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COURT OF APPEALS
STATE OF WASHINGTON

NATIONAL ASSOCIATION OF CHAIN DRUG STORES,
WASHINGTON STATE PHARMACY ASSOCIATION, and the
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION,
Petitioners/Appellants,
vs.

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

OPENING BRIEF OF PETITIONERS

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INTRODUCTION

Under the federal Medicaid program, each state sets fees to reimburse pharmacies for dispensing drugs to low-income persons. Those fees must compensate pharmacies for the actual costs incurred, yet Washington's fees do not. Washington reimburses pharmacies far less than it costs pharmacies to serve the state's Medicaid patients. And because Washington's fees do not reimburse pharmacies for their costs, those fees are dramatically lower than those of any other state in the country.

The central question here is whether the Medicaid dispensing fees established by the respondent, Washington State Health Care Authority ("Agency") are contrary to federal and state law. This issue turns not on questions of fact, but on the interpretation of the federal law governing Medicaid reimbursements and the Agency's selecting data favorable to its conclusion and ignoring that which was not.

In 2016, the federal agency administering Medicaid reimbursements, the Center for Medicare and Medicaid Services (CMS), implemented a new rule changing how states must reimburse pharmacies (CMS Rule). The centerpiece of this new

rule was that states must reimburse pharmacies for their actual costs in dispensing drugs to Medicaid patients. This CMS Rule requires states to reimburse pharmacies for: (1) the costs of purchasing drugs at wholesale (“ingredient costs”); and (2) the costs of dispensing drugs to Medicaid patients (“dispensing fees”). Ingredient costs must cover the actual amount the pharmacy pays to acquire the drug from a wholesaler. Dispensing fees must cover other costs of serving Medicaid patients, including reimbursing pharmacies for their overhead and labor costs for dispensing drugs.

Here, the Agency failed to comply with the new CMS Rule for cost-based dispensing fees. Rather than adopt cost-based dispensing fees, the Agency decided at the outset that it would keep dispensing fees unchanged. To do so, it had to rely on data for what *private* insurance plans pay pharmacies, which does not track actual costs as required by the CMS Rule. In addition, the Agency ignored a report from the Washington Insurance Commissioner concluding that dispensing fees should be close to double what they are currently. The state also ignored the fact that all other states that have implemented the CMS Rule’s

requirements have significantly higher dispensing fees. The Agency could have sought out data to identify the costs of dispensing for a Washington pharmacy serving Medicaid patients. It did not. Instead, the Agency kept in place the same dispensing fees it established many years ago before the CMS Rule was promulgated.

The Agency's decision to continue imposing below-cost dispensing fees is based on misreading the requirements of the federal rule and a biased selection of data to ensure a predetermined outcome. As a result, the Agency's actions exceed its authority and are arbitrary and capricious. Its rule and decision to pay below-cost dispensing fees should be declared unlawful and this case remanded for it to set new rates that follow federal law.

ASSIGNMENT OF ERROR

The Superior Court erroneously dismissed the petitioners' challenge to the Agency's rule and decision to keep dispensing fees unchanged.

STATEMENT OF ISSUES

The new CMS Rule requires state agencies to set rates to reimburse pharmacies for the actual costs of serving Medicaid patients. The questions presented for review are:

1. Did the Agency fail to comply with the federal law requiring pharmacies to be reimbursed for their actual costs in dispensing drugs to Medicaid patients?
2. Was the Agency's reliance on non-cost dispensing fee data for private insurers that do not handle Medicaid patients, while ignoring cost-based data, a form of cherry-picking data that was arbitrary and capricious?

STATEMENT OF THE CASE

A. Petitioners represent pharmacies of every size throughout Washington.

The petitioners are three non-profit associations whose members include Washington pharmacies participating in the Medicaid program (collectively "Pharmacies"). CP 4-5.¹ They

¹ Record citations are to the clerk's papers, "CP." The CP contains relevant documents taken from the Administrative Record. The Brief cites to the CP for the Court's ease of use. The appellate record was

include the Washington State Pharmacy Association (“WSPA”), the National Community Pharmacists Association (“NCPA”), and the National Association of Chain Drug Stores (“NACDS”).

Id. The WSPA represents pharmacists, technicians, and interns, as well as clinics, nursing homes, and hospitals. Many of its members participate in Washington’s Medicaid program providing care to patients throughout the state’s urban, rural, and underserved communities.

NCPA represents more than 22,000 independent community pharmacies across the country, including Washington. These pharmacies employ over 300,000 persons who dispense nearly half of the nation’s retail prescriptions, much it for Medicaid patients.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies, and supplier partners. Nationally, its members operate over 40,000 pharmacies, which include regional chains with at least four stores as well as

prepared before the effective date of this Court’s 2018-1 General Order.

national companies. Together, its members employ over 3.2 million persons, including 178,000 pharmacists. Its members operate 932 pharmacies in Washington and employ more than 72,000 employees in the state.

B. Dispensing fees have remained unchanged for 12 years.

The Agency's dispensing fees are based on prescription volume. *See* WAC 182-530-7050. Pharmacies that dispense a higher volume of prescriptions receive a lower Medicaid dispensing fee for each prescription. *Id.* The current dispensing fees of \$4.24 to \$5.25 have been in place for 12 or more years. CP 1609. The Agency has not re-evaluated them over that time. *Id.* The dispensing fees are published by the Agency on its website and are not contained in the text of its own rule.²

² CP 102; 232; *see also* Washington Health and Recovery Services Administration (HRSA), Prescription Drug Program: Billing Instructions, Washington State Health Care Authority (October 20, 2008), <https://goo.gl/EfDBVZ>, at 83. *See also* RCW 34.05.030(4); *McGee Guest Home, Inc. v. Dep't of Soc. & Health Servs.*, 142 Wn. 2d 316, 323 (2000) (noting legislative change). Accordingly, the Pharmacies are challenging both the state's rule as well as the agency action in setting a dispensing fee that fails to take into account costs as required by the CMS Rule. *See* RCW 34.05.570(1), (2), and (4).

C. CMS moves to reimbursing pharmacies based on actual costs.

With Medicaid, Congress established a cooperative program between the federal and state governments to provide medical care for those “whose income and resources are insufficient to meet the costs of necessary medical services.” 42 U.S.C. § 1396-1. Any state seeking to participate in Medicaid must submit a state plan to CMS for approval. 42 U.S.C. § 1396a(a); 42 C.F.R. § 430.10. Any amendment to a state plan must also be submitted to CMS. 42 C.F.R. § 430.12(c). The Secretary of Health and Human Services (HHS), of which CMS is a part, evaluates each state’s compliance with the Medicaid statute. 42 U.S.C. §§ 1316(a)–(b), 1396a(b).

In February 2016, CMS issued a new regulation changing how states must reimburse pharmacies. *See* 81 Fed. Reg. 5170 (2016) (“CMS Rule”). The CMS Rule requires states to adopt reimbursement rates that cover the costs incurred by pharmacies participating in Medicaid, by reflecting those costs in two distinct components: (1) ingredient costs and (2) professional dispensing fees. *See* 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1), 447.518(a)(2).

The CMS Rule requires states to calculate ingredient costs based on pharmacies' "Actual Acquisition Cost," also known as "ACC." 42 C.F.R. § 447.502, 447.512(b), 447.518(a)(2). The CMS Rule defines ACC as the "actual prices paid to acquire drug products marketed or sold by specific manufacturers." 42 C.F.R. § 447.502.

Similarly, the CMS Rule defines "professional dispensing fees" as those covering a list of specified "pharmacy costs" associated with operating pharmacies. *See Id.* (definition of "professional dispensing fees" at subparagraph (2)). In particular, the CMS Rule defines dispensing fees as those "incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed" and "[i]ncludes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary." *Id.* Each state must ensure that dispensing fees cover those costs. *Id.* at §§ 447.518(b).

The CMS Rule further provides that when proposing changes to *either* the ingredient cost or dispensing fees

reimbursement, 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 requirements of section 1902(a) (30) (A) of the [Social Security] Act.”³ 42 C.F.R. § 47.518(d) (emphasis added). States must also “*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” and submit any changes to CMS for review. *Id.* (emphasis added).

D. Other states implement cost-based reimbursement in compliance with the CMS Rule.

Beginning in 2016, states across the nation began adjusting their reimbursements to comply with the CMS Rule.

³ Section 1902(a)(30)(A) of the Social Security Act provides 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 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(a)(30)(A).

See CP 120; 152. States that have moved to the cost-based reimbursement model required by CMS have dispensing fees far higher than Washington.⁴ Indeed, CMS itself has recognized that “Washington’s proposed professional dispensing fee is significantly lower than all other approved professional dispensing fees nationally, including [its] contiguous neighboring states.” CP 1112.

E. The Agency cut ingredient costs but failed to adopt cost-based dispensing fees.

In response to the new CMS Rule, the Agency engaged in a rulemaking that lowered reimbursement for ingredient costs substantially. *See generally* CP 301-305 ¶¶ 8-18 (Affidavit of Dr. Laura Miller); *id.* at ¶¶40-41. But modifying the ingredient cost

⁴ *See generally* Medicaid Prescription Drug Reimbursement Information by State, available online at [Medicaid.gov](https://www.medicare.gov), <https://goo.gl/LbcBam>. Judicial notice is proper for facts that are not subject to reasonable dispute, are generally known within the jurisdiction of the court, or are capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. ER 201(b); *see also State ex rel. Helm v. Kramer*, 82 Wn. 2d 307, 319 (1973) (taking judicial notice of publicly available U.S. Department of Labor statistics). A court may also take notice of other government publications, such as the Washington Insurance Commissioner's report. *See Pudmaroff v. Allen*, 138 Wn. 2d 55, 65 (1999) (taking judicial notice of a publication by the Washington Traffic Safety Commission).

reimbursement was just one part of the equation. The CMS Rule also requires that states “evaluate” each component when they propose changes “and consider the impacts of *both* the ingredient cost reimbursement *and* the professional dispensing fee reimbursement when proposing such changes....” CP 293-94. CMS has recognized that “reimbursement for drug ingredient cost and professional dispensing fee must be adjusted in tandem.” *Id.* To adjust one means adjusting the other.

Each state must also submit proof to CMS that its dispensing fees cover pharmacy costs. 42 C.F.R. § 447.518(d). Here, however, while the Agency lowered ingredient cost reimbursements significantly, it did nothing to update the *dispensing fee* to reflect pharmacy costs. In doing so, the Agency left untouched the existing language from its *own* rule allowing it to consider other factors such as “dispensing fees paid by *other third party payers*, including, but not limited to, health care plans and State Medicaid agencies.” CP 72 (emphasis added). But the CMS Rule does not authorize the Agency to consider such other factors. *See* 42 C.F.R. §§ 447.502 (Professional dispensing fee definition includes “only pharmacy costs associated with ensuring

that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary”).

- 1. The Agency commissions a study to justify keeping dispensing fees unchanged.**

In May 2016, just a month after the CMS Rule was published, the Agency prepared an internal working paper containing several “immediate next steps” needed to comply with the CMS Rule. CP 269. But it intentionally avoided seeking a study reflecting the costs to Washington pharmacies for dispensing drugs to Medicaid patients. Instead, it looked to “obtain an external and very credible report displaying current *market rates* paid by *private insurers* for point-of-sale pharmacy drugs and dispensing.” *Id.* (emphasis added).

And the Agency was candid as to why it wanted to rely on this sort of study—namely, to avoid raising Medicaid dispensing fees for Washington pharmacies: “We need this external report in order to avoid being forced into higher rates that are not appropriate in our market.” *Id.* It sought to conduct this external study to “defend against the pressure to increase dispensing fees” *Id.* In fact, in January 2017, an Agency staff member in charge of pharmacy rates stated in an email that CMS’s efforts

to raise dispensing fees to around \$10 nationally “would be completely inappropriate” for Washington and concluded—before any rulemaking had taken place—that “[w]e don’t need to infuse money into pharmacy rates.” *Id.*

To justify keeping dispensing fees unchanged, the Agency retained the actuarial consulting firm Milliman to “summarize retail pharmacy reimbursement and dispensing fees for brand, generic, and specialty prescriptions in the *commercial* and *Medicare* markets for informational purposes as directed by [the Agency].” CP 1289 (emphasis added). The Milliman study delivered exactly what the Agency asked of it: proof of extremely low *non*-Medicaid dispensing fees—from zero to \$1.22 per prescription—paid to pharmacies by private insurance plans. This is because low, non-Medicaid dispensing fees are offset by higher non-Medicaid ingredient cost reimbursement. CP 41-42. Yet, the Milliman report did not contain data on the *costs* incurred by pharmacies when they dispense drugs to *Medicaid patients*.

In fact, the Milliman report recognized this very limitation and noted that it should not be relied on to justify

lower Medicaid rates by stating that a “Medicaid population will utilize a different drug mix than a commercial or Medicare population” and that it relied only on national data—and not data specific to Washington. *See* CP 288-89. Further, the Milliman report did not conduct a cost of dispensing study for Washington pharmacies. CP 308.

The Agency also relied on another report by another consultant, Moda, which also relied only on private insurance plan data. CP 1605. This report shows national “market” data involving private health insurance plans and confirms that dispensing fees for such plans range from zero to \$1.22 per prescription. Like the Milliman report, nothing in this report indicates that it captures the specific costs incurred by Washington pharmacies when dispensing drugs to Medicaid beneficiaries. And again, low dispensing fees paid by private plans are offset by higher reimbursements for ingredient costs. CP 41-42.

Relying on this data alone, the Agency kept Medicaid dispensing fees for all Washington pharmacies across the state at their more than decade-old levels of \$4.24 to \$5.25. Its

justification for not increasing dispensing fees was unrelated to pharmacy costs, but instead was based on what *private* insurers paid. *See* CP 279 (“Our dispensing fees are significantly higher than other [private] payers (2-4 X commonly paid rates)”).

Further, the Agency ignored the verbal guidance from CMS that it is “*expecting the dispensing fees to be raised* and that Medicaid does not compare itself to commercial payers, instead the comparison should be to other Medicaid states.” CP 276 (emphasis added). (Agency phone notes).

After the comment period for its new rule closed, in March 2017, the Agency announced for the first time, in an e-mail, that the dispensing fees would remain flat. CP 110 (“[d]ispensing fees are unaffected by this change.”). The Agency then prepared a summary of the rule, but still nowhere discussed the adequacy or amount of professional dispensing fees. CP 113-118. On April 1, 2017, the Agency’s rule became effective. *Id.*

2. The Insurance Commissioner recognizes that other state dispensing fees are far higher than Washington’s fees.

During the period the Agency was implementing its rule and considering its dispensing fees, the Washington Office of the

Insurance Commissioner conducted its own “Study of the Pharmacy Chain of Supply.” CP 120-226. This study compared not only commercial payer trends but also reviewed Medicaid dispensing fees. The report concluded that dispensing fees for pharmacies serving Medicaid patients are generally above \$10 per prescription:

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.... 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*.

CP 120; 152 (emphasis added). The Agency had access to this report when deciding to leave the dispensing fees unchanged. CP 1605.

3. The CMS Rule requires states to assemble reliable cost data to justify both the ingredient costs and dispensing fees.

The CMS Rule requires adequate and reliable cost data to support for any new ingredient costs and dispensing fees and

states in part: “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.”42 C.F.R. § 447.518(d) (emphasis added).

The CMS Rule repeatedly emphasizes that each state’s dispensing fee must be sufficient to cover pharmacy costs. *See, e.g.*, CP 298 (“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.”); CP 293, 295, 296-7 (“[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...”) and (“states are in the best position to establish fees based on *data reflective of the cost of dispensing drugs in their state* ”)(emphasis added).

But, as noted, the Agency did not conduct a cost of dispensing study or otherwise assess pharmacy costs. *See* CP 266 (“[t]here is no cost of dispensing study that would produce

the dispensing fee amounts that we currently pay....”); CP 279-80 (Agency’s “basis of payment for pharmacies has never been tied to operating costs of pharmacies”). In fact, the Agency’s Manager of Pharmacy Rates did not want such a cost-based study because it would lead to higher dispensing fees. CP 279 (“The cost of dispensing studies typically produce much higher numbers for dispensing fees than are commonly paid in the market....I think this would result in a large unnecessary expense, plus be a significant strategic error....”). Rather than rely on a study of *actual costs* for Washington pharmacies to dispense drugs to Medicaid beneficiaries, it relied instead on the Milliman and Moda reports dealing with what private insurance companies paid in the *non*-Medicaid market.

