required to "consider **both** the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes" and to "**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 … the components of the reimbursement methodology." 42 C.F.R. § 447.518(d) (emphasis added).

D. State Study of the Pharmacy Chain of Supply

On June 9, 2016, the Washington legislature passed 5ESSB 5857, which required the Washington Office of the Insurance Commissioner ("OIC") to conduct a Study of the Pharmacy Chain of Supply ("OIC Study"). Nicholson Decl., Ex. 1. Pursuant to the legislature's directive, OIC made the following findings, as relevant to this action:

> In adopting the [actual acquisition cost] 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. CMS views inadequate reimbursement as a possible violation of federal statute that requires states to reimburse providers in a manner that is sufficient to ensure provider participation and beneficiary access. **Accordingly, the states that have adopted the [actual acquisition cost] reimbursement for ingredient cost have performed cost of dispensing surveys and currently have dispensing fees**

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that are generally in excess of $10 per prescription.

*Id***.** at p. 33 (emphasis added).

E. Changes to Current Rule and Inadequate Email Notice

On June 29, 2016, the State filed Preproposal Statement of Inquiry WSR 16-14-053 in the Washington State Register. Nicholson Decl., Ex. 2. On January 4, 2017, the State published notice of its Proposed Rule-Making Order WSR 17-02-083 in the Code Reviser. Nicholson Decl., Ex. 3. The Order identified February 7, 2017 as both the date for the public hearing and the deadline to submit written comments on the New Rule. *Id.* at p. 1. On March 1, 2017, the State filed Permanent Rule-Making Order WSR 17-07-001. Nicholson Decl., Ex. 4. The New Rule states that it is revising WAC Chapter 182-530 "to align with [CMS'] new covered outpatient drug rule, CMS-2345-FC." *Id.* at p. 1.

The New Rule makes major changes to Medicaid reimbursement for pharmacies by replacing drug ingredient cost reimbursement based on "estimated acquisition cost" with drug ingredient cost reimbursement based on "actual acquisition cost (AAC)." *Id.* at pp. 17-18; WAC 182-530-1050; WAC 182-530-7000.

In addition, the New Rule changes the standards for dispensing fees paid to pharmacies. Prior to amendment in the New Rule, the term "dispensing fee" was defined as:

> The fee the Medicaid agency or its designee sets to pay pharmacy providers for dispensing agency covered prescriptions. The fee is the agency's maximum reimbursement for expenses involved in the practice of pharmacy and is in addition to the agency's reimbursement for the costs of covered ingredients.

Id. at p. 6. However, the New Rule provides that the term "dispensing fee" now "means professional dispensing fee," which is defined as:

> (1) The fee the medicaid agency . . . pays pharmacists . . . for covered prescriptions. The fee pays for costs in excess of the ingredient cost of a covered outpatient drug when a covered outpatient drug is dispensed; and
>
> (2) Includes only costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a medicaid beneficiary. Pharmacy and dispensing provider costs include, but are not limited to, reasonable costs associated with a prescriber's time in checking

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> 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 dispensing entity.

Id. at p. 6; 10-11 amending WAC 182-530-1050. Note, however, that although the New Rule adopts a definition of professional dispensing fee that purports to comply with the CMS Rule, the New Rule leaves in place as part of its dispensing fee calculation factors that have nothing to do with pharmacies' cost of dispensing. *Id.; see also* discussion at 16, *infra.*

On or about March 2, 2017, the State sent written notice to all pharmacies announcing that the changes made to ingredient cost reimbursement under the New Rule would be effective on April 1, 2017. Nicholson Decl., Ex. 5. Additionally, HCA for the *first time* officially notified all pharmacies that "**[d]ispensing fees are unaffected by this change**." *Id.* (emphasis added). The State cited no basis for this decision to leave in place the old below-cost dispensing fees. Because the comment period closed on February 7, 2017, Petitioners were unable to submit comments on the State's failure to increase the professional dispensing fee to cover the cost of dispensing drugs to Medicaid patients. *See* Nicholson Decl., Ex. 3 at p. 1.