CMS has already questioned the validity of the Agency’s decision to leave dispensing fees unchanged. CP 1596-98. In a letter to the Agency, CMS asked:

Please explain ... why the state is *opting to not pay pharmacies at their average actual cost of dispensing*. The State Medicaid Director’s letter issued on February 11, 2016 states that the dispensing fee should reflect the pharmacist’s professional services and

cost to dispense a drug to a Medicaid beneficiary. The fact that pharmacists are willing to “accept” a dispensing fee paid by managed care plans in the state in order to stay in the Medicaid fee-for-service (FFS) network does not negate the regulatory requirement of professional dispensing fee as defined in 42 CFR 447.502.

CP 1597-98 (emphasis added). CMS continued: “Please indicate how the proposed fees reimburse pharmacies for their average cost of dispensing.” *Id.*

CMS has also told the Agency of its “intent to deny” approval of the State dispensing fees if the Agency does not increase fees based upon a cost-of-dispensing approach required by the CMS Rule. *See* CP 281. The Agency has conceded that it has no such survey or data from neighboring states that would support its proposed rates. *See* CP 266 (“[t]here is no cost of dispensing study that would produce the dispensing fee amounts that we currently pay....”). The Agency also conceded that it never has paid cost-based dispensing fees. CP 279-80 (Agency’s “basis of payment for pharmacies *has never been tied to operating costs of pharmacies,*” even as CMS was “continuing to

require” that dispensing fees must be based on pharmacy costs) (emphasis supplied).

CMS also instructed the Agency to “raise the dispensing fees and to use a ‘Cost of Dispensing Study’ to set the amount of the increase. They [CMS] are ‘expecting to see’ something in the \$10.50, \$11.50 or \$12.00 range. Higher amounts would be acceptable.” CP 281. Despite these directions from the CMS, the Agency refused to modify its dispensing fees, claiming that it would be a “substantial unnecessary expense to the state.” *Id.* To date, however, the CMS has not taken formal action to disallow the Agency’s dispensing fees.⁵

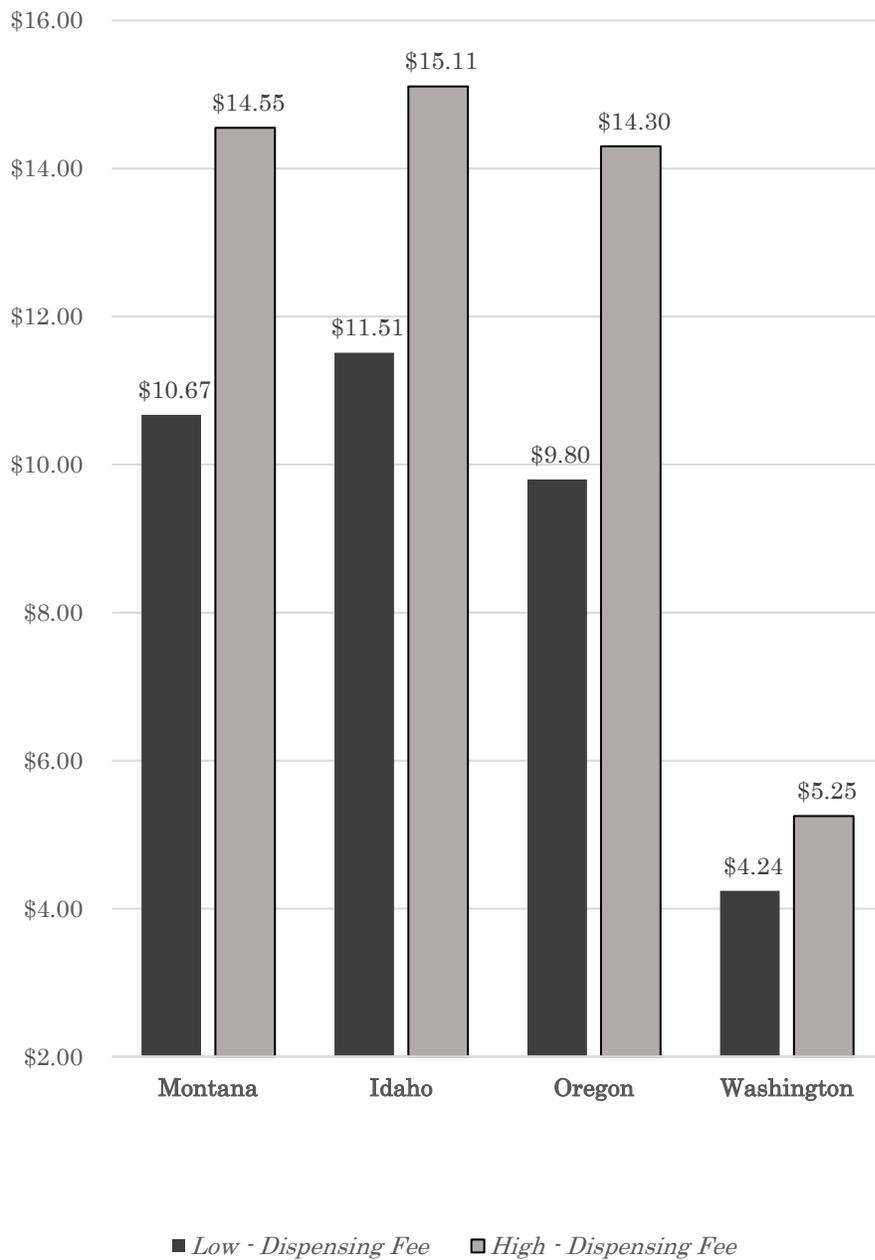
⁵ Though CMS has not yet taken formal action either approving or denying the Agency's State Plan Amendment ("SPA"), any potential approval in the future would not moot this litigation. *See, e.g., KY Health & Family Servs. v. Saint Joseph Health Sys., Inc.*, 521 S.W.3d 576, 587 (Ky. Ct. App. 2017) (CMS approval of an SPA does not constitute rulemaking that would merit deference to the federal agency and permits a state court to find that the state agency violated the APA); *RCJ Med. Servs., Inc. v. Bonta*, 91 Cal. App. 4th 986, 1011 (2001) (party may continue challenging state plan as “arbitrary, capricious...or otherwise not in accordance with law” even after CMS approval of plan).

F. Washington's dispensing fees are far less than in states that have implemented the CMS Rule.

Currently the Agency's dispensing fees range from \$4.24 to \$5.25. CMS has recognized that the Agency's Medicaid dispensing fees are the lowest in the nation among all other approved states. CP 1112. Yet, cost of dispensing studies reveal that Washington's dispensing fee should be about \$10.48. CP 305 at ¶26. This figure of \$10.48 aligns with what neighboring states have implemented as new dispensing fees to comply with the CMS Rule. *See* CP 1113.⁶ The following chart illustrates the major disparity between Washington and its neighboring states in Medicaid dispensing fees.

⁶ The data contained in the CMS letter at CP 1113 was accurate as of September 21, 2017. Since then, the rates for Montana and Oregon apparently have been adjusted slightly. *See* Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State (Quarter Ending March 2018), available online at <https://goo.gl/L2hJFw>. Both charts rely on the most recent data available on CMS' website.

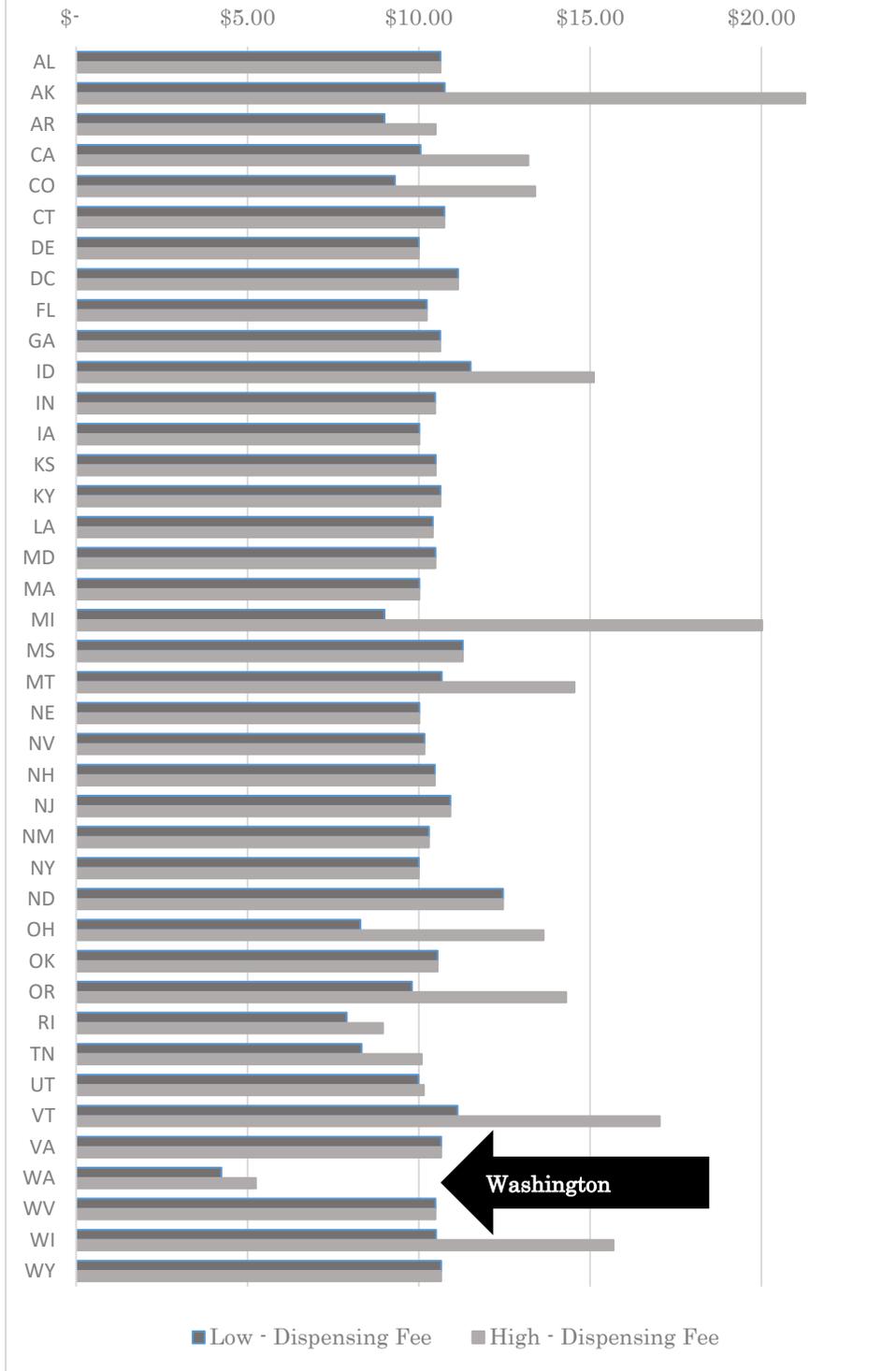
Current Medicaid Dispensing Fees Among Neighboring States



What is more, as shown in the next chart, the Agency's dispensing fees also place Washington last—and by a significant amount—among the 41 states that have already issued new dispensing fees to comply with the CMS Rule.⁷

⁷ As of the date of this filing, CMS has approved new State Plan Amendments (“SPA”) from 40 states and D.C. which include new dispensing fees to comply with the CMS Rule. This chart shows the fee of those 40 states and D.C. (with the exception of Texas) based upon publicly available data from CMS. *See* Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State (Quarter Ending March 2018), available online at <https://goo.gl/L2hJFw>. Texas is not included in the chart because it does not have a specific dispensing fee but rather a formula to calculate a fee for each drug. The Texas calculation will typically yield more than \$7.93-\$8.58, with an upper limit of \$200. *See* <https://goo.gl/LgmCtX>. CMS recently approved Vermont's \$11.13/\$17.03 dispensing fee, but it is not yet reflected on the CMS website. Vermont's SPA approval is available at <https://goo.gl/CAo5fn>. Six states (Illinois, Maine, Minnesota, Missouri, Pennsylvania, and as discussed above, Washington) have submitted SPAs to CMS and those remain pending. Additionally, neither Arizona nor Hawaii need to satisfy the CMS Rule because their Medicaid programs are managed care, and the CMS Rule applies only to Medicaid fee for service. *See* AZ Medicaid, <https://goo.gl/CJS1xB>; HI Medicaid, <https://goo.gl/tTQfW7>. Two states, South Carolina and South Dakota have not yet submitted SPAs. Finally, North Carolina's dispensing fees were approved prior to the effective date of the CMS Rule. *See* NC Medicaid Bulletin, <https://goo.gl/7Eo4M1>; NC Medicaid Tracks, <https://goo.gl/AgAewu>; NC SPA Notice, <https://goo.gl/P5DTQr>.

National Comparison of Post-CMS Rule Dispensing Fee Ranges



G. Washington’s pharmacies are now reimbursed \$12 million below their actual costs.

Keeping dispensing fees frozen for more than a decade has meant that Washington pharmacies are now being reimbursed approximately \$12 million a year below the true cost of dispensing prescribed medications to Medicaid patients. CP 310. And pharmacies serving communities in Washington with the most Medicaid patients are hardest hit by reimbursements that are substantially below their actual costs.

H. The Superior Court rejects the pharmacies’ petition for relief.

The petitioners challenged the Agency’s rulemaking and dispensing fee actions in the Superior Court under the Administrative Procedure Act.⁸ CP 1-15; 230-252. After briefing by the parties, the court heard oral argument in December 2017. *See* VRP. The court overruled the petitioners’ arguments that the Agency exceeded its statutory authority by keeping pharmacy dispensing fees unchanged and that its actions were arbitrary and capricious. VRP 56:2; 57:2-58:7. The Court did not elaborate on the reasoning for its decision. *Id.*

⁸ The petitioners also challenged the Agency’s procedures in establishing its rule as contrary to due process. They have not raised the due process issue in this appeal.

The court entered a final judgment dismissing the action on January 26, 2018 CP 1575-76. On January 31, 2018, the Pharmacies timely moved for reconsideration and to supplement the record based on new evidence from the Agency and CMS. CP 1578-2359. The Court denied that motion on February 16, 2018. CP 2366-7. The Pharmacies filed a timely appeal on February 26, 2018 under RAP 2.2(a), RAP 5.2, and RCW 34.05.526. CP 2369-2371.

STANDARD OF REVIEW

This appeal presents two grounds under the Administrative Procedure Act (APA) to reverse the Agency's decision to leave dispensing fees unchanged: (1) the Agency exceeded its statutory authority and (2) its decision is arbitrary and capricious. RCW § 34.05.570(2)(c); RCW 34.05.570(4). Whether an agency has exceeded its statutory authority is reviewed de novo. *Estate of Ackerly v. Wash. Dept of Revenue*, 187 Wn.2d 906, 909 (2017). And in particular, Washington courts review an agency's interpretation of federal law de novo. *Jenkins v. Washington Dept. of Social and Health Services*, 160 Wn. 2d 287, 296 (2007).

The abuse of discretion test applies to the arbitrary and

capricious standard. RCW 34.05.574(1); *See Lenca v. Employment Sec. Dep't of State*, 148 Wn. App. 565, 575 (2009) (agency must exercise its discretion “in accordance with the law”). If an agency violates a statute, then that is “by definition, arbitrary and capricious, or contrary to law.” *Skamania Cty. v. Columbia River Gorge Comm'n*, 144 Wn. 2d 30, 57 (2001).

When applying the arbitrary and capricious standard, courts consider, among other things, the evidence that an agency relied on in making its decision. *Id.* at 871. And when an agency selects data favorable to a predetermined conclusion and ignores contrary data, such reliance on biased data is arbitrary and capricious. For example, the District of Columbia Circuit, well-known for its experience with administrative review, recently overturned an agency decision in *Genuine Parts Co. v. Envtl. Prot. Agency*, 890 F.3d 304, 313 (D.C. Cir. 2018) because “it was arbitrary and capricious for [the agency] to rely on portions of studies in the record that support its position, while ignoring cross sections in those studies that do not.”

Finally, under the APA, the reviewing court sits in the same position as the superior court and its review is *de novo*.

Washington State Hosp. Assn v. Washington State Dept. of Health, 183 Wn. 2d 590, 594 (2015) (court overturns agency decision as contrary to statute).

ARGUMENT

- A. **The Agency has violated the CMS Rule by failing to implement cost-based dispensing fees.**
1. **Lowering the ingredient costs without adjusting the dispensing fees conflicts with the CMS Rule.**

The Agency lowered reimbursement for ingredient costs, but left the dispensing fees unchanged. But the CMS Rule makes plain that changes to one component require reevaluating the other: “When proposing changes to *either* the ingredient cost reimbursement *or* the 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.” 42 C.F.R. § 447.518(d) (emphasis added).

Moreover, the Agency had to do more than merely *consider* whether it would adjust the professional dispensing fee. The CMS Rule required it to provide adequate and reliable data “to support any proposed changes to either or both of the components of the reimbursement methodology.” *Id.* As CMS explained when proposing the rule, “states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change *reflects actual costs* and does not negatively impact access.” 81 Fed. Reg. 5201 (emphasis added).

Here, the Agency had three reports to consider: (1) the Milliman report it commissioned dealing only with private insurance plans reflecting dispensing fees paid without a consideration of cost, (2) the Moda report which was similarly limited to private insurance, and (3) the State Insurance Commissioner’s report showing that the proper cost-based dispensing fees for pharmacies serving Medicaid patients was in the range of \$10. CP 1605. Moreover, CMS has confirmed that its rule is not to be used to set a market rate that might be accepted by a pharmacy. Instead, the CMS Rule is designed so that states

reimburse pharmacies for the costs incurred in serving Medicaid patients. *See* CP 1967 (even if pharmacies willing to accept dispensing fees paid by managed care plans do not negate the CMS Rule’s requirement).

2. Ignoring the actual costs to dispense, while relying on private party data, conflicts with the CMS Rule.

By basing its decision on factors that are wholly unrelated to pharmacies’ cost of dispensing, the Agency acted contrary to the CMS Rule. Specifically, the Agency’s rule for calculating dispensing fees allows the Agency to adjust pharmacy dispensing fees based on factors such “dispensing fees *paid by other third-party payers* including, but not limited to, health care plans” and “legislative appropriations for vendor rates....” CP 72 (quoting WAC 182-530-7050(3)(a), (d)) (emphasis added). That is directly contrary to the CMS Rule’s requirement that dispensing fees must be based on pharmacy *costs*. Nowhere does the CMS Rule allow dispensing fees to be tied to such non-cost data from “third party payers” such as health care plans.

What a private insurance company might pay pharmacies in a privately negotiated contract has no bearing on the costs

that pharmacies actually incur. This is especially so because, unlike state Medicaid programs, private plans are not legally required to reimburse pharmacies for costs of dispensing. As a result, the Insurance Commissioner's report found that dispensing fees paid by private health plans are *not* sufficient to cover pharmacy costs:

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.

CP 149 (emphasis supplied; footnotes omitted); *see also id.* at 179, 188 (citing \$11.65 average actual cost to dispense for Washington pharmacies).

Therefore, dispensing fees paid by *private* health plans do not and cannot reflect pharmacy costs within the meaning of the CMS Rule. Private plans' low dispensing fees are offset by higher reimbursement for ingredient costs. *See* CP 160 ("[I]t is not surprising that the majority of the [health plans' pharmacy benefit managers] reimbursed pharmacies with rates greater than actual acquisition cost."). In contrast, under the CMS Rule, state Medicaid programs must set both their dispensing fees and

their ingredient cost reimbursement based on *pharmacy costs alone*.

But rather than adhering to the terms of the CMS Rule, the Agency elected to keep dispensing fees unchanged purely because such fees are lower for private insurance. CP 1609. Such a decision runs directly contrary to the very touchstone of the CMS Rule which is to base pharmacy dispensing fees on “adequate” and “reliable” data reflecting specific pharmacy costs. 42 C.F.R. § 447.518(d).

3. The Agency’s below-cost dispensing fees violate the CMS Rule.

Since the Agency’s rates became effective in April 2017, reimbursements for Washington pharmacies serving the state’s Medicaid patients have been far below their actual cost. As discussed above, despite lowering ingredient costs significantly, the Agency has kept dispensing fees unchanged for the past 12 years—keeping those fees between \$4.24 and \$5.25 for each prescription, depending on the volume of prescriptions a pharmacy dispenses each year. That means under the Agency’s current rates, Washington’s pharmacies are being paid

approximately \$12 million a year below their actual costs of dispensing to Medicaid patients. CP 310.

Dispensing fees that are so far below the actual costs incurred by Washington pharmacies cannot comply with the CMS Rule. *See* 42 C.F.R. 447.514(b)(1) and 447.518(b) (noting dispensing fee intended to address pharmacy operational costs). And if the Agency’s own dispensing fees and its underlying rule conflict with the CMS Rule, then the fees cannot stand. *See Washington State Hosp. Assn.*, 183 Wn.2d 590, 595–96 (2015) (striking down new state rule because it was inconsistent with a governing statute).

B. By cherry-picking data, the Agency’s decision is arbitrary and capricious.

1. The Agency selected only the data that would justify keeping dispensing fees flat.

Every state must provide “adequate” and “reliable” data under the CMS Rule to show that the state’s dispensing fees cover the costs specified in the CMS Rule’s definition of “professional dispensing fee.” 42 C.F.R. §§ 447.502, 447.518(d). But even before issuing its new rule, the Agency had already decided internally that it would not raise dispensing fees. From

the outset, the Agency made clear its intent to keep dispensing fees unchanged. Its manager of pharmacy rates stated the way to do that was to rely on data from private party plans: “We must obtain an external and very credible report displaying current market rates paid by *private insurers* for point-of-sale pharmacy drugs and dispensing.” CP 269 (emphasis added). The same manager continued: “We need this external report in order to avoid being forced into higher rates that are not appropriate in our market” and so that the Agency could “defend against the pressure to increase dispensing fees.” *Id.*

Hence from the beginning, and without the benefit of public rulemaking, the Agency had already decided that dispensing fees should stay the same. To reach the pre-determined result, the Agency looked to the Milliman report reflecting what private insurance companies pay pharmacies for non-Medicaid patients. Such data is wholly different from the actual costs that pharmacies incur in serving Medicaid patients. And such non-cost data is a long way from satisfying the CMS Rule’s requirement for “adequate” and “reliable” data reflecting actual pharmacy costs.

The Milliman report merely confirmed that private insurance companies reimburse pharmacies at anywhere from zero to a mere \$1.22 for dispensing fees. But the reason dispensing fees for private plans are so low is because these private companies pay pharmacies more for ingredient costs, which in turn offset the lower dispensing fees. CP 160. But mimicking the extremely low fees paid by private plans—without mimicking the higher ingredient cost reimbursements paid by those private plans—is obviously not what the CMS Rule mandates. That rule requires fees based on “adequate” and “reliable” data for the *actual costs* pharmacies incur to fill Medicaid prescriptions, not what private insurance companies pay. By relying solely on data for private insurance carriers, the Agency has strayed far from the CMS Rule that data must reflect the actual costs of Washington pharmacies that serve Medicaid patients.

The Milliman report itself acknowledged its own limitations. It noted (1) that comparing wholesale price discounts and dispensing fee benchmarks to other markets [such as Medicaid] *should be done with caution* due to differences in

drug mix and demographics, (2) *Medicaid* patients utilize different drugs than those in private insurance or the *Medicare* program, and (3) the data in the Milliman report is national and not specific to Washington. *See* CP 288-89.

The Moda report also limits itself to private insurance plan data. CP 1926-47. Using that same basic data, not surprisingly, the Moda report produces the same result as the Milliman report—that dispensing fees for private insurance plans are either zero or only up to \$1.22. The Moda report also does not address costs for Washington pharmacies to dispense drugs to Medicaid patients.

2. Courts consistently overturn pre-determined agency decisions relying on cherry-picked data.

Not only did the Agency rely exclusively on private insurance company data that could in no way accurately reflect the actual costs to Washington pharmacies, it also ignored the report of the insurance commissioner unequivocally concluding that dispensing fees should be in the range of \$10. By embracing the data that fit its pre-determined outcome and ignoring data

that did not, the Agency engaged in a process commonly known as “cherry picking.”

Federal courts in particular have consistently overturned agency decisions hinging, as here, on cherry-picked data.⁹ For example, In *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579 (10th Cir. 1985), the court overturned an agency decision based on biased data. There, hospitals sought to strike down a federal regulation that would have reduced reimbursements for certain malpractice insurance costs. The Tenth Circuit overturned the agency decision because it relied on a report containing limited data sets, including several cautionary statements about the data sets used, and cautions, as in this case, about relying on that data. *Id.* at 1583. The court explained that “an agency need not await perfect data before taking regulatory action.” But, “[t]here are limits ... to the degree of imperfection that is

⁹ The APA expressly recognizes that “courts should interpret provisions of this chapter consistently with decisions of other courts interpreting similar provisions of other states, *the federal government*, and model acts. RCW 34.05.001 (emphasis supplied); *see also KS Tacoma Holdings, LLC v. Shorelines Hearings Bd.*, 166 Wn. App. 117, 126–27 (Div. 2, 2012).

permissible” *Id.* at 1582–83. And, “[w]hen an agency adopts a regulation based on a study not designed for the purpose and which is limited and criticized by its authors on points essential to the use sought to be made of it, the administrative action is arbitrary and capricious and a clear error in judgment.” *Id.*

Again, in *Sierra Club v. Bosworth*, 510 F.3d 1016, 1026 (9th Cir. 2007), the court overruled an agency’s decision based on flawed data. There, the Ninth Circuit reversed the district court because the agency had made its decision before first conducting the necessary “data call” that would have informed its decision. It stated that “[p]ost-hoc examination of data to support a pre-determined conclusion is not permissible because ‘[t]his would frustrate the fundamental purpose of [the statute], which is to ensure that federal agencies take a ‘hard look’ at the environmental consequences of their actions, early enough so that it can serve as an important contribution to the decision making process.’” *Id.* The court concluded that such pre-determined decision making was arbitrary and capricious under the APA. *Id.*

This fundamental principle that agencies may not rely on one-sided or unsuitable data has been reinforced time and again. Recently, in *Genuine Parts Co. v. Env'tl. Prot. Agency*, 890 F.3d 304, 313 (D.C. Cir. 2018), the District of Columbia Circuit held that “it was arbitrary and capricious for [the agency] to rely on portions of studies in the record that support its position, while ignoring cross sections in those studies that do not.”

Similarly, in *Lakeland Bus Lines, Inc. v. Nat'l Labor Relations Bd.*, 347 F.3d 955, 962-63 (D.C. 2003), the court reversed an agency's decision on unfair labor practices because it failed “to take account of contradictory evidence” and engaged in a “clipped view of the record it chose to take.” Again, in *Guindon v. Pritzker*, 31 F. Supp. 3d 169, 195 (D.D.C. 2014), the court stated that an agency may not “disregard superior data in reaching its conclusion,” and held that the agency's final rule was arbitrary and capricious conduct because it ignored “superior or contrary data.”

And, in *Nat. Res. Def. Council v. U.S. E.P.A.*, 808 F.3d 556, 574 (2d Cir. 2015), the court overturned an agency decision as arbitrary and capricious because it failed to develop

information necessary to the underlying issue and failed to consider an “important aspect of the problem.” Finally, this federal case law aligns squarely with Washington case law. As the court stated in *Puget Sound Harvesters Assn v. Washington State Dep’t of Fish & Wildlife*, 157 Wn. App. 935, 950 (Div. 2 2010), “it is not rational for [the Agency] to ignore the considerable information that it does have” and therefore, “[w]hen an agency makes rules without considering their effect on agency goals, it acts arbitrarily and capriciously, without regard to the attending facts or circumstances.”

What the Agency did here fits the same pattern of relying on skewed data that was overturned in the cases above. At the outset, the Agency determined that it would not raise dispensing fees. CP 277. With the Milliman and Moda reports, it found non-cost data that it could cite to justify the result it wanted. Those reports had nothing to do, however, with the actual costs for Washington pharmacies to dispense drugs to Medicaid patients. Further, neither report contained pharmacy cost data from a reliable source, such as a cost of dispensing study. CP 308.

The Agency could have commissioned a cost-of-dispensing study among pharmacies in Washington. It did not. Or it could have relied on the many cost of dispensing studies conducted by many states and others, all of which show that the Agency's dispensing fees are far too low to cover pharmacies' cost of dispensing. It did not. And when the insurance commissioner's own report concluded that Washington dispensing fees should be in the range of \$10, this too was ignored.

Arbitrary and capricious decisions may arise in many forms. The decisions discussed above illustrate one such form. They show that when an agency relies only on data reinforcing its pre-determined conclusion and ignores any other competing evidence, then a decision hinging on such one-sided data cannot stand. So too in this case. Because the Agency relied on cherry-picked non-cost data to the exclusion of all else, its actions should be overturned.

C. No deference is owed to the Agency's interpretation of the CMS Rule.

In the superior court, the Agency argued that its conduct and its application of the CMS Rule is entitled to deference. CP 1129; VRP. But deference to an agency decision is not absolute.

When dealing with the Medicaid statute in particular, the Supreme Court in *Jenkins* ruled that when a certain portion of that statute is unambiguous, then the state agency's interpretation of it is not entitled to deference. 160 Wn.2d 297-98.

The CMS Rule was designed to provide pharmacies with reimbursements that more accurately reflect their actual costs. 42 C.F.R. § 447.502. The CMS Rule defines "professional dispensing fees" as those adequately covering a list of specified "pharmacy costs" associated with operating pharmacies. *Id.* (definition of "professional dispensing fees" at subparagraph (2)). In particular, the CMS Rule defines dispensing fees as those "incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed" and "[i]ncludes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred *to a Medicaid beneficiary.*" *Id.* (emphasis supplied).

The CMS Rule further provides that, when proposing changes to either the ingredient cost or dispensing fees

reimbursement, 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 requirements of section 1902(a)(30)(A) of the [Social Security] Act.”¹⁰ 42 C.F.R. § 447.518(d) (emphasis added). Additionally, states must also “*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.” *Id.* (emphasis added).

An example of when deference is not due to an agency’s interpretation of the Medicaid statute may be found in *Hoag Mem’l Hosp. Presbyterian v. Price*, 866 F.3d 1072, 1077 (9th Cir. 2017). In *Hoag*, hospitals serving Medicaid beneficiaries challenged the Secretary of Health and Human Services’

¹⁰ Section 1902(a)(30) (A) of the Social Security Act states: “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(a)(30)(A).

approval the California agency's rate reduction for outpatient services. *Id.* at 1076. Specifically at issue was an "equal access" requirement and the language of the Medicaid statute requiring evidence as to "the extent that such care and services are available to the general population in the geographic area." *Id.* at 1078. This language, requiring a comparison of Medicaid patients' access to care versus the general public's was, as the Ninth Circuit pointed out, unambiguous. When the state agency failed to provide such a comparison and the federal agency approved it, then it was owed no deference, because such agency action was contrary to the express language of the statute. *Id.* at 1080. Accordingly, the Ninth Circuit overturned the agency's decision as arbitrary and capricious. *Id.* at 1081-82.

The court in *Hoag* was careful to distinguish its earlier decision in *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235 (9th Cir. 2013), in which it had deferred to the agency's interpretation of the same Medicaid statute. In *Managed Pharmacy*, the language at issue involved a broadly-worded grant of authority in § 30(A) of the statute requiring that payments be consistent with the general concepts of "efficiency,

economy, and quality of care.” Such language, the court explained, showed a congressional intent to give the agency broad discretion as to the meaning of those general terms and therefore deference was owed under the Supreme Court’s decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

In this case, the CMS Rule is far closer to the unambiguous language in *Hoag* than the broad grant of authority in *Managed Pharmacy*. First, the CMS Rule expressly defines “actual acquisition cost” (ACC) as “the agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.” 42 C.F.R. § 447.502. Additionally, it defines “professional dispensing fee” as including costs needed to provide drugs *for a Medicaid patient* (not for a patient covered by private insurance) and specifies costs such as “pharmacist’s time” in checking coverage, “drug utilization review,” “measuring or mixing a drug,” “filing the container” and so on. *Id.*

The CMS Rule also states that in addition to calculating the actual costs, the payments to pharmacies must include a

“professional dispensing fee” to determine limits on reimbursements. *Id.* at §§ 447.512(b)(1); 447.514(b)(1). It also requires that each agency “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 requirements of [§30(A)].” 42 C.F.R. § 447.518(d) (emphasis added). In the context of all this, the CMS Rule makes plain that states “must provide *adequate data* such as State or national survey of retail pharmacy providers or other *reliable data* other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology.” *Id.* (emphasis added).