On March 17, 2017—after formally adopting the New Rule—the State prepared a "Concise Explanatory Statement" ("CES"). Nicholson Decl., Ex. 6; RCW § 34.05.325(6)(a) ("Before it files an adopted rule with the code reviser, an agency shall prepare a concise explanatory statement of the rule…[s]ummarizing all comments received regarding the proposed rule, and responding to the comments by category or subject matter, indicating how the final rule reflects agency consideration of the comments, or why it fails to do so."). The CES outlines and responds to ten comments on the New Rule; however, it does not address the adequacy or amount of professional dispensing fees, undoubtedly because the State did not notify pharmacies until after the comment period had ended. *See* Nicholson Decl., Ex. 6 at pp. 2-6. On April 1,

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2017, the New Rule becomes effective. *See* Nicholson Decl., Ex. 4.

F. The New Rule Injures the Petitioners' Member Pharmacies

By adopting "actual acquisition cost (AAC)" as the basis for ingredient cost reimbursement, the New Rule reduces Medicaid reimbursement to pharmacies by $6.4 million each year. *See* Declaration of Dr. Laura Miller ("Miller Decl.") at ¶¶ 19, 35. Combined with the State's failure to increase dispensing fees to cover the cost of dispensing, "the proposed reimbursement formula will compensate pharmacies $12.38 million **below** actual cost." *See id.* at ¶¶ 36, 38. In fact, even the State's own study found that by decreasing the amount of reimbursements for ingredient costs while failing to increase professional dispensing fees, pharmacies will be injured by receiving diminished total reimbursements that result in pharmacies operating at net losses when providing Medicaid services. *See* Nicholson Decl., Ex. 1 at p. 30 ("According to cost to dispense surveys performed by various states and pharmacy organizations, the actual cost to dispense a prescription is in excess of $10. Washington pharmacies indicated … dispensing costs were [between] $13 to $16.").

III. ARGUMENT

A. Legal Standard

The Administrative Procedure Act ("APA"), RCW § 34.05, *et seq.*, provides that the validity of a rule may be reviewed at any time by petition for declaratory judgment when it appears that the threatened application of a rule immediately threatens to interfere with or impair the petitioner's legal rights or privileges. RCW § 34.05.570; *see also Washington Indep. Telcomms. Ass'n v. Washington Utils. & Transp. Comm'n*, 148 Wn.2d 887, 906, 64 P.3d 606 (2003) ("the validity of a rule is determined as of the time the agency took the action adopting the rule"). The declaratory judgment order may be entered whether or not the petitioner has first requested the agency to pass upon the validity of the rule in question. RCW § 34.05.570(2). Furthermore, the petitioner need not have participated in the rule-making proceeding upon which the rule is based, have petitioned for its amendment or repeal, have petitioned the joint

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administrative rules committee for its review, or have appealed a petition for amendment or repeal to the governor. RCW § 34.05.534(1). In short, the APA does not require that Petitioners first exhaust administrative remedies prior to seeking invalidation of the New Rule in court.

After a petition for judicial review has been filed, a party may file a motion in the reviewing court seeking a stay or other temporary remedy. RCW § 34.05.550(2).[4] The court's determination of whether to grant a stay under the APA is reviewed under an abuse of discretion standard. *McKinlay v. Dep't of Social & Health Servs.*, 51 Wn. App. 491, 497, 754 P.2d 143 (1988). Discretion is abused if the decision is based upon untenable grounds or the decision is manifestly unreasonable or arbitrary. *Washington Fed'n of State Employees v. State*, 99 Wn.2d 878, 888, 665 P.2d 1337 (1983).

B. The New Rule Should Be Stayed Pending the Outcome on the Merits of Petitioners' Declaratory Judgment Action because it is Invalid.

The APA provides that a court must declare a rule invalid if it finds that: (1) the rule exceeds the statutory authority of the agency; (2) the rule is arbitrary and capricious; or (3) the rule was adopted without compliance with statutory rule-making procedures. RCW § 34.05.570(2)(c). The party challenging a rule bears the burden of proof. RCW § 34.05.570(1)(a); *Wash. Pub. Ports Ass'n v. Dep't of Revenue*, 148 Wn.2d 637, 645, 62 P.3d 462 (2003). The validity of an administrative agency rule is a question of law that is reviewed *de novo*. *Ass'n of Washington Business v. Dep't of Revenue*, 155 Wn. 2d 430, 120 P.3d 46 (2005). Under this standard, a court is authorized to substitute its judgment for that of the administrative body. *Ames*

[4] Washington's APA contains specific standards for authorizing courts to grant a stay of agency action, RCW § 34.05.550(2), as well as standards authorizing courts to review an agency's grant or denial of a stay or other temporary remedy based upon public health, safety, or welfare grounds, RCW § 34.05.550(3). Washington's APA (RCW Chapter 34.05) is based upon the Uniform Law Commissioners' Model State Administrative Procedure Act (1981) ("Model Act"). In RCW § 34.05.001, the Washington legislature expressly directs the courts to interpret provisions of Washington's APA consistently with decisions of other courts interpreting similar provisions of model acts. RCW § 34.05.550(3) is based upon Model Act section 5-111(c), which makes clear that RCW 34.50.330(3) applies to a court's analysis of whether to alter a stay that has been imposed by the agency itself. In the instant matter, no such stay or other temporary remedy has been imposed by HCA. Accordingly, the criteria of RCW 34.05.550(3) do not apply.

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v. Wash. State Health Dep't Med. Quality Health Assurance Comm'n, 166 Wn. 2d 255, 260-61, 208 P.3d 549 (2009).

The New Rule should be stayed pending the outcome on the merits of Petitioners' declaratory judgment action because it exceeds HCA's statutory authority, is arbitrary and capricious, and was adopted without complying with statutory rule-making procedures.

1. The New Rule is Invalid because it Exceeds HCA's Authority.

Administrative "[r]ules must be written within the framework and policy of the applicable statutes," *Dep't of Labor & Indus. v. Gongyin*, 154 Wn.2d 38, 50, 109 P.3d 816 (2005), and so long as the rule is "reasonably consistent with the controlling statute[s]," an agency does not exceed its statutory authority. *Wash. Pub. Ports Ass'n*, 148 Wn.2d at 646. However, "[a]dministrative rules or regulations cannot amend or change legislative enactments;" *Dep't of Ecology v. Campbell & Gwinn, LLC*, 146 Wn. 2d 1, 19, 43 P.3d 4 (2002), thus, rules that are not consistent with the statutes that they implement are invalid. *Bostain v. Food Express, Inc.*, 159 Wn.2d 700, 715, 153 P.3d 846 (2007). Courts review an agency interpretation of federal law *de novo* under an "error of law" standard. *Skamania County v. Columbia River Gorge Comm'n*, 144 Wn.2d 30, 42, 26 P.3d 241 (2001).

a. The New Rule Fails to Reassess and Increase the Dispensing Fee in Contravention of Federal Standards.

As discussed, *supra*, the CMS Rule provides that State Medicaid programs must establish a "professional dispensing fee" that reimburses pharmacies for a list of costs associated with dispensing prescription medications to Medicaid patients. 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1); *see also* Miller Decl., ¶¶ 20-25 (detailing categories of costs impacting pharmacy cost of dispensing). The CMS Rule also requires States to issue findings and assurances that their ingredient cost reimbursement is sufficient to cover the cost of purchasing drugs, and their new professional dispensing fee is sufficient to cover pharmacy costs associated with dispensing those drugs to Medicaid patients. 42 C.F.R. § 447.518(b). Throughout the CMS

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Rule, CMS repeatedly emphasizes that each State Medicaid Agency's professional dispensing fee must be sufficient to cover pharmacies' costs of dispensing drugs to Medicaid patients:

- Our proposal to revise the term dispensing fee to professional dispensing fee is designed to reinforce our position that the dispensing fee should reflect the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary. 81 Fed. Reg. at p. 5201.

- States should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate [drug] is transferred to a Medicaid beneficiary. *Id.* at p, 5294.

- [T]he total reimbursement should consider not only the pharmacy's cost to acquire the drug, but also the pharmacist's professional services in dispensing the drug … . [S]tates are in the best position to establish fees based on data reflective of the cost of dispensing drugs in their state. *Id.* at pp. 5310-11.

- In accordance with the definition of professional dispensing fee that we are finalizing at § 447.502 … states should calculate their professional dispensing fees to include those costs which are associated with ensuring that possession of the appropriate [drug] is transferred to a Medicaid beneficiary. *Id.* at p. 5338.

Importantly, the CMS Rule also requires States to implement this new professional dispensing fee at the same time they change the ingredient cost reimbursement:

- [S]tates must review their current professional dispensing fee whenever they propose to change their reimbursement methodology. …[W]hen 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. *Id.* at p. 5201.

- Many commenters commended our recognition that reimbursement for drug ingredient cost and professional dispensing fee must be adjusted in tandem. *Id.* at p. 5338.

- [S]tates are required to reconsider their professional dispensing fee in light of the revised requirement to reimburse at [actual acquisition cost].

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Id. at p. 5342.