Just as in *Hoag*, this case does not turn on the broad and general terms of § 30(A). Instead, the focus here is on the express language of the CMS Rule requiring states to consider both ingredient costs and dispensing fees based on pharmacies’ actual costs and provide adequate and reliable data reflecting those costs to pharmacies. None of that is ambiguous and none gives rise to deference to the Agency’s interpretation that its dispensing fees need not be based upon costs. The CMS Rule governs this dispute

and the Agency's refusal to adopt cost-based dispensing fees is an action that is not entitled to deference.

CONCLUSION

The CMS Rule requires states to reimburse pharmacies across the nation serving Medicaid patients. Of the many states that have issued new rates and rules in response to the CMS Rule, all but one have met its terms and purpose. But Washington has not. Here, the Agency's rates, which are dramatically below those of any of the other states, fail to comply.

Washington's reimbursements are far below those of any other state because the Agency failed to do what the CMS Rule requires—base reimbursements on the actual costs for pharmacies to dispense drugs to Medicaid patients. Instead, the Agency decided at the outset that it would not raise dispensing fees and then looked to data from private plans to shore up this pre-determined decision, while ignoring the decision of the insurance commission concluding that the dispensing fees should be almost double what they were. Courts have consistently held that when an agency selectively relies on

biased data to reach such a pre-determined result, then its decision is arbitrary and capricious.

This Court should invalidate both the Agency's rule for establishing dispensing fees and the Agency's action in keeping the dispensing fees unchanged for more than a decade at amounts that are well below pharmacies' costs. This conduct is contrary to the express terms of the CMS Rule and is arbitrary and capricious. The case should be remanded to the Agency to set rates consistent with the CMS Rule which would include providing for proper reimbursements retroactively.

Respectfully submitted,

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APPENDIX A

impact on small rural hospitals although they are required to place NDCs on all claims, including MCO claims, for physician administered drugs since states are required to bill manufacturers for rebates for these drugs. However, the impact on these entities would be minimal because there would be no other requirement except for providing NDC numbers for physician administered drugs. Therefore, the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. At this time, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries.

VI. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately \$144 million. This final rule imposes no mandate on drug manufacturers and other private entities. We believe the rule would not impose additional mandates on states and local governments. This final rule has tribal implications, and in accordance with E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

VII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule does not impose substantial direct requirement costs on state or local governments, preempts state law, or otherwise has federalism implications.

VIII. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been

transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

- 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

- 2. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Sec.

- 447.500 Basis and purpose.
- 447.502 Definitions.
- 447.504 Determination of average manufacturer price.
- 447.505 Determination of best price.
- 447.506 Authorized generic drugs.
- 447.507 Identification of inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs).
- 447.508 Exclusion from best price of certain sales at a nominal price.
- 447.509 Medicaid drug rebates (MDR).
- 447.510 Requirements for manufacturers.
- 447.511 Requirements for States.
- 447.512 Drugs: Aggregate upper limits of payment.
- 447.514 Upper limits for multiple source drugs.
- 447.516 Upper limits for drugs furnished as part of services.
- 447.518 State plan requirements, findings, and assurances.
- 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.
- 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart:

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and best prices and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in

expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(4) Implements section 1903(m)(2)(A)(xiii) of the Act, in part, and section 1927(b) of the Act with regard to rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid managed care organizations (MCOs).

(5) Implements section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

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.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

Bona fide service fee means a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means any arrangement regardless of physical packaging under

which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit national drug code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by CMS and posted on the CMS Web site.

Consumer Price Index—Urban (CPI-U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Covered outpatient drug means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or

304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

(iv) Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):

- (i) Inpatient Services;
- (ii) Hospice Services;
- (iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
- (iv) Physician services;
- (v) Outpatient hospital services;
- (vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;
- (vii) Other laboratory and x-ray services; or
- (viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;

(ii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iii) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(iv) Over-the-counter products that are not drugs.

Customary prompt pay discount means any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA). For purposes of this definition and the Medicaid drug rebates (MDR) program, an original NDA means an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) For authorized generic products, the term “manufacturer” will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term “manufacturer” will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug for which there is at least one other drug product which meets the following criteria:

(1) Is rated as therapeutically equivalent as reported in the FDA’s

“Approved Drug Products with Therapeutic Equivalence Evaluations” which is available at <http://www.accessdata.fda.gov/scripts/cder/ob/>.

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA.

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his or her designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means:

(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;

(2) A multiple source drug that is marketed under an ANDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or

(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type.

Oral solid dosage form means capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3 that defines solid oral dosage form.

Over-the-counter (OTC) drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group meaning from birth through 16 years of age, or a subset of this group as specified in the “Indication and Usage” section of the

FDA approved labeling, or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.

Professional dispensing fee means the professional fee which:

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by FDA and has an approved NDA number issued by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA). For purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

States means the 50 States and the District of Columbia and beginning April 1, 2017, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

United States means the 50 States and the District of Columbia and beginning April 1, 2017 also includes the Commonwealth of Puerto Rico, the

Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

§ 447.504 Determination of average manufacturer price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Average manufacturer price (AMP) means, for a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Average unit price means a manufacturer's sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

Net sales means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term

care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP.* Except for those sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.

(3) Sales to retail community pharmacies (including those sales, nominal price sales, and associated discounts, rebates (other than rebates under section 1927 of the Act or as specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies).

(c) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions excluded from AMP.* AMP excludes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA).

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(4) Sales outside the United States.

(5) Sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales

can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(8) Sales to mail order pharmacies.

(9) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, and mental health centers).

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees, as defined in § 447.502, paid by manufacturers to wholesalers or retail community pharmacies.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D-14A of the Act.

(18) Payments received from and rebates and discounts provided to pharmacy benefit manufacturers (PBM).

(19) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers

and patient assistance programs, but only to the extent that: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(29) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(30) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(d) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* Except for those sales, nominal price sales, and associated discounts, rebates, payments, and other financial transactions identified in paragraph (e) of this section, AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i) covered outpatient drugs identified in accordance with § 447.507 shall include sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions to all entities specified in paragraph (b) of this section, as well as the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

(6) Sales to clinics and outpatient facilities (for example, surgical centers,

ambulatory care centers, dialysis centers, mental health centers).

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(9) Sales to hospices (inpatient and outpatient).

(10) Sales to manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy.

(e) *Sales, nominal price sales, and associated discounts, rebates, payments, or other transactions excluded from AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* AMP for 5i covered outpatient drugs identified in accordance with § 447.507 excludes the following sales, nominal price sales, and associated discounts, rebates, or other financial transactions:

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA).

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(4) Sales outside the United States.

(5) Bona fide service fees as defined in § 447.502 paid by manufacturers to wholesalers or retail community pharmacies.

(6) Customary prompt pay discounts extended to wholesalers.

(7) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only these costs.

(8) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-

PD plan under Part C of such title for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D-22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act.

(9) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(10) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(11) Sales to patients.

(12) Free goods, not contingent upon any purchase requirement.

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(17) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(18) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(19) Sales to charitable pharmacies.

(20) Sales to not-for-profit pharmacies.

(f) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees (other than bona fide service fees), and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

§ 447.505 Determination of best price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

Provider means a hospital, HMO, including an MCO, or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(b) *Prices included in best price.* Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in paragraph (a) of this section.

(c) *Prices excluded from best price.* Best price excludes the following:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, or the PHS.

(2) Any prices charged to a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(3) Any prices charged under the FSS of the GSA.

(4) Any prices, rebates, or discounts provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-PD plan under Part C of such title for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D-22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act.

(7) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(8) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.

(10) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but

only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only these costs.

(15) Nominal prices to certain entities as set forth in § 447.508.

(16) Bona fide service fees as defined in § 447.502.

(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.

(18) Sales outside the United States.

(19) Direct sales to patients.

(d) *Further clarification of best price.*

(1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling, or identifiers on the dosage form or product or package.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Primary manufacturer means a manufacturer that holds the NDA of the authorized generic drug.

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.

(b) *Inclusion of authorized generic drugs in AMP by a primary manufacturer.* The primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price by a primary manufacturer.* A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding the NDA.

(d) *Inclusion of authorized generic in AMP and best price by a secondary manufacturer.* The secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in §§ 447.504 and 447.505.

§ 447.507 Identification of inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs).

(a) *Identification of a 5i drug.* A manufacturer must identify to CMS each covered outpatient drug that qualifies as a 5i drug.

(b) *Not generally dispensed through a retail community pharmacy.* A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 70 percent or more of the sales (based on units at the NDC-9 level) of the 5i drug, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining and reporting to CMS whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly basis.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are

excluded from best price when purchased by the following entities:

- (1) A covered entity as described in section 340B(a)(4) of the PHSA.
- (2) An ICF/IID providing services as set forth in § 440.150 of this chapter.
- (3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.
- (4) A public or non-profit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides family planning services described under section of 1001(a) of PHSA, 42 U.S.C. 300.
- (5) An entity that:
 - (i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and
 - (ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but does not receive funding under a provision of law referred to in such section.

(b) *Nonapplication.* This restriction does not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38 U.S.C. 8126.

(c) *Rule of construction.* Nothing in this section is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a)(5) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates (MDR).

(a) *Determination of rebate amount—*

(1) *Basic rebate for single source drugs and innovator multiple source drugs.* The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of:

- (i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and
- (ii) The greater of:

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages:

- (1) For a clotting factor, 17.1 percent;
- (2) For a drug approved by FDA exclusively for pediatric indications, 17.1 percent; or
- (3) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) *Additional rebate for single source and innovator multiple source drugs.* In

addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) *Total rebate.* The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) *Treatment of new formulations.* (i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) The alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the drug.

(6) *Rebate for noninnovator multiple source drugs.* The amount of the rebate for each dosage form and strength of a noninnovator multiple source drug will be equal to the product of:

(i) The total number of units of such dosage form and strength for which

payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(b) *Rebates for drugs dispensed through Medicaid managed care organizations (MCOs).* (1) Manufacturers participating in the Medicaid drug rebate program will provide a rebate for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are the following:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and

(ii) Discounted under section 340B of the PHSA.

(c) *Federal offset of rebates.* States must remit to the Federal government the amount of the savings resulting from the following increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8.0 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting factors and drugs approved by FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2.0 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the unit rebate amount (URA) calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For noninnovator multiple source drugs, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include the following:

(1) AMP, calculated in accordance with § 447.504.

(2) Best price, calculated in accordance with § 447.505.

(3) Customary prompt pay discounts, which are reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction; that is, not based on any

changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

(2) A manufacturer must report revised AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report—(1) Reporting period.* A manufacturer may report a revised Deficit Reduction Act (DRA) base date AMP to CMS within the first 4 full calendar quarters following July 17, 2007.

(2) *Recalculation of the DRA base date AMP.* (i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in § 447.504 in effect from October 1, 2007 to December 14, 2010.

(ii) A manufacturer may choose to recalculate the DRA base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the DRA base date AMP.

(3) *Reporting a revised Affordable Care Act base date AMP.* A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first 4 full calendar quarters following April 1, 2016.

(4) *Recalculation of the Affordable Care Act base date AMP.* (i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in § 447.504.

(ii) A manufacturer may choose to recalculate the Affordable Care Act base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the Affordable Care Act base date AMP.

(d) *Monthly AMP—(1) Definition.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP is calculated based on § 447.504, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged AMP-eligible price concessions using a 12-month rolling percentage in accordance with the methodology described in this paragraph (d)(2).

(A) For each NDC-9 with at least 12 months of AMP-eligible sales, after adjusting for sales excluded from AMP, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period (inclusive of the current reporting period) available associated with sales subject to the AMP reporting requirement divided by the total in dollars for the sales subject to the AMP reporting requirement for the same 12-month period.

(B) For each NDC-9 with less than 12 months of AMP-eligible sales, the calculation described in paragraph (d)(2)(iii)(A) of this section is performed for the time period equaling the total number of months of AMP-eligible sales.

(iv) The manufacturer multiplies the applicable percentage described in paragraph (d)(2)(iii)(A) or (B) of this section by the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The result of this multiplication is then subtracted from the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted.

(v) The manufacturer uses the result of the calculation described in paragraph (d)(2)(iv) of this section as the numerator and the number of units sold in the month (after adjusting for sales excluded from AMP) as the denominator to calculate the manufacturer's AMP for the NDC for the month being submitted.

(vi) *Example.* After adjusting for sales excluded from AMP, the total lagged price concessions over the most recent 12-month period available associated with sales for NDC 12345-6789 subject to the AMP reporting requirement equal \$200,000, and the total in dollars for the sales subject to the AMP reporting requirement for the same period equals \$600,000. The lagged price concessions percentage for this period equals $200,000/600,000 = 0.33333$. The total in dollars for the sales subject to the AMP

reporting requirement for the month being reported equals \$50,000 for 10,000 units sold. The manufacturer's AMP calculation for this NDC for this month is: $\$50,000 - (0.33333 \times \$50,000) = \$33,334$ (net total sales amount); $\$33,334 / 10,000 = \3.33340 (AMP).

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due, except as allowed in paragraph (b)(1) of this section.

(4) *Exception.* A manufacturer must report revisions to monthly AMP within the 36-month time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(6) *Monthly AMP units.* A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP to CMS not later than 30 days after the last day of each month.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO).

(2) The manufacturer's chief financial officer (CFO).

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (e)(1) through (3) of this section.

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations.

(ii) The 10-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the 10-year period if all of the following circumstances exist:

(i) The records are the subject of an audit, or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format designated by CMS.

§ 447.511 Requirements for States.

(a) *Invoices submitted to participating drug manufacturers.* Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data:

(1) The State code.

(2) National Drug Code.

(3) Period covered.

(4) Product FDA list name.

(5) Unit rebate amount.

(6) Units reimbursed.

(7) Rebate amount claimed.

(8) Number of prescriptions.

(9) Medicaid amount reimbursed.

(10) Non-Medicaid amount reimbursed.

(11) Total amount reimbursed.

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers.

(c) *State that has participating Medicaid Managed care organizations (MCO).* A State that has participating Medicaid managed care organizations (MCO) which includes covered outpatient drugs in its contracts with the MCOs, must report data described in paragraph (a) of this section for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is required under contract for coverage of such drugs under section 1903 of the Act. These data must be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance

with § 447.514. If a specific limit has not been established under § 447.514, then the rule for "other drugs" set forth in paragraph (b) of this section applies.

(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.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.

(2) The agency must decide what certification form and procedure are used.

(3) A check off box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs available for purchase by retail community pharmacies on a nationwide basis that FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in the "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.accessdata.fda.gov/scripts/cder/ob/>. Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those equivalent drug products.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* (1) The agency's payments for multiple source drugs identified and listed periodically

by CMS in Medicaid Program issuances must not exceed, in the aggregate, prior to the application of any federal or state drug rebate considerations, payment levels determined by applying for each pharmaceutically and therapeutically equivalent multiple source drug product, a professional dispensing fee established by the state agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMPs for such multiple source drugs, using manufacturer submitted utilization data for each multiple source drug for which a Federal upper limit (FUL) is established.

(2) *Exception.* If the amount established by CMS in paragraph (b)(1) of this section for a pharmaceutically and therapeutically equivalent multiple source drug product is lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs, CMS will use a percent of the weighted average of the most recently reported monthly AMPs that equals the most current average acquisition costs paid by retail community pharmacies as determined by such survey.

(c) *Ensuring a drug is for sale nationally.* To assure that a multiple source drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the termination date reported by the manufacturer to CMS.

(2) The monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL.

(d) The FUL will be applied as an aggregate upper limit.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings, and assurances.

(a) *State plan.* (1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(i) A covered entity described in section 1927(a)(5)(B) of the Act.

(ii) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(iii) An Indian Health Service, tribal and urban Indian pharmacy.