As a result, the CMS Rule provides, in relevant part, that "[w]hen 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 [subpart d] …" 42 C.F.R. § 447.518(d). Subpart (d) requires States to consider *both* the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of Section 1902(a)(30)(A) of the [Social Security] Act." *Id.* (emphasis added). Section 1902(a)(30)(A) provides, in relevant part, that a "State plan for medical assistance 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 …" 42 U.S.C. § 1396a(a)(30)(A). Throughout the CMS Rule, CMS repeatedly links compliance with Section 1902(a)(30)(A) of the Social Security Act to the requirement that professional dispensing fees must cover pharmacies' cost of dispensing:

> - Payment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act, and we believe the total reimbursement should take into account the pharmacy's cost to acquire the drug and the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary. … [A]fter evaluating all the 'pharmacy costs' listed in the definition of professional dispensing fee, '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,' which will 'allow states to establish sufficient fees to cover costs and ensure adequate participation.' 81 Fed. Reg. at p. 5291.
>
> - Reimbursing providers based on the ingredient cost representative of the cost of the drug alone and a dispensing fee representative of the cost to dispense the drug to the patient is in keeping with section 1902(a)(30)(A) of the Act. … In accordance with section 1902(a)(30)(A) of the Act, a state must establish payments that are consistent with efficiency, economy and quality of care and are sufficient to enlist enough providers

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> so that care and services are available. Thus, it is the responsibility of individual states to develop methodologies that ensure that pharmacy providers, including 340B entities, are reimbursed adequately for their provision of pharmacy services which include dispensing [drugs]. *Id.* at p. 5318.
>
> - [P]ayment to Medicaid pharmacy providers must be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, consistent with section 1902(a)(30)(A) of the Act, and we believe the total reimbursement should take into account the pharmacy's cost to acquire the drug and the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary. *Id.* at p. 5339.

States are also required to 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." 42 C.F.R. § 447.518(d). As CMS explains, "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." 81 Fed. Reg. at p. 5201 (emphasis added).

Here, the New Rule adopts actual acquisition cost as the basis for drug ingredient cost reimbursement. *See* WAC 182-530-7000(3)(a). This change reduces drug ingredient cost reimbursement to pharmacies by $6.4 million each year. *See* Miller Decl., ¶¶ 19, 35. The CMS Rule clearly required HCA to establish new professional dispensing fees at the same time it adjusted ingredient cost reimbursement in the New Rule. HCA did not properly consider, as required under the CMS Rule discussed above, whether the professional dispensing fee should have been increased to cover the cost of dispensing when it changed the ingredient cost reimbursement.

The aforementioned lack of consideration is patently obvious because if HCA had conducted a cost of dispensing study, reviewed the OIC Study, or utilized any of the cost of dispensing studies developed by other States or other entities, it would have established

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professional dispensing fees significantly higher than $4.24-$5.25. *See* Miller Decl., ¶ 28. ("Generally, most cost of dispensing studies in the past ten years have found a cost of dispensing between $8 and $14. The average over all studies is approximately $11.20.") ; *see also id*. ¶¶ 26-27 (reviewing numerous cost of dispensing studies which all conclude that the cost of dispensing is significantly higher than Washington's dispensing fees). Notably, the State's own report, which HCA purportedly relied upon, acknowledges that "the states 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." Nicholson Decl., Ex. 1 at p. 33. In fact, there is not one state that has adopted actual acquisition cost reimbursement for ingredient costs that has a professional dispensing fee anywhere nearly as low as those adopted by HCA.[5] According to data provided by CMS for the quarter ending December 2016, the state with the lowest professional dispensing fee that also adopted actual acquisition cost reimbursement is Colorado, which provides a $9.31 professional dispensing fee on the low end of its tiered reimbursement range.[6]

Additionally, the CMS Rule requires States to "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." 42 C.F.R. § 447.518(d). To date, HCA has not provided any data to support its position that cutting the reimbursement rate for ingredient costs without increasing the professional dispensing fee complies with the CMS Rule's requirement that total reimbursement to pharmacies covers costs in accordance with requirements of the Social Security Act. Nor could it, as all of the data available to HCA at the time it promulgated the New Rule plainly indicates that its professional dispensing fee of $4.24-$5.25 is woefully inadequate to cover such costs, and when coupled with the reduced ingredient cost reimbursement rates results in providers operating at a net loss. *See*

[5] Drug Reimbursement Chart, *supra* note 3.

[6] *Id.* at 2.

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Miller Decl., ¶¶ 34-39; Nicholson Decl., Ex. 1 at pp. 30, 33.

Moreover, even assuming that HCA actually relied on a cost of dispensing study to support its professional dispensing fee reimbursement rates of $4.24-$5.25, the overwhelming data to the contrary indicates that such a study is an outlier at best or contained cherry-picked statistics at worst. In either event, such reliance was erroneous, resulting in professional dispensing fees that are significantly lower than what is required to cover costs incurred to provide drugs to Medicaid patients. *See* 42 C.F.R. § 447.502 (definition of "professional dispensing fee").

As such, HCA exceeded its statutory authority by promulgating a rule that conflicts with the CMS Rule and the Social Security Act provisions that the CMS Rule implements. *See Jenkins v. Washington State Dep't of Soc. & Health Servs.*, 160 Wn. 2d 287, 291, 157 P.3d 388 (2007) (holding that DSHS exceeded its statutory authority by promulgating a rule that conflicts with federal Medicaid comparability requirements under 42 U.S.C. § 1396); *Samantha A.*, 171 Wn.2d at 638 (same); *see also Whidbey Island Manor, Inc. v. Dep't of Soc. & Health Servs.*, 56 Wn. App. 245, 257, 783 P.2d 109 (1989) (holding that DSHS was required to utilize federal regulations in calculating amount of Medicaid reimbursement for provider of nursing home services); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes."). Accordingly, the Court should immediately stay implementation of the New Rule pending a resolution on the merits.

b. <u>The New Rule Improperly Allows Consideration of Dispensing Fees Paid by Other Third-Party Payers in Violation of the CMS Rule.</u>

The CMS Rule requires States to "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." 42 C.F.R. § 447.518(b), (d). Despite repeated requirements that professional dispensing fees must be based on pharmacies' cost of dispensing medications, the New Rule bases dispensing fees in part

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on factors that are unrelated to pharmacies' cost of dispensing. The New Rule provides that HCA may adjust pharmacy dispensing fees based on factors such as "legislative appropriations for vendor rates" and "dispensing fees paid by other third-party payers including, but not limited to, health care plans …" WAC 182-530-7050(3)(a), (d).

There is no evidence suggesting that health plan reimbursement rates or legislative appropriations reflect the costs that should be included in professional dispensing fees under the CMS Rule. Unlike State Medicaid programs, health plans are not legally required to reimburse pharmacies for costs of dispensing. In fact, the State's own report found that dispensing fees paid by health plans are *not* sufficient to cover the costs incurred by pharmacies:

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

Nicholson Decl., Ex. 1 at p. 30 (footnotes omitted); *see also id.* at pp. 60, 69 (citing $11.65 average actual cost to dispense for Washington pharmacies). Dispensing fees paid by health plans clearly do not reflect pharmacy costs, as plans are able to offset their below-cost dispensing fees with above-cost ingredient cost reimbursement,[7] whereas under the CMS Rule, State Medicaid programs must set both their professional dispensing fees and their ingredient cost reimbursement based on pharmacy costs. WAC 182-530-7050(d) conflicts with the CMS Rule in that it allows the State to set Medicaid professional dispensing fees based on factors other than pharmacies' cost of dispensing. As such, HCA exceeded its statutory authority and the New Rule must be invalidated.

[7] *See* Nicholson Decl., Ex. 1 at p. 41 ("[I]t is not surprising that the majority of the [health plans' pharmacy benefit managers] reimbursed pharmacies with rates greater than actual acquisition cost.").

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2. The New Rule is Invalid because it is Arbitrary and Capricious.

An agency rule is arbitrary and capricious if it is willful and unreasoning and taken without regard to the attending facts or circumstances. *Rios v. Dep't of Labor & Indus.*, 145 Wn.2d 483, 501, 39 P.3d 961 (2002). The APA requires an agency to keep a rule-making file, which serves as the record for review. RCW § 34.05.370(1), (4). The file must contain a CES identifying the agency's reasons for adopting the rule. RCW § 34.05.325(6)(a)(i). Therefore, when a rule is challenged as arbitrary and capricious, the reviewing court considers the relevant portions of the rule-making file and the agency's explanations for adopting the rule as part of its review. *See Washington Indep. Telcomms. Ass'n*, 148 Wn.2d at 906; *Aviation West Corp. v. Washington State Dep't of Labor & Indus.*, 138 Wn.2d 413, 427, 980 P.2d 701 (1999) ("The court must scrutinize the record to determine if the result was reached through a process of reason."). Washington courts often look to the CES to determine whether a rule was promulgated by a reasonable process. *See Aviation West Corp.*, 138 Wn.2d at 436 ("Here the administrative record was extensive. The CES expressly states that the EPA report in that record, among other reports, was relied upon in determining that ETS poses lung cancer and cardiovascular disease risks."). The petitioner bears the burden of proof to show that a rule is arbitrary and capricious based on the administrative record. *See Puget Sound Harvesters Ass'n v. Washington State Dep't of Fish & Wildlife*, 157 Wn. App. 935, 945, 239 P.3d 1140 (2010).