(2) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a), are in accordance with the upper limits specified in § 447.514(b).

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(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 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.

§ 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers to secure rebates.

(2) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(b) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers to secure rebates.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

§ 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

(a) Medicaid coverage of investigational drugs may be provided at State option under section 1905(a)(12) of the Act when such drug is the subject of an investigational new drug application (IND) that has been allowed by FDA to proceed.

(b) A State agency electing to provide coverage of an investigational drug must include in its State plan a description of the coverage and payment for such drug.

(c) The State plan must indicate that any reimbursement for investigational drugs by the State are consistent with FDA regulations at 21 CFR part 312 if they are to be eligible to receive FFP for these drugs.

(d) Medicaid coverage of other drugs may be provided at State option under section 1905(a)(12) of the Act provided that they are not eligible to be covered as covered outpatient drugs in the Medicaid Drug Rebate program.

(e) Investigational drugs and other drugs are not subject to the rebate requirements of section 1927 of the Act provided they do not meet the definition of a covered outpatient drug as set forth in section 1927(k) of the Act.

Dated: October 1, 2015.

Andrew M. Slavitt,

*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Dated: November 24, 2015.

Sylvia M. Burwell,

*Secretary, Department of Health and Human
Services.*

[FR Doc. 2016-01274 Filed 1-21-16; 4:15 pm]

BILLING CODE 4120-01-P



RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Health Care Authority, Washington Apple Health

Permanent Rule Only

Effective date of rule:

Permanent Rules

- 31 days after filing.
- Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes
 - No
- If Yes, explain:

Purpose: The agency is revising this chapter to align with the Centers for Medicare and Medicaid Services (CMS) new covered outpatient drug rule, CMS-2345-FC. The agency is also amending these rules to increase the number of drug classes eligible for supplemental rebates. Changes include but are not limited to definition updates; new language about drugs, devices, and drug-related supplies; authorization updates; new language about point-of-sale and actual acquisition costs; updates to therapeutic interchange program; clarified processes for mail order and specialty pharmacy services; added information on 340B providers; added information on Medicare Part A, B, and C; and revised section on drugs purchased under the Public Health Services act.

Citation of existing rules affected by this order:

Repealed: None
 Amended: 182-530-1050, 182-530-3000, 182-530-3100, 182-530-3200, 182-530-4100, 182-530-4125, 182-530-4150, 182-530-6000, 182-530-7000, 182-530-7050, 182-530-7150, 182-530-7250, 182-530-7300, 182-530-7700, 182-530-7900, 182-530-8000, 182-530-8100, 182-530-8150
 Suspended: None

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 17-02-083 on January 4, 2017.
Describe any changes other than editing from proposed to adopted version: See Appendix

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: _____ phone () _____
 Address: _____ fax () _____
 e-mail _____

Date adopted: March 1, 2017

CODE REVISER USE ONLY

NAME (TYPE OR PRINT)
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 01, 2017
TIME: 12:29 PM

WSR 17-07-001

(COMPLETE REVERSE SIDE)

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in the agency's own initiative:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	_____	Amended	<u>18</u>	Repealed	_____
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	<u>18</u>	Repealed	_____

Appendix

Note: Strikeouts and underlines indicate language deleted or added since the proposal.

WAC 182-530-1050

Dispensing fee - ~~"Means professional dispensing fee."~~ See professional dispensing fee.

WAC 182-530-1050

"Evidence-based drug reviews" ~~and evidence-based medicine (EBM)~~ The application of a set of principles and a methods ~~for comprehensive independent and objective evaluation of clinical evidence provided in for the review of well-designed and well-conducted~~ studies and objective clinical data to determine the level of evidence that proves to the greatest extent possible, that a health care service is safe, effective and beneficial when making population-based coverage policies or individual medical necessity decisions. Classifying evidence by its epistemologic strength and requiring that only the strongest types (coming from meta-analyses, systematic reviews, and randomized controlled trials) can yield strong recommendations; weaker types (such as from case-control studies) can yield weak recommendations.

WAC 182-530-1050

"Evidence-based practice center" or "EPC" – A research organization that has been designated by the Agency for Healthcare Research and Quality (AHRQ) to develop evidence reports and technology assessments on topics relevant to clinical and other health care organization and delivery issues, specifically those that are common, expensive, or significant for the medicare and medicaid populations.

WAC 182-530-1050

"Medicaid preferred drug list (medicaid PDL)" - The list of all drugs in drug classes approved for inclusion by the Washington medicaid drug use review (DUR) board and each drug's preferred or nonpreferred status as ~~determined approved~~ by the agency director or designee. The list includes at minimum all drugs and drug classes on the Washington PDL and may include additional drugs and drug classes ~~at the discretion of~~ recommended by the DUR board and approved by the agency director or designee.

WAC 182-530-3100 (1)(b)

In performing this evaluation the clinical team may consult with other agency clinical staff, financial experts, and program managers. The agency clinical team may also consult with an evidence-based practice center (EPC), evidence-based drug reviews, other purchasers, the drug use review (DUR) board, and medical experts in this evaluation.

WAC 182-530-4100(2)

The pharmacy and therapeutics (P&T) committee or the drug use review (DUR) board reviews and evaluates the safety, efficacy, and outcomes of prescribed drugs, using evidence-based drug reviews information ~~provided by the vendor.~~

WAC 182-530-4100 (5)

Drugs in a drug class on the medicaid PDL ~~only but which are~~ not on the Washington PDL are not subject to therapeutic interchange program (TIP) and dispense as written (DAW) rules under WAC 182-530-4150.

WAC 182-530-7900(4):

Exceptions to the 340B AAC billing requirement are only made for:

- (a) Outpatient hospital claims paid under the enhanced ambulatory payment group (EAPG) methodology (see WAC 182-550-7000); and
- (b) Ambulatory surgery claims paid under payment groups methodology; ~~and~~
- (c) ~~Family planning clinics billing contraceptives designated by the agency to be paid at 340B ceiling price plus a professional dispensing fee.~~

AMENDATORY SECTION (Amending WSR 13-18-035, filed 8/28/13, effective 9/28/13)

WAC 182-530-1050 Definitions. In addition to the definitions and abbreviations found in chapter 182-500 WAC, Medical definitions, the following definitions apply to this chapter.

"Active ingredient" - The chemical component of a drug responsible for a drug's prescribed/intended therapeutic effect. The medicaid agency or its designee limits coverage of active ingredients to those with an eleven-digit national drug code (NDC) and those specifically authorized by the agency or its designee.

"Actual acquisition cost (AAC)" - ~~((The net cost a provider paid for a drug, device, or drug-related supply marketed in the package size purchased. The AAC includes discounts, rebates, charge backs and other adjustments to the price of the drug, device or drug-related supply, but excludes dispensing fees.))~~ Refers to one of the following:

(1) Provider AAC - The true cost a provider paid for a specific drug or product in the package size purchased, including discounts, rebates, charge backs that affect the provider's invoice price, and other adjustments to the price of the drug, device or drug-related supply, excluding dispensing fees;

(2) 340B AAC - The true cost paid by a public health service (PHS)-qualifying entity for a specific drug, excluding dispensing fees; or

(3) POS AAC - The agency-determined rate paid to pharmacies through the point-of-sale (POS) system, and intended to reflect pharmacy providers' actual acquisition cost.

"Administer" - Includes the direct application of a prescription drug or device by injection, insertion, inhalation, ingestion, or any other means, to the body of a patient by a practitioner, or at the direction of the practitioner.

"Appointing authority" - ~~((For the evidence-based prescription drug program of the participating agencies in the state operated health care programs, the following persons acting jointly: The director of the health care authority (HCA), the secretary of the department of social and health services (DSHS), and the director of the department of labor and industries (L&I).))~~ Means the following people acting jointly: The director of the Washington state health care authority and the director of the Washington state department of labor and industries.

"Authorized generic drug" - Any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

"Automated authorization" - Adjudication of claims using submitted NCPDP data elements or claims history to verify that the medicaid agency's or its designee's authorization requirements have been satisfied without the need for the medicaid agency or its designee to request additional clinical information.

"Automated maximum allowable cost (AMAC)" - The rate established by the medicaid agency or its designee for a multiple-source drug that is not on the maximum allowable cost (MAC) list and that is designated

by two or more products at least one of which must be under a federal drug rebate contract.

"Average manufacturer price (AMP)" - The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies.

"Average sales price (ASP)" - The weighted average of all nonfederal sales to wholesalers net of charge backs, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer.

"Average wholesale price (AWP)" - ~~((The average))~~ A reference price of a drug product that is ((calculated from wholesale list prices nationwide)) published at a point in time and reported to the medicaid agency or its designee by the agency's drug file contractor.

~~("Combination drug" - A commercially available drug including two or more active ingredients.)~~ **"Brand name drug"** - A single-source or innovator multiple-source drug.

"Compendia of drug information" includes the following:

- (1) The American Hospital Formulary Service Drug Information;
- (2) The United States Pharmacopeia Drug Information; and
- (3) DRUGDEX Information System.

"Compounding" - The act of combining two or more active ingredients or adjusting therapeutic strengths in the preparation of a prescription.

"Deliver or delivery" - The transfer of a drug or device from one person to another.

"Dispense as written (DAW)" - An instruction to the pharmacist forbidding substitution of a generic drug or a therapeutically equivalent product for the specific drug product prescribed.

~~"Dispensing fee" - ((The fee the medicaid agency or its designee sets to pay pharmacy providers for dispensing 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.~~

~~"Drug evaluation matrix" - The criteria based scoring sheet used to objectively and consistently evaluate the food and drug administration (FDA) approved drugs to determine drug coverage status.)~~ Means professional dispensing fee. See professional dispensing fee.

"Drug file" - A list of drug products, pricing and other information provided to the medicaid agency or its designee and maintained by a drug file contractor.

"Drug file contractor" - An entity which has been contracted to provide regularly updated information on drugs, devices, and drug-related supplies at specified intervals, for the purpose of pharmaceutical claim adjudication. Information is provided specific to individual national drug codes, including product pricing.

~~("Drug rebates" - Reimbursements provided by pharmaceutical manufacturers to state medicaid programs under the terms of the manufacturers' agreements with the Department of Health and Human Services (DHHS).)~~

"Drug-related supplies" - Nondrug items necessary for the administration, delivery, or monitoring of a drug or drug regimen.

"Drug use review (DUR)" - A review of covered outpatient drug use that assures prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

"Effectiveness" - The extent to which a given intervention is likely to produce beneficial results for which it is intended in ordinary circumstances.

"Efficacy" - The extent to which a given intervention is likely to produce beneficial effects in the context of the research study.

"Emergency kit" - A set of limited pharmaceuticals furnished to a nursing facility by the pharmacy that provides prescription dispensing services to that facility. Each kit is specifically set up to meet the emergency needs of each nursing facility's client population and is for use during those hours when pharmacy services are unavailable.

"Endorsing practitioner" - A practitioner who has reviewed the Washington preferred drug list (Washington PDL) and has enrolled with the health care authority (HCA), agreeing to allow therapeutic interchange (substitution) of a preferred drug for any nonpreferred drug in a given therapeutic class on the Washington PDL.

"Estimated acquisition cost (EAC)" - The medicaid agency's estimate of the price providers generally and currently pay for a drug marketed or sold by a particular manufacturer or labeler.

"Evidence-based (~~"~~ and ~~"evidenced-based medicine (EBM)"~~) drug reviews" - The application of a set of principles and ((a method for the review of)) methods for comprehensive independent and objective evaluation of clinical evidence provided in well-designed and well-conducted studies and objective clinical data to determine the level of evidence that proves to the greatest extent possible, that a health care service is safe, effective and beneficial when making population-based coverage policies or individual medical necessity decisions. Classifying evidence by its epistemologic strength and requiring that only the strongest types (coming from meta-analyses, systematic reviews, and randomized controlled trials) can yield strong recommendations; weaker types (such as from case-control studies) can yield weak recommendations.

"Evidence-based practice center" or "EPC" - A research organization that has been designated by the Agency for Healthcare Research and Quality (AHRQ) ((of the U.S. government to conduct systematic reviews of all the evidence to produce evidence tables and technology assessments to guide health care decisions)) to develop evidence reports and technology assessments on topics relevant to clinical and other health care organization and delivery issues, specifically those that are common, expensive, or significant for the medicare and medicaid populations.

"Federal drug rebates" - Dollars returned to medicaid from pharmaceutical manufacturers under the terms of the manufacturers' national rebate agreement with the federal Department of Health and Human Services (DHHS).

"Federal upper limit (FUL)" - The maximum allowable reimbursement set by the Centers for Medicare and Medicaid Services (CMS) for a multiple-source drug.

((**"Four brand name prescriptions per calendar month limit"** - The maximum number of paid prescription claims for brand name drugs that the medicaid agency or its designee allows for each client in a calendar month without a complete review of the client's drug profile.))

"Generic drug" - A ((nonproprietary)) drug that is ((required to meet the same bioequivalency tests as the original brand name drug)) approved by the Food and Drug Administration (FDA) under an abbreviated new drug application.

"Inactive ingredient" - A drug component that remains chemically unchanged during compounding but serves as the:

(1) Necessary vehicle for the delivery of the therapeutic effect;

or

(2) Agent for the intended method or rate of absorption for the drug's active therapeutic agent.

"Ingredient cost" - The portion of a prescription's cost attributable to the covered drug ingredients or chemical components.

"Innovator multiple-source drug" - ~~((As set forth in Section 1927(k)(7)(A)(ii) of the Social Security Act, includes all covered outpatient drugs approved under a new drug application (NDA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved new drug application will be included as an innovator multiple source drug when the drug product meets this definition.))~~ A multiple-source drug that was originally marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. This includes:

(1) A drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA; or

(2) A covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).

"Less than effective drug" or "DESI" - A drug for which:

(1) Effective approval of the drug application has been withdrawn by the Food and Drug Administration (FDA) for safety or efficacy reasons as a result of the drug efficacy study implementation (DESI) review; or

(2) The secretary of the federal Department of Health and Human Services (DHHS) has issued a notice of an opportunity for a hearing under section 505(e) of the federal Food, Drug, and Cosmetic Act on a proposed order of the secretary to withdraw approval of an application for such drug under such section because the secretary has determined the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling.

~~((**"Long-term therapy"** - A drug regimen a client receives or will receive continuously through and beyond ninety days.))~~

"Maximum allowable cost (MAC)" - The maximum amount ~~((that))~~ the medicaid agency or its designee reimburses for a drug, device, or drug-related supply.

"Medicaid preferred drug list (medicaid PDL)" - The list of all drugs in drug classes approved for inclusion by the Washington medicaid drug use review (DUR) board and each drug's preferred or nonpreferred status as approved by the agency director or designee. The list includes at minimum all drugs and drug classes on the Washington PDL and may include additional drugs and drug classes recommended by the DUR board and approved by the agency director or designee.

"Medically accepted indication" - Any use for a covered outpatient drug:

(1) Which is approved under the federal Food, Drug, and Cosmetic Act; or

(2) The use of which is supported by one or more citations included or approved for inclusion in any of the compendia of drug information, as defined in this chapter.

"Modified unit dose delivery system" (also known as blister packs or "bingo/punch cards") - A method in which each patient's medication is delivered to a nursing facility:

(1) In individually sealed, single dose packages or "blisters"; and

(2) In quantities for one month's supply, unless the prescriber specifies a shorter period of therapy.

"Multiple-source drug" - A drug ((~~marketed or sold by:~~

~~(1) Two or more manufacturers or labelers; or~~

~~(2) The same manufacturer or labeler;~~

~~(a) Under two or more different proprietary names; or~~

~~(b) Under a proprietary name and a generic name)) for which there is at least one other drug product sold in the United States that is pharmaceutically equivalent and bioequivalent, as determined by the Food and Drug Administration (FDA).~~

"National drug code (NDC)" - ~~The eleven-digit ((number the FDA and manufacturer or labeler assigns to a pharmaceutical product and attaches to the product container at the time of packaging. The NDC is composed of digits in 5-4-2 groupings. The first five digits comprise the labeler code assigned to the manufacturer by the Food and Drug Administration (FDA). The second grouping of four digits is assigned by the manufacturer to describe the ingredients, dose form, and strength. The last grouping of two digits describes the package size.~~

"Noncontract drugs" - ~~Are drugs manufactured or distributed by manufacturers/labelers who have not signed a drug rebate agreement with the federal Department of Health and Human Services)) numerical code that includes the labeler code, product code, and package code.~~

"National rebate agreement" - ~~The agreement developed by the Centers for Medicare and Medicaid Services (CMS) to implement section 1927 of the Social Security Act, and entered into by a manufacturer and the federal Department of Health and Human Services (DHHS).~~

"Noninnovator multiple-source drug" - ~~A drug that is:~~

~~(1) A multiple-source drug that is not an innovator multiple-source drug or a single-source drug;~~

~~(2) A multiple-source drug marketed under an abbreviated new drug application (ANDA) or an abbreviated antibiotic drug application;~~

~~(3) A covered outpatient drug that entered the market before 1962 and was originally marketed under a new drug application (NDA); or~~

~~(4) Any drug that has not gone through a Food and Drug Administration (FDA) approval process but otherwise meets the definition of a covered outpatient drug.~~

~~If any of the drug products listed in this definition of a noninnovator multiple-source drug subsequently receive an NDA or ANDA approval from the FDA, the product's drug category changes to correlate with the new product application type.~~

"Nonpreferred drug" - ~~A drug ((that has not been selected as a preferred drug)) within ((the)) a therapeutic ((class(es))) class of drugs on the medicaid preferred drug list (medicaid PDL) that has not been selected as a preferred drug.~~

"Obsolete NDC" - ~~A national drug code replaced or discontinued by the manufacturer or labeler.~~

"Over-the-counter (OTC) drugs" - ~~Drugs that do not require a prescription before they can be sold or dispensed.~~

"Peer reviewed medical literature" - ~~A research study, report, or findings regarding the specific use of a drug that has been submitted to one or more professional journals, reviewed by experts with appropriate credentials, and subsequently published by a reputable professional journal. A clinical drug study used as the basis for the publication must be a double blind, randomized, placebo or active control study.~~

"Pharmacist" - ~~A person licensed in the practice of pharmacy by the state in which the prescription is filled.~~

"Pharmacy" - Every location licensed by the state board of pharmacy in the state where the practice of pharmacy is conducted.

"Pharmacy and therapeutic (P&T) committee" - The independent Washington state committee created by RCW 41.05.021 (1)(a)(iii) and 70.14.050. At the election of the medicaid agency or its designee, the committee may serve as the drug use review board provided for in WAC 182-530-4000.

"Point-of-sale (POS)" - A pharmacy claims processing system capable of receiving and adjudicating claims online.

"Practice of pharmacy" - The practice of and responsibility for:

- (1) Accurately interpreting prescription orders;
- (2) Compounding drugs;
- (3) Dispensing, labeling, administering, and distributing of drugs and devices;
- (4) Providing drug information to the client that includes, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices;
- (5) Monitoring of drug therapy and use;
- (6) Proper and safe storage of drugs and devices;
- (7) Documenting and maintaining records;
- (8) Initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for a pharmacist's practice by a practitioner authorized to prescribe drugs; and
- (9) Participating in drug use reviews and drug product selection.

"Practitioner" - An individual who has met the professional and legal requirements necessary to provide a health care service, such as a physician, nurse, dentist, physical therapist, pharmacist or other person authorized by state law as a practitioner.

"Preferred drug" - ~~((Drug(s) of choice within a selected therapeutic class that are selected based on clinical evidence of safety, efficacy, and effectiveness.~~

"Preferred drug list (PDL)" - ~~The medicaid agency's list of drugs of choice within selected therapeutic drug classes.)~~ A drug within a therapeutic class of drugs on the medicaid preferred drug list (medicaid PDL) that has been selected as a preferred drug.

"Prescriber" - A physician, osteopathic physician/surgeon, dentist, nurse, physician assistant, optometrist, pharmacist, or other person authorized by law or rule to prescribe drugs. See WAC 246-863-100 for pharmacists' prescriptive authority.

"Prescription" - An order for drugs or devices issued by a practitioner authorized by state law or rule to prescribe drugs or devices, in the course of the practitioner's professional practice, for a legitimate medical purpose.

"Prescription drugs" - Drugs required by any applicable federal or state law or regulation to be dispensed by prescription only or that are restricted to use by practitioners only.

"Professional dispensing fee":

(1) The fee the medicaid agency or its designee pays pharmacists and dispensing providers 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 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.

"Prospective drug use review (Pro-DUR)" - A process in which a request for a drug product for a particular client is screened, before the product is dispensed, for potential drug therapy problems.

"Reconstitution" - The process of returning a single active ingredient, previously altered for preservation and storage, to its approximate original state. Reconstitution is not compounding.

"Retrospective drug use review (Retro-DUR)" - The process in which drug utilization is reviewed on an ongoing periodic basis to identify patterns of fraud, abuse, gross overuse, or inappropriate or not medically necessary care.

~~(("Risk/benefit ratio" - The result of assessing the side effects of a drug or drug regimen compared to the positive therapeutic outcome of therapy.)~~

"Single-source drug" - A drug produced or distributed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA) (-

~~"Substitute" - To replace a prescribed drug, with the prescriber's authorization, with:~~

~~(1) An equivalent generic drug product of the identical base or salt as the specific drug product prescribed; or~~

~~(2) A therapeutically equivalent drug other than the identical base or salt)) with an approved new drug application (NDA) number issued by the FDA. This includes:~~

~~(1) A drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA; or~~

~~(2) A drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).~~

For the purposes of this definition, an ANDA is not an NDA.

"Systematic review" - A specific and reproducible method to identify, select, and appraise all the studies that meet minimum quality standards and are relevant to a particular question. The results of the studies are then analyzed and summarized into evidence tables to be used to guide evidence-based decisions.

"Terminated NDC" - An eleven-digit national drug code (NDC) that is discontinued by the manufacturer for any reason. The NDC may be terminated immediately due to health or safety issues or it may be phased out based on the product's shelf life.

"Therapeutic alternative" - A drug product that contains a different chemical structure than the drug prescribed, but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage.

"Therapeutic class" - A group of drugs used for the treatment, remediation, or cure of a specific disorder or disease.

"Therapeutic interchange" - To dispense a therapeutic alternative to the prescribed drug when an endorsing practitioner who has indicated that substitution is permitted, prescribes the drug. See therapeutic interchange program (TIP).

"Therapeutic interchange program (TIP)" - The process developed by participating state agencies under RCW 69.41.190 and 70.14.050, to

allow prescribers to endorse a Washington preferred drug list, and in most cases, requires pharmacists to automatically substitute a preferred, equivalent drug from the list.

"Therapeutically equivalent" - Drug products that contain different chemical structures but have the same efficacy and safety when administered to an individual, as determined by:

- (1) Information from the Food and Drug Administration (FDA);
- (2) Published and peer-reviewed scientific data;
- (3) Randomized controlled clinical trials; or
- (4) Other scientific evidence.

"Tiered dispensing fee system" - A system of paying pharmacies different dispensing fee rates, based on the individual pharmacy's total annual prescription volume and/or the drug delivery system used.

"True unit dose delivery" - A method in which each patient's medication is delivered to the nursing facility in quantities sufficient only for the day's required dosage.

"Unit dose drug delivery" - True unit dose or modified unit dose delivery systems.

"Usual and customary charge" - The fee that the provider typically charges the general public for the product or service.

"Washington preferred drug list (Washington PDL)" - The list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for purchase of drugs in state-operated health care programs.

"Wholesale acquisition cost" - ~~((The price))~~ Refers to either the actual wholesale cost paid by a wholesaler for drugs purchased from a manufacturer or a list price published as wholesale acquisition cost.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-3000 ~~When the medicaid agency requires authorization. ((Pharmacies must obtain authorization for covered drugs, devices, or drug-related supplies in order to receive reimbursement as described in this section.))~~ Covered drugs, devices, or drug-related supplies require authorization for reimbursement when:

(1) The medicaid agency's pharmacists ~~((and))~~ or medical consultants:

(a) Have determined that authorization for the drug, device, or drug-related supply is required, as described in WAC 182-530-3100; or

(b) Have not yet reviewed the ~~((manufacturer's dossier of drug information submitted in the Academy of Managed Care Pharmacy (AMCP) format))~~ drug, device, or drug-related supply as described in WAC 182-530-3100.

(2) The drug, device, or drug-related supply is in ~~((the))~~ a therapeutic drug class on the Washington preferred drug list and the product is one of the following:

(a) Nonpreferred as described in WAC 182-530-4100; and

(i) The prescriber is a nonendorsing practitioner; or

(ii) The drug is designated as exempt from the therapeutic interchange program per WAC 182-530-4100(6) or 182-530-4150 (2)(a);

(b) Preferred for a special population or specific indication and has been prescribed by a nonendorsing practitioner under conditions

for which the drug, device, or drug-related supply is not preferred;
or

(c) Determined to require authorization for safety.

(3) ~~((For the purpose of))~~ The agency is promoting safety, efficacy, and effectiveness of drug therapy, or the agency identifies clients or groups of clients who would benefit from further clinical review.

(4) The agency designates the prescriber(s) as requiring authorization because the prescriber(s) is under agency review or is sanctioned for substandard quality of care.

(5) Utilization data indicate there are health and safety concerns or the potential for misuse and abuse. Examples of utilization concerns include:

(a) Multiple prescriptions filled ~~((ef))~~ for the same drug in the same calendar month;

(b) Prescriptions filled earlier than necessary for optimal therapeutic response;

(c) Therapeutic duplication;

(d) Therapeutic contraindication;

(e) Excessive dosing, excessive duration of therapy, or subtherapeutic dosing as determined by FDA labeling or the compendia of drug information; and

(f) Number of prescriptions filled per month in total or by therapeutic drug class.

(6) The pharmacy requests reimbursement in excess of the maximum allowable cost and the drug has been prescribed with instructions to dispense as written.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-3100 How the medicaid agency determines when a drug requires authorization. (1) The medicaid agency's pharmacists ~~((and))~~ or medical consultants periodically evaluate ~~((new))~~ covered drugs, ~~((new))~~ covered indications, or new dosages approved by the Food and Drug Administration (FDA) to determine the drug authorization requirement.

(a) The clinical team ~~((uses a drug evaluation matrix to evaluate and score the benefit/risk assessment and cost comparisons of drugs to similar existing drugs))~~ evaluates and grades available information for each drug or drug class based on quality evidence contained in compendia of drug information and peer-reviewed medical literature. The information evaluated includes, but is not limited to:

(i) Evidence for efficacy and safety;

(ii) Cost comparisons of drugs with similar existing drugs;

(iii) Potential for clinical misuse;

(iv) Potential for client misuse or abuse;

(v) Drugs with a narrow therapeutic index;

(vi) Other safety concerns; or

(vii) Product cost and outcome data demonstrating the cost effectiveness of the drug, device, or drug-related supply.

(b) In performing this evaluation the clinical team may consult with other agency clinical staff, financial experts, and program managers. The agency clinical team may also consult with an evidence-

based practice center (EPC), evidence-based drug reviews, other purchasers, the drug use review (DUR) board, and medical experts in this evaluation.

(c) ~~((Information reviewed in the drug evaluation matrix includes, but is not limited to, the following:~~

~~(i) The drug, device, or drug-related supply's benefit/risk ratio;~~

~~(ii) Potential for clinical misuse;~~

~~(iii) Potential for client misuse/abuse;~~

~~(iv) Narrow therapeutic indication;~~

~~(v) Safety concerns;~~

~~(vi) Availability of less costly therapeutic alternatives; and~~

~~(vii) Product cost and outcome data demonstrating the drug, device, or drug-related supply's cost effectiveness.~~

~~(d)) Based on the clinical team's evaluation ((and the drug evaluation matrix score)), the agency may determine that the drug, device, or drug-related supply:~~

~~(i) Requires authorization;~~

~~(ii) Requires authorization to exceed agency-established limitations; or~~

~~(iii) Does not require authorization.~~

~~(2) ((Drugs in therapeutic classes on the Washington preferred drug list are not subject to determination of authorization requirements through the drug evaluation matrix. Authorization requirements are determined by their preferred status according to WAC 182-530-4100.~~

~~(3)) The agency periodically reviews existing drugs, devices, or drug-related supplies and reassigns authorization requirements as necessary according to the same provisions as outlined above for new drugs, devices, or pharmaceutical supplies.~~

~~((4)) (3) For any drug, device, or drug-related supply with limitations or requiring authorization, the agency may elect to apply automated authorization criteria according to WAC 182-530-3200.~~

AMENDATORY SECTION (Amending WSR 16-17-071, filed 8/16/16, effective 9/16/16)

WAC 182-530-3200 The medicaid agency's authorization process.

(1) The agency may establish automated ways for pharmacies to meet authorization requirements for specified drugs, devices, and drug-related supplies, or circumstances as listed in WAC 182-530-3000 ~~((3) and (4))~~ including, but not limited to:

(a) Use of expedited authorization codes as published in the agency's prescription drug program billing instructions ~~((and numbered memoranda))~~;

(b) Use of specified values in national council of prescription drug programs (NCPDP) claim fields;

(c) Use of diagnosis codes; and

(d) Evidence of previous therapy within the agency's claim history.

(2) When the automated requirements in subsection (1) of this section do not apply or cannot be satisfied, the pharmacy provider must request authorization from the agency before dispensing. The pharmacy provider must:

(a) Ensure the request states the medical diagnosis and includes medical justification for the drug, device, drug-related supply, or circumstance as listed in WAC 182-530-3000 (~~(3) and (4)~~); and

(b) Keep documentation on file of the prescriber's medical justification that is communicated to the pharmacy by the prescriber at the time the prescription is filled. The records must be retained for the period specified in WAC 182-502-0020(5).

(3) When the agency receives the request for authorization:

(a) The agency acknowledges receipt:

(i) Within twenty-four hours if the request is received during normal state business hours; or

(ii) Within twenty-four hours of opening for business on the next business day if received outside of normal state business hours.

(b) The agency reviews all evidence submitted and takes one of the following actions within fifteen business days:

(i) Approves the request;

(ii) Denies the request if the requested service is not medically necessary; or

(iii) Requests the prescriber submit additional justifying information.

(A) The prescriber must submit the additional information within ten days of the agency's request.

(B) The agency approves or denies the request within five business days of the receipt of the additional information.

(C) If the prescriber fails to provide the additional information within ten days, the agency will deny the requested service. The agency sends a copy of the request to the client at the time of denial.

(4) The agency's authorization determination may be based on, but not limited to:

(a) Requirements under this chapter and WAC 182-501-0165;

(b) Client safety;

(c) Appropriateness of drug therapy;

(d) Quantity and duration of therapy;

(e) Client age, gender, pregnancy status, or other demographics; and

(f) The least costly therapeutically equivalent alternative.

(5) The agency evaluates request for authorization of covered drugs, devices, and drug-related supplies that exceed limitations in this chapter on a case-by-case basis in conjunction with subsection (4) of this section and WAC 182-501-0169.

(6) If a provider needs authorization to dispense a covered drug outside of normal state business hours, the provider may dispense the drug without authorization only in an emergency. The agency must receive justification from the provider within seven days of the fill date to be reimbursed for the emergency fill.

(7) The agency may remove authorization requirements under WAC 182-530-3000 for, but not limited to, the following:

(a) Prescriptions written by specific practitioners based on consistent high quality of care; or

(b) Prescriptions filled at specific pharmacies and billed to the agency at the pharmacies' lower acquisition cost.

(8) Authorization requirements in WAC 182-530-3000 are not a denial of service.

(9) Rejection of a claim due to the authorization requirements listed in WAC 182-530-3000 is not a denial of service.

(10) When a claim requires authorization, the pharmacy provider must request authorization from the agency. If the pharmacist fails to

request authorization as required, the agency does not consider this a denial of service.

(11) Denials that result as part of the authorization process will be issued by the agency in writing.

(12) The agency's authorization:

- (a) Is a decision of medical appropriateness; and
- (b) Does not guarantee payment.