As discussed above, when proposing changes to the components of the reimbursement methodology, the CMS Rule requires a State to provide adequate data, such as a cost of dispensing study, supporting proposed changes to ensure that total reimbursement to the pharmacy provider is in accordance with Section 1902(a)(30)(A) of the Social Security Act. 42 C.F.R. § 447.518(d). Additionally, according to Washington's own Rule, HCA is required to examine the sufficiency of pharmacy dispensing fees by considering, among other factors, "[i]nput from state-employed or contracted actuaries." WAC 182-530-7050(3)(c).

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Here, however, the CES contains no indication that HCA relied on any type of study at all in making changes to the Rule, much less a specific study for its decision to not increase the professional dispensing fee. Nicholson Decl., Ex. 6 at p. 1. This was clearly unreasonable given that HCA's own sister agency conducted a study analyzing the very subject matter of the contemplated rule. Specifically, according to the OIC Study, a study from the State's own executive branch:

> 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. CMS views inadequate reimbursement as a possible violation of federal statute that requires states to reimburse providers in a manner that is sufficient to ensure provider participation and beneficiary access. Accordingly, the states that have adopted the [actual acquisition cost] reimbursement for ingredient cost have performed cost of dispensing surveys and currently have dispensing fees that are generally in excess of $10 per prescription.

Nicholson Decl., Ex. 1 at p. 33. Despite OIC's repeated findings throughout its report that dispensing fees above $10 are needed to cover pharmacy costs, HCA chose instead to leave its below-cost dispensing fees of $4.24-$5.25 unchanged. Such a decision could not have been the result of a process of reason as it both conflicts with the CMS Rule and an actuarial report from its sister agency.

Furthermore, to highlight that the State's decision could not have been the result of a process of reason, Petitioners point to Proposed Rule-Making Order WSR 17-02-083, which baldy states "the agency has determined that the proposed filing does not impose a disproportionate impact on small business" to justify its failure to prepare a small business impact statement as required under RCW § 34.05.320 and also notes that a cost-benefit analysis as required under RCW § 34.05.328 "does not apply to the Health Care Authority unless requested by the Joint Administrative Rules Review Committee or applied voluntarily." Nicholson Decl., Ex. 3 at p. 2. Even if HCA is not required to submit a cost-benefit analysis pursuant to Section 34.05.328, its decision not to was unreasonable given the New Rule's stark

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inconsistencies with the CMS Rule and OIC's Study.

Because HCA adopted the New Rule without regard to attending facts or circumstances, it is willful and unreasoning. As such, the New Rule must be invalidated as arbitrary and capricious.

3. The New Rule is Invalid because HCA Failed to Provide Pharmacies an Opportunity to Meaningfully Participate in the Development of the Rule in Violation of Statutory Rule-Making Procedures.

The APA provides that where a regulation of general applicability meets the definition of a rule, the agency must comply with statutory rule-making procedures. RCW §34.05.375 ("[n]o rule…is valid unless it is adopted in substantial compliance" with rule-making procedures); *see also McGee Guest Home, Inc. v. Dep't of Social & Health Servs.*, 142 Wn.2d 316, 322, 12 P.3d 144 (2000) ("We have been vigilant in insisting that administrative agencies treat policies of general applicability as rules and comply with necessary APA procedures."). "The remedy when an agency has made a decision which should have been made after engaging in rule-making procedures is invalidation of the action." *Hillis v. Dep't of Ecology*, 131 Wn.2d 373, 399-400, 932 P.2d 139 (1997); *see also* RCW § 34.05.570(2)(c).

A "rule" is defined to include "any agency order, directive, or regulation of general applicability…which establishes, alters, or revokes any qualification or requirement relating to the enjoyment of benefits or privileges conferred by law." RCW § 34.05.010(16). Washington courts have held that where the State changes the reimbursement methodology for participants in the Medicaid program, such action constitutes a rule that must be enacted in compliance with rule-making procedures. *See Failor's Pharmacy v. Dep't of Soc. & Health Servs.*, 125 Wn.2d 488, 886 P.2d 147 (1994) (holding that where the State added an additional requirement to those set out in the federal regulations, and thus had improperly established, altered, or revoked a qualification for the enjoyment of a benefit, the action was invalid without adherence to APA rule-making).

However, where HCA merely enacts a change to fee schedules, or the rates themselves,

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such action does not require adherence to statutory rule-making procedures. *See McGee Guest Home, Inc.*, 142 Wn.2d at 327 ("The Department was not required to undertake rule making before setting rates."); *see also* S.B. Rep. to ESB 6404, 53d Leg., Reg. Sess. (Wash. 1994). But where there is a change to the fee reimbursement *methodology*, as distinguished from mere *arithmetic calculations of rates*, the Washington Supreme Court has maintained that rule-making procedures apply. *See McGee Guest Home, Inc.*, 142 Wn.2d at 323 ("[The court] distinguished *Failor's*, noting it rested on the fact the Department had changed the methodology of reimbursement for participants in the Medicaid program by essentially adding an element to the cost calculation.").

Likewise, here, altering a qualification for the enjoyment of a benefit, *i.e.*, the methodology used to determine Medicaid reimbursement rates, constitutes a rule that must be enacted in compliance with rule-making procedures. The CMS Rule requires State Medicaid Agencies to establish new ingredient cost reimbursement and professional dispensing fees that reflect actual pharmacy costs. HCA did adopt a new ingredient cost reimbursement metric known as National Average Drug Acquisition Cost ("NADAC").[8] *See* Miller Decl., ¶ 13. However, HCA failed to simultaneously adopt a new professional dispensing fee, despite the requirements of the CMS Rule and despite the fact that HCA adopted regulatory language that calls for a new professional dispensing fee. Because HCA failed to afford pharmacies an opportunity to meaningfully participate in the development of this aspect of the New Rule in contravention of the statutory rule-making procedures, it must be immediately stayed and, ultimately, invalidated.

a. <u>HCA Foreclosed Public Comment on the New Rule's Inconsistencies with the CMS Rule and the OIC Study.</u>

The purpose of rule-making procedures is to ensure that the citizenry can participate

[8] NADAC is a set of specific reimbursement amounts for drugs that is disseminated by CMS. *See* Prescription Drug Pharmacy Pricing: NADAC, Medicaid, https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html (last visited March 27, 2017).

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meaningfully in the development of agency policies which affect them. *See Hillis*, 131 Wn.2d at 399. The APA's rule-making procedures require, among other things, providing notice to the public of the proposed rule and an opportunity to comment in order to prevent "unfair surprise." *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170 (2007); *see also, Washington Indep. Telecomms. Ass'n*, 148 Wn.2d at 902.

The APA provides that prior to filing a notice of a proposed rule, the agency must prepare a "Statement of Inquiry" and identify, among other things, "other federal and state agencies that regulate this subject, and describe[] the process whereby the agency would coordinate the contemplated rule with these agencies." RCW § 34.05.272(1)(a)(iii). Though HCA filed its Statement of Inquiry on June 29, 2016, the only agency it identified was CMS. *See* Nicholson Decl., Ex. 2 at p.1. HCA was required to identify OIC given that Senate Bill 5ESSB 5857, enacted on June 9, 2016, called upon OIC to review "the pharmaceutical acquisition cost from national or regional wholesalers that serve pharmacies in Washington, and consider when or whether to make an adjustment and under what standards." *See* Nicholson Decl., Ex. 1 at p.3. By failing to include OIC, the public was not aware that HCA's sister agency was studying the costs associated with the subject matter of the contemplated rule nor was it given an opportunity to confer with OIC regarding its findings. By failing to identify OIC, commentators were unable to query as to why HCA largely ignored the Study's findings that HCA's current dispensing fees are well below the cost of dispensing, as shown by numerous studies.

Additionally, although the State identified CMS, it failed to include a plan of coordination. Nicholson Decl., Ex. 2 at p. 1. If it had, the State would have had to reconcile the New Rule's inconsistencies with the CMS Rule; specifically, the State would have had to provide reasoning as to why the professional dispensing fee should not be increased given changes to the corresponding ingredient cost reimbursement.