AMENDATORY SECTION (Amending WSR 15-12-093, filed 6/2/15, effective 7/3/15)

WAC 182-530-4100 ((Washington)) Medicaid preferred drug list (medicaid PDL). ~~((Under RCW 69.41.190 and 70.14.050, the medicaid agency and other state agencies cooperate in developing and maintaining the Washington preferred drug list (PDL).~~

~~((1) Washington state)) (1) The medicaid agency contracts with ((evidence-based practice centers for)) a vendor to perform systematic evidence-based drug reviews.~~

(2) The pharmacy and therapeutics (P&T) committee or the drug use review (DUR) board reviews and evaluates the safety, efficacy, and outcomes of prescribed drugs, using evidence-based ~~((information provided by the evidence-based practice centers))~~ drug reviews.

(3) The P&T committee makes recommendations to state agencies as to which drugs to include on the Washington PDL under chapter 182-50 WAC. The DUR board makes recommendations to the medicaid agency about which additional drug classes to include in the medicaid PDL.

(4) The ~~((appointing authority))~~ agency director or designee makes the final selection of drugs or drug classes included on the ~~((Washington))~~ medicaid PDL.

(5) Drugs in a drug class on the ~~((Washington PDL that have been studied by an evidence-based practice center and reviewed by the P&T committee and which have not been selected as preferred are considered nonpreferred drugs and are subject to the))~~ medicaid PDL which are not on the Washington PDL are not subject to therapeutic interchange program (TIP) and dispense as written (DAW) rules under WAC 182-530-4150.

(6) Drugs in a drug class on the ~~((Washington))~~ medicaid PDL that ((have not been studied by an evidence-based practice center and)) have not been reviewed by the P&T committee ((will)) or the DUR board may be treated as nonpreferred drugs and are not subject to ((the dispense as written (DAW) or the therapeutic interchange program (TIP)) DAW or TIP.

(7) A nonpreferred drug ~~((which the agency determines as covered))~~ is considered for authorization after the client has:

(a) Tried and failed or is intolerant to at least one preferred drug; and

(b) Met agency-established criteria for the nonpreferred drug.

(8) Drugs in a drug class on the ~~((Washington))~~ medicaid PDL may be designated as preferred drugs for special populations or specific indications.

(9) Drugs in a drug class on the ~~((Washington))~~ medicaid PDL may require authorization ~~((for safety))~~ regardless of preferred or non-preferred status.

~~(10) ((Combination drugs that have been studied by an evidence-based practice center and have been reviewed by the P&T committee may be included in the Washington PDL.~~

~~(11)) When a ((brand name)) preferred innovator drug ((has been reviewed by the P&T committee)) or biological product on the Medicaid PDL loses its patent, the agency may ((immediately)):~~

~~(a) Designate an available, ((less expensive,)) equally effective, generic equivalent, or biosimilar biological product as a preferred drug((. For the purpose of this chapter, generic equivalent drugs are those identified in the Food and Drug Administration's approved drug products with therapeutic equivalence evaluations (orange book).~~

~~(12) The dispensing of a brand name or nonpreferred generic drug in a drug class on the Washington PDL as a client's first course of treatment within that therapeutic class may be subject to restrictions under WAC 182-530-4125 and 182-530-4150(10)); and~~

~~(b) Make the innovator drug or biological product nonpreferred.~~

AMENDATORY SECTION (Amending WSR 15-12-093, filed 6/2/15, effective 7/3/15)

WAC 182-530-4125 Generics first for a client's first course of treatment. ~~((The Medicaid agency uses point-of-sale (POS) claim messaging to tell pharmacies to use a preferred generic drug for the client's first course of treatment in specific drug classes.)) (1) The Medicaid agency may require preferred generic drugs on the Washington preferred drug list (Washington PDL) be used before any brand name or nonpreferred generic drugs for a client's first course of treatment within that therapeutic class of drugs, ((when:~~

~~(a) There is a less expensive, equally effective therapeutic alternative generic product available to treat the condition; and~~

~~(b) The drug use review (DUR) board established under WAC 182-530-4000 has reviewed the drug class and recommended to the agency that the drug class is appropriate to require generic drugs as a client's first course of treatment)) according to RCW 69.41.190.~~

(2) For drug classes selected by the agency that meet the criteria of subsection (1) of this section, only preferred generic drugs are covered for a client's first course of treatment, except as identified in subsection (3) of this section.

(3) Endorsing practitioners' prescriptions written "dispense as written (DAW)" for preferred and nonpreferred brand name drugs and nonpreferred generics in the specific drug classes on the Washington PDL reviewed by the drug use review (DUR) board will be subject to authorization to establish medical necessity as defined in WAC 182-500-0070.

(4) The agency uses point-of-sale (POS) claim messaging to tell pharmacies to use a preferred generic drug for the client's first course of treatment in specific drug classes.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-4150 Therapeutic interchange program (TIP). This section contains the medicaid agency's rules for the endorsing practitioner therapeutic interchange program (TIP). TIP is established under RCW 69.41.190 and 70.14.050 (~~(. The statutes require state-operated prescription drug programs to allow physicians and other prescribers to endorse a Washington preferred drug list (PDL) and, in most cases, requires pharmacists to automatically substitute a preferred, equivalent drug from the list).~~).

(1) (~~The therapeutic interchange program (TIP)~~) TIP applies only to drugs:

(a) Within therapeutic classes on the Washington preferred drug list (Washington PDL);

(b) (~~Studied by the evidence-based practice center or centers;~~
~~(c) Reviewed~~) Included in a motion passed by the pharmacy and therapeutics (P&T) committee; and

(~~(d)~~) (c) Prescribed by an endorsing practitioner.

(2) TIP does not apply to a drug when:

(a) (~~When~~) The P&T committee determines that TIP does not apply to the drug or its therapeutic class on the Washington PDL; (~~or~~)

(b) (~~To a drug~~) Prescribed by a nonendorsing practitioner;

(3) ~~A practitioner who wishes to become an endorsing practitioner must specifically enroll with the health care authority (HCA) as an endorsing practitioner under the provisions of chapter 182-50 WAC and RCW 69.41.190(2).~~

(4) ~~When an endorsing practitioner writes a prescription for a client for a nonpreferred drug, or for a preferred drug for a special population or indication other than the client's population or indication, and indicates that substitution is permitted, the pharmacist must:~~

(a) ~~Dispense a preferred drug in that therapeutic class in place of the nonpreferred drug; and~~

(b) ~~Notify the endorsing practitioner of the specific drug and dose dispensed.~~

(5) ~~With the exception of subsection (7) and (10) of this section, when an endorsing practitioner determines that a nonpreferred drug is medically necessary, all of the following apply:~~

(a) ~~The practitioner must indicate that the prescription is to be dispensed as written (DAW);~~

(b) ~~The pharmacist dispenses the nonpreferred drug as prescribed; and~~

(c) ~~The agency does not require prior authorization to dispense the nonpreferred drug in place of a preferred drug except when the drug requires authorization for safety.~~

(6) ~~In the event the following therapeutic drug classes are on the Washington PDL, pharmacists will not substitute a preferred drug for a nonpreferred drug in these therapeutic drug classes when the endorsing practitioner prescribes a refill (including the renewal of a previous prescription or adjustments in dosage):~~

- (a) ~~Antipsychotic;~~
- (b) ~~Antidepressant;~~
- (c) ~~Antiepileptic;~~
- (d) ~~Chemotherapy;~~
- (e) ~~Antiretroviral;~~

~~(f) Immunosuppressive; or
(g) Immunomodulator/antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty-four weeks but no more than forty-eight weeks.~~

~~(7)):~~

~~(c) The endorsing practitioner signs the prescription "dispense as written (DAW)"; or~~

~~(d) Otherwise prohibited under RCW 69.41.190.~~

~~(3) The agency may impose nonendorsing status on an endorsing practitioner only under the ((following)) circumstances ((+~~

~~(a) The agency runs three quarterly reports demonstrating that, within any therapeutic class of drugs on the Washington PDL, the endorsing practitioner's frequency of prescribing DAW varies from the prescribing patterns of the endorsing practitioner's agency-designated peer grouping with a ninety-five percent confidence interval; and~~

~~(b) The medical director has:~~

~~(i) Delivered by mail to the endorsing practitioner the quarterly reports described in (a) of this subsection, which demonstrate the endorsing practitioner's variance in prescribing patterns; and~~

~~(ii) Provided the endorsing practitioner an opportunity to explain the variation in prescribing patterns as medically necessary as defined under WAC 182-500-0070; or~~

~~(iii) Provided the endorsing practitioner two calendar quarters to change their prescribing patterns to align with those of the agency-designated peer groupings.~~

~~(8) While the endorsing practitioner is engaged in the activities described in subsection (7) (b) (ii) or (iii) of this section, their endorsing practitioner status is maintained.~~

~~(9) The nonendorsing status restrictions imposed under this section will remain in effect until the quarterly reports demonstrate that the endorsing practitioner's prescribing patterns no longer vary in comparison to the endorsing practitioner's agency-designated peer grouping over a period of four calendar quarters, with a ninety-five percent confidence interval.~~

~~(10)) outlined in RCW 69.41.190.~~

~~(4) Except as otherwise provided in subsection ((11)) (5) of this section, ((for)) the agency may restrict a client's first course of treatment within a therapeutic class ((of drugs, the endorsing practitioner's option to write DAW does not apply when:~~

~~(a) There is a less expensive, equally effective therapeutic alternative generic product available to treat the condition; and~~

~~(b) The drug use review (DUR) board established under WAC 182-530-4000 has reviewed the drug class and recommended to the agency that the drug class is appropriate to require generic drugs as a client's first course of treatment.~~

~~(11)), according to the provisions in RCW 69.41.190.~~

~~(5) In accordance with WAC 182-530-4125(3) and 182-501-0165, the agency will request and review the endorsing practitioner's medical justification for preferred and nonpreferred brand name drugs and non-preferred generic drugs for the client's first course of treatment.~~

WAC 182-530-6000 Mail-order and specialty pharmacy services.

~~((The medicaid agency provides a contracted mail-order pharmacy service for client use. The mail-order contractor is selected as a result of a competitive procurement process.~~

~~(1) The contracted mail-order pharmacy service is available as an option to all Washington apple health clients, subject to the:~~

~~(a) Scope of the client's medical care program;~~

~~(b) Availability of services from the contracted mail-order provider; and~~

~~(c) Special terms and conditions described in subsection (2) and (3) of this section.~~

~~(2) The mail-order prescription service may not dispense medication in a quantity greater than authorized by the prescriber. (See RCW 18.64.360(5), Nonresident pharmacies.)~~

~~(3) Prescribed medications may be filled by the mail-order pharmacy service within the following restrictions:~~

~~(a) Drugs available from mail-order in no more than a ninety-day supply include:~~

~~(i) Preferred drugs (see WAC 182-530-4100);~~

~~(ii) Generic drugs; and~~

~~(iii) Drugs that do not have authorization requirements (see WAC 182-530-3000 through 182-530-3200).~~

~~(b) Drugs available in no more than a thirty-four-day supply:~~

~~(i) Controlled substances (schedules II through V); and~~

~~(ii) Drugs having authorization requirements (see WAC 182-530-3000).~~

~~(c) Other pharmacy restrictions (chapter 182-530 WAC Prescription drugs (outpatient)) continue to apply.~~

~~(4) The contracted mail-order pharmacy services are reimbursed at levels lower than those established for the regular outpatient pharmacy services.) Clients may elect to receive pharmacy services through any mail-order or specialty pharmacy enrolled with the agency.~~

(1) Mail-order pharmacies or specialty pharmacies licensed to do business in Washington state under RCW 18.64.360 may enroll with the agency in the same manner as other pharmacies according to chapter 182-502 WAC, including out-of-state mail-order or specialty pharmacies.

(2) The agency considers mail-order and specialty classes of trade the same as retail class of trade for the purpose of enrollment with the agency. When enrolling with the agency, a mail-order or specialty pharmacy must enroll as a retail pharmacy unless participating with the agency under a mail-order or specialty pharmacy contract. Mail-order and specialty pharmacies cannot enroll under a mail-order designation by taxonomy or other indicator except when providing services under a mail-order contract with the agency separate from and in addition to the pharmacy's core provider agreement.

(3) Out-of-state pharmacies must comply with all applicable Revised Code of Washington and Washington Administrative Code when serving agency clients.

(4) The provisions of this chapter apply equally to all pharmacies and services provided by pharmacies regardless of the pharmacy's class of trade, except when those services are provided under a con-

tract with the agency separate from and in addition to the pharmacy's core provider agreement.

(5) The agency may contract with one or more mail-order or specialty pharmacies separate from and in addition to the pharmacy's core provider agreement.

(a) Provisions of the contract may differ from requirements detailed in this chapter including, but not limited to, reimbursement rates, dispensing limitations, and authorization requirements.

(b) Mail-order or specialty pharmacy contract provisions supersede individual sections or subsections of this chapter when specifically cited in contract, leaving in effect all other provisions of this chapter.

(c) Mail-order contract provisions for a dispensing pharmacy must not allow for a higher reimbursement than is allowed under this chapter for a retail pharmacy.

(d) When opening enrollment under a mail-order or specialty contract, the agency will make publicly available the contract provisions and minimum requirements to participate under the contract including, but not limited to, the reimbursement rate and methodology the provider must accept. Any pharmacy enrolled with Washington medicaid as a billing provider may choose to accept and participate with the agency under the terms of the mail-order or specialty pharmacy contract.

(e) The agency may use the same contract for both mail-order and specialty pharmacies, or may have separate standard contracts for each class of trade.

(f) The agency may base contract provisions on information supplied through a request for information to interested parties before making the finalized contract publicly available.

(6) The agency may implement programs or contract provisions that provide favorable conditions to contracted mail-order pharmacies, specialty pharmacies, or clients to encourage participation by pharmacies or the use of mail-order and specialty services by clients.

(7) The agency may designate specific products or classes of products to be made available to clients through mail-order or specialty pharmacies only.

AMENDATORY SECTION (Amending WSR 12-16-061, filed 7/30/12, effective 11/1/12)

WAC 182-530-7000 Reimbursement. (1) The agency's ~~((total))~~ reimbursement for a prescription drug dispensed through point-of-sale (POS) must not exceed the ~~((lowest of-~~

~~(a) Estimated acquisition cost (EAC) plus a dispensing fee,))~~ lesser of actual acquisition cost (AAC) plus a professional dispensing fee or the provider's usual and customary charge.

(2) The agency selects the sources for pricing information used to set POS AAC.

(3) The POS AAC is calculated as the lowest of:

(a) National average drug acquisition cost (NADAC);

(b) Maximum allowable cost (MAC) ~~((plus a dispensing fee))~~;

(c) Federal upper limit (FUL) ~~((plus a dispensing fee))~~;

(d) 340B Actual acquisition cost (340B AAC) ~~((plus a dispensing fee))~~ for drugs purchased under section 340B of the Public Health Service (PHS) Act (see WAC 182-530-7900 for exceptions); or

(e) Automated maximum allowable cost (AMAC) (~~plus a dispensing fee; or~~

~~(f) The provider's usual and customary charge to the nonmedicaid population.~~

~~(2) The agency selects the sources for pricing information used to set EAC and MAC.~~

~~(3) The agency may solicit assistance from pharmacy providers, pharmacy benefit managers (PBM), other government agencies, actuaries, and/or other consultants when establishing EAC and/or MAC).~~

(4) Where NADAC does not exist, other available reference prices from national sources such as wholesale acquisition cost, or average manufacturer price will be used as the basis of the reimbursement.

(5) Where NADAC does not accurately reflect the actual acquisition costs in Washington state, a percentage adjustment to NADAC will be made to the reimbursement.

(6) The agency may set POS AAC for specified drugs or drug categories at a maximum allowable cost other than that determined in subsection (2) of this section based on specific product acquisition costs. The agency considers product acquisition costs in setting a rate for a drug or a class of drugs.

(7) The agency bases POS AAC drug reimbursement on the actual package size dispensed.

(8) The agency reimburses a pharmacy for the least costly dosage form of a drug within the same route of administration, unless the prescriber has designated a medically necessary specific dosage form or the agency has selected the more expensive dosage form as a preferred drug.

~~((5))~~ (9) If the pharmacy provider offers a discount, rebate, promotion or other incentive which directly relates to the reduction of the price of a prescription to the individual nonmedicaid customer, the provider must similarly reduce its charge to the agency for the prescription.

~~((6))~~ (10) If the pharmacy provider gives an otherwise covered product for free to the general public, the pharmacy must not submit a claim to the agency.