Furthermore, when changes to "significant legislative rules" are contemplated, the APA provides additional rule-making requirements. *See* RCW § 34.05.328. "A 'significant legislative

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rule' is a rule other than a procedural or interpretive rule that…**adopts a new, or makes significant amendments to, a policy or regulatory program.**" RCW 34.05.328(5)(c)(iii) (emphasis added). Section 34.05.328(5)(a) specifically provides its applicability to "[s]ignificant legislative rules of the department[] of…social and health services." RCW § 34.05.328(5)(a)(i). Such rules are generally binding on courts unless they are adopted without adherence to the statutory rule-making procedures. *Ass'n of Washington Business*, 155 Wn.2d at 446. Here, the New Rule is subject to the provisions of RCW § 34.05.328 because it significantly amends the reimbursement methodology for pharmacies in the Medicaid program.

Section 34.05.328 provides that *before* adopting a significant legislative rule, the agency must, among other things:

> (h) Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by the following:
>
> (i) A state statute that explicitly allows the agency to differ from federal standards; or
>
> (ii) Substantial evidence that the difference is necessary to achieve the general goals and specific objectives stated under (a) of this subsection; and
>
> (iii) Coordinate the rule, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

RCW § 34.05.328(2)(h). However, HCA failed to acknowledge that the New Rule differs at all from the CMS Rule; in fact, HCA does not consider the changes contemplated by the New Rule to be "significant." Nicholson Decl., Ex. 6 at p. 1 ("For Rules Not Considered Significant"). By ignoring the provisions of Section 34.05.328, pharmacies were again denied notice of the Rule's inconsistencies with the CMS Rule and thus were unable to provide comment.

The State's failure to (1) identify OIC, (2) coordinate with CMS and OIC, or (3) provide any justification for its failure to increase the professional dispensing fee effectively foreclosed public comment on the Rule's inconsistences with the OIC Study and CMS Rule. Because HCA did not comply with the APA's rule-making procedures, the New Rule must be invalidated.

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b. HCA Denied Pharmacies an Opportunity to Meaningfully Participate in the Development of the New Rule.

The underlying purpose of the APA's rule-making procedures is to ensure that members of the public can meaningfully participate in the development of rules. *Hillis*, 131 Wn. 2d at 399. An agency is required to file notice of a proposed rule to facilitate participation from the general public, and more specifically, those directly affected by the proposed rule. RCW § 34.05.320; *see also Washington Indep. Tel. Ass'n*, 148 Wn. 2d at 902 (no statutory rule-making violation where all *affected* companies had an ample opportunity to comment on the proposed rule).

Although the State seemingly complied with Section 34.05.320 by filing a notice of the proposed rule, holding a public hearing, and soliciting public comment, the State failed to notify pharmacies until on or about March 2, 2017 that the new professional dispensing fee would not be established. This was both after the period for comment ended and after the State formally adopted the New Rule. The State chose to neither publish public notice nor afford pharmacies an opportunity to comment.

Further illustrating the mosaic of procedural issues is the State's CES which too was filed *after* adoption of the rule in violation of the APA. *See* RCW § 34.05.325(6)(a) ("[b]efore it files an adopted rule with the code reviser, an agency shall prepare a concise explanatory statement of the rule"). Not only did HCA apparently fail to consider the summary of comments in the CES until *after* adoption of the final rule, such consideration likely would have proved futile because of the ten comments it reviewed, not one addressed the proposed rule's failure to increase the professional dispensing fee, which is improper but unsurprising given that pharmacies were notified after the comment period ended, and more problematically, after HCA adopted the New Rule. Pharmacies affected by the New Rule were therefore denied a meaningful opportunity to comment. *C.f. Washington Indep. Telcomms. Ass'n,* 148 Wn.2d at 910 (no procedural violation where companies had a full opportunity to present their views and it is obvious that the agency considered them).

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By failing to adhere to the basic notice and comment requirements, the State eviscerated the intent and purpose underlying the APA's statutory rule-making procedures. Because pharmacies were denied an opportunity to meaningfully participate in a crucial aspect of the development of the New Rule, it is procedurally defunct and must be invalidated.

IV. CONCLUSION

The State's current reimbursement rate has been in effect for over six years; living with it for an additional few months to litigate this suit will not prejudice the State. Petitioners request an emergency stay of the New Rule, effective April 1, 2017, pending the outcome on the merits of the declaratory judgment action to prevent imminent harm to their member pharmacies.

Dated this 29th day of March, 2017.

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