~~((7))~~ (11) The agency does not reimburse for:

(a) Prescriptions written on presigned prescription blanks filled out by nursing facility operators or pharmacists;

(b) Prescriptions without the date of the original order;

(c) Drugs used to replace those taken from a nursing facility emergency kit;

(d) Drugs used to replace a physician's stock supply;

(e) Outpatient drugs, biological products, insulin, supplies, appliances, and equipment included in other reimbursement methods including, but not limited to:

(i) Diagnosis-related group (DRG);

(ii) Ratio of costs-to-charges (RCC);

(iii) Nursing facility daily rates;

(iv) Managed care capitation rates;

(v) Block grants; or

(vi) Drugs prescribed for clients who are on the agency's hospice program when the drugs are related to the client's terminal illness and related condition.

(f) Hemophilia and von Willebrand related products shipped to clients for administration in the home unless the products are provided through a qualified hemophilia treatment center of excellence (COE) as defined in WAC 182-531-1625.

WAC 182-530-7050 Reimbursement—Dispensing fee determination.

(1) Subject to the provisions of WAC 182-530-7000 and the exceptions permitted in WAC 182-530-2000, the medicaid agency pays a dispensing fee for each covered, prescribed drug.

(2) The agency does not pay a dispensing fee for:

(a) Nondrug items, devices, or drug-related supplies; or

(b) Drugs administered by a health care professional.

(3) The agency periodically examines the sufficiency of pharmacy dispensing fees and may adjust((~~s~~)) the dispensing fee by considering factors including, but not limited to:

(a) Legislative appropriations for vendor rates;

(b) Input from provider and advocacy groups;

(c) Input from state-employed or contracted actuaries; and

(d) Dispensing fees paid by other third-party payers including, but not limited to, health care plans and other states' medicaid agencies.

(4) The agency uses a tiered dispensing fee system which pays higher volume pharmacies at a lower fee and lower volume pharmacies at a higher fee.

(5) The agency uses total annual prescription volume (both medicaid and nonmedicaid) reported to the agency to determine each pharmacy's dispensing fee tier.

(a) A pharmacy which fills more than thirty-five thousand prescriptions annually is a high-volume pharmacy. The agency considers hospital-based pharmacies that serve both inpatient and outpatient clients as high-volume pharmacies.

(b) A pharmacy which fills between fifteen thousand one and thirty-five thousand prescriptions annually is a mid-volume pharmacy.

(c) A pharmacy which fills fifteen thousand or fewer prescriptions annually is a low-volume pharmacy.

(6) The agency determines a pharmacy's annual total prescription volume as follows:

(a) The agency sends out a prescription volume survey form to pharmacy providers during the first quarter of the calendar year;

(b) Pharmacies return completed prescription volume surveys to the agency each year. Pharmacy providers not responding to the survey by the specified date are assigned to the high volume category;

(c) Pharmacies must include all prescriptions dispensed from the same physical location in the pharmacy's total prescription count;

(d) The agency considers prescriptions dispensed to nursing facility clients as outpatient prescriptions; and

(e) Assignment to a new dispensing fee tier is effective on the first of the month, following the date specified by the agency.

(7) A pharmacy may request a change in dispensing fee tier during the interval between the annual prescription volume surveys. The pharmacy must substantiate such a request with documentation showing that the pharmacy's most recent six-month dispensing data, annualized, would qualify the pharmacy for the new tier. If the agency receives the documentation by the twentieth of the month, assignment to a new dispensing fee tier is effective on the first of the following month.

(8) The agency grants general dispensing fee rate increases only when authorized by the legislature. Amounts authorized for dispensing

fee increases may be distributed nonuniformly (e.g., tiered dispensing fee based upon volume).

(9) The agency may pay true unit dose pharmacies at a different rate for unit dose dispensing.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-7150 Reimbursement—Compounded prescriptions. (1)

The medicaid agency does not consider reconstitution to be compounding.

(2) The agency covers a drug ingredient used for a compounded prescription only when the manufacturer has a signed rebate agreement with the federal Department of Health and Human Services (DHHS).

(3) The agency considers bulk chemical supplies used in compounded prescriptions as nondrug items, which do not require a drug rebate agreement. The agency covers such bulk chemical supplies only as specifically approved by the agency.

(4) The agency reimburses pharmacists for compounding drugs only if the client's drug therapy needs are unable to be met by commercially available dosage strengths or forms of the medically necessary drug.

(a) The pharmacist must ensure the need for the adjustment of the drug's therapeutic strength or form is well-documented in the client's file.

(b) The pharmacist must ensure that the ingredients used in a compounded prescription are for an approved use as defined in "medically accepted indication" in WAC 182-530-1050.

(5) The agency requires that each drug ingredient used for a compounded prescription be billed to the agency using its eleven-digit national drug code (NDC) number.

(6) Compounded prescriptions are reimbursed as follows:

(a) The agency allows only the lowest cost for each covered ingredient, whether that cost is determined by actual acquisition cost (AAC), (~~estimated acquisition cost (EAC)~~), federal upper limit (FUL), maximum allowable cost (MAC), automated maximum allowable cost (AMAC), or amount billed.

(b) The agency applies current prior authorization requirements to drugs used as ingredients in compounded prescriptions, except as provided under (c) of this subsection. The agency denies payment for a drug requiring authorization when authorization is not obtained.

(c) The agency may designate selected drugs as not requiring authorization when used for compounded prescriptions. For the list of selected drugs, refer to the agency's prescription drug program billing instructions.

(d) The agency pays a professional dispensing fee as described under WAC 182-530-7050 for each drug ingredient used in compounding when the conditions of this section are met and each ingredient is billed separately by the eleven-digit NDC.

(e) The agency does not pay a separate fee for compounding time.

(7) The agency requires pharmacists to document the need for each inactive ingredient added to the compounded prescription. The agency limits reimbursement to the inactive ingredients that meet the follow-

ing criteria. To be reimbursed by the agency, each inactive ingredient must be:

- (a) A necessary component of a compounded drug; and
- (b) Billed by an eleven-digit national drug code (NDC).

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-7250 Reimbursement—Miscellaneous. (1) The medicaid agency reimburses for covered drugs, devices, and drug-related supplies provided or administered by nonpharmacy providers under specified conditions, as follows:

~~((1))~~ (a) The agency reimburses for drugs administered or prepared and delivered for individual use by an authorized prescriber during an office visit according to specific program rules found in:

~~((a))~~ (i) Chapter 182-531 WAC, Physician-related services;
~~((b))~~ (ii) Chapter 182-532 WAC, Reproductive health/family planning only/~~TAKE CHARGE~~; and
~~((c))~~ (iii) Chapter 182-540 WAC, Kidney disease program and kidney center services.

~~((2))~~ (b) Providers who are purchasers of Public Health Services (PHS) discounted drugs must comply with PHS 340B program requirements and Washington medicaid requirements for 340B providers participating with medicaid. (See WAC 182-530-7900.)

~~((3))~~ (2) The agency may request providers to submit a current invoice for the actual cost of the drug, device, or drug-related supply billed. If an invoice is requested, the invoice must show the:

- (a) Name of the drug, device, or drug-related supply;
- (b) Drug or product manufacturer;
- (c) NDC of the product or products;
- (d) Drug strength;
- (e) Product description;
- (f) Quantity; and
- (g) Cost, including any discounts or free goods associated with the invoice.

~~((4))~~ (3) The agency does not reimburse providers for the cost of vaccines obtained through the state department of health (DOH). The agency does pay physicians, advanced registered nurse practitioners (ARNP), and pharmacists a fee for administering the vaccine.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-7300 Reimbursement—Requesting a change. Upon request from a pharmacy provider, the medicaid agency may reimburse at the provider's actual acquisition cost (provider AAC) for a drug that would otherwise be reimbursed at maximum allowable cost (MAC) when:

(1) The availability of lower cost equivalents in the marketplace is severely curtailed and the price disparity between AAC for the drug and the MAC reimbursement affects clients' access; and

(2) An invoice documenting actual acquisition cost relevant to the date the drug was dispensed is provided to the agency.

AMENDATORY SECTION (Amending WSR 13-14-052, filed 6/27/13, effective 7/28/13)

WAC 182-530-7700 Reimbursement—Dual eligible clients/medicare. For clients who are dually eligible for medical assistance and medicare benefits, the following applies:

(1) ~~((Medicare Part B, the agency pays providers for:~~
~~(a) An amount up to the agency's maximum allowable fee for drugs medicare does not cover, but the agency covers; or~~
~~(b) Deductible and/or coinsurance amounts up to medicare's or the agency's maximum allowable fee, whichever is less, for drugs medicare and the agency cover.))~~ The agency pays medicare coinsurance, copayments, and deductibles for Part A, Part B, and medicare advantage Part C, subject to the limitations in WAC 182-502-0110.

(2) Medicare Part D:
(a) Medicare is the payer for drugs (~~((covered under))~~) included in the medicare Part D benefit.
(b) The agency does not pay for Part D drugs or Part D copayments.
(c) For drugs excluded from the (~~((basic))~~) medicare Part D benefit:
(i) The agency offers the same drug benefit as a nondual eligible client has within those same classes;
(ii) If the client has another third party insurer, that insurer is the primary payer; and
(iii) The agency is the payer of last resort.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-7900 Drugs purchased under the Public Health Service (PHS) Act. (1) ~~((Drugs purchased under section 340B of the Public Health Service (PHS) Act can be dispensed to Washington apple health clients only by PHS-qualified health facilities and must be billed to the medicaid agency at actual acquisition cost (AAC) as required by laws governing the PHS 340B program.~~

~~(2))~~ Providers dispensing ((drugs under this section)) or administering 340B drugs to Washington apple health clients are required to submit their valid medicaid provider number(s) or national provider identification (NPI) number to the PHS health resources and services administration, office of pharmacy affairs. ((This requirement is to ensure that claims for drugs dispensed under this section and paid by the agency are excluded from the drug rebate claims that are submitted to the manufacturers of the drugs.)) See WAC 182-530-7500 for information on the drug rebate program.

~~((3) The agency reimburses drugs under this section at actual acquisition cost plus a dispensing fee set by the agency.))~~ (2) Drugs

purchased under section 340B of the Public Health Service (PHS) Act can be billed to Washington apple health only by PHS-qualified entities. The Washington medicaid rebate process excludes 340B claims from invoicing only when the drug is billed by a medicaid provider number or national provider identification (NPI) number listed on the PHS office of pharmacy affairs national medicaid exclusion file. See WAC 182-530-7500 for information on the drug rebate program.

(3) With the exception of claim types identified in subsection (4) of this section, all 340B purchased drugs must be billed to the medicaid agency at the 340B actual acquisition cost (340B AAC).

(4) Exceptions to the 340B AAC billing requirement are only made for:

(a) Outpatient hospital claims paid under the enhanced ambulatory payment group (EAPG) methodology (see WAC 182-550-7000); and

(b) Ambulatory surgery claims paid under payment groups methodology.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-8000 Reimbursement method—(~~Estimated~~) **Actual acquisition cost** (~~EAC~~) **(AAC)**. (~~(1)~~) The medicaid agency (~~determines estimated~~) uses the following sources to determine point-of-sale actual acquisition cost (~~EAC~~) using:

(~~a~~) (~~POS AAC~~) including, but not limited to:

(1) National average drug acquisition cost (NADAC) published by the Centers for Medicare and Medicaid Services (CMS);

(2) Acquisition cost data made available to the agency (~~or~~

(~~b~~) information provided by any of the following) by:

(~~i~~) (a) Audit (~~agencies~~) results from federal or state agencies;

(~~ii~~) (b) Other state health care purchasing (~~agencies~~) organizations;

(~~iii~~) (c) Pharmacy benefit managers;

(~~iv~~) (d) Individual pharmacy providers participating in the agency's programs;

(~~v~~) Centers for Medicare and Medicaid Services (CMS);

(~~vi~~) (e) Other third-party payers;

(~~vii~~) (f) Drug file data bases; and

(~~viii~~) (g) Actuaries or other consultants.

(2) The agency implements EAC by applying a percentage adjustment to available reference pricing from national sources such as wholesale acquisition cost, average wholesale price (AWP), average sale price (ASP), and average manufacturer price (AMP).

(3) The agency may set EAC for specified drugs or drug categories at a maximum allowable cost other than that determined in subsection (1)(a) of this section when the agency considers it necessary. The factors the agency considers in setting a rate for a class of drugs under this subsection include, but are not limited to:

(a) Product acquisition cost;

(b) The agency's documented clinical concerns; and

(c) The agency's budget limits.

~~(4) The agency bases EAC drug reimbursement on the actual package size dispensed.~~

~~(5) The agency uses EAC as the agency's reimbursement for a drug when EAC is the lowest of the rates calculated under the methods listed in WAC 182-530-7000, or when the conditions of WAC 182-530-7300 are met.)~~

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-8100 Reimbursement—Maximum allowable cost (MAC).

(1) The medicaid agency establishes a maximum allowable cost (MAC) for a multiple-source drug which is available from at least two manufacturers/labelers.

(2) The agency determines the MAC for a multiple-source drug:

(a) When specific regional and local drug acquisition cost data is available, the agency:

(i) Identifies what products are available from wholesalers for each drug being considered for MAC pricing;

(ii) Determines pharmacy providers' approximate acquisition costs for these products; and

(iii) Establishes the MAC at a level which gives pharmacists access to at least one product from a manufacturer with a qualified rebate agreement (see WAC 182-530-7500(4)).

(b) When specific regional and local drug acquisition cost data is not available, the agency may estimate acquisition cost based on national pricing sources.

(3) The MAC established for a multiple-source drug does not apply if the written prescription identifies that a specific brand is medically necessary for a particular client. In such cases, the ~~((estimated))~~ actual acquisition cost ~~((EAC))~~ (AAC) for the particular brand applies, provided authorization is obtained from the agency as specified under WAC 182-530-3000.

(4) Except as provided in subsection (3) of this section, the agency reimburses providers for a multiple-source drug at the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

(5) The MAC established for a multiple-source drug may vary by package size, including those identified as unit dose national drug codes (NDCs) by the manufacturer or manufacturers of the drug.

AMENDATORY SECTION (Amending WSR 16-01-046, filed 12/9/15, effective 1/9/16)

WAC 182-530-8150 Reimbursement—Automated maximum allowable cost (AMAC).

(1) The medicaid agency uses the automated maximum allowable cost (AMAC) pricing methodology for multiple-source drugs that are:

(a) Not on the published maximum allowable cost (MAC); and

(b) Produced by two or more manufacturers/labelers, at least one of which must have a current, signed federal drug rebate agreement.

(2) The agency establishes AMAC as a specified percentage of the published (~~average wholesale price (AWP)~~) national average drug acquisition cost (NADAC) or other nationally accepted pricing source in order to estimate acquisition cost.

(3) The agency sets the percentage discount from ((AWP)) NADAC for AMAC reimbursement using any of the information sources identified in WAC 182-530-8000.

(4) The agency may set AMAC reimbursement at different percentage discounts from ((AWP)) NADAC for different multiple source drugs. The agency considers the same factors as those in WAC 182-530-8000.

(5) AMAC reimbursement for all products with the same ingredient, form and strength is at the AMAC determined for the second lowest priced product, or the AMAC of the lowest priced drug from a manufacturer with a current, signed federal rebate agreement.

(6) The agency recalculates the AMAC each time the drug file contractor provides a pricing update.

(7) Except as provided in WAC 182-530-7300, the agency reimburses at the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

From: Washington Health Care Authority [mailto:WaHCA@public.govdelivery.com]
Sent: Thursday, March 02, 2017 1:31 PM
Subject: Fee-for-Service (FFS) Point-of-Sale Pharmacy Rates – Change in basis of payment



Apple Health (Medicaid): Pharmacy Provider Alert

Date: March 1, 2017

Change in basis of payment for Apple Health Fee-for-Service pharmacy claims: Fee-for-Service (FFS) Point-of-Sale Pharmacy Rates

Effective for dates of service on and after April 1, 2017, Washington Apple Health (Medicaid) administered by the Health Care Authority will be implementing the Actual Acquisition Cost (AAC) provisions of the federal Covered Outpatient Drug Rule (CODR).

As required by the federal law, the Agency's FFS point-of-sale (POS) system will replace the current Estimated Acquisition Cost (EAC) of AWP-16%, with an Actual Acquisition Cost (AAC) methodology.

The Agency will be using the National Average Drug Acquisition Cost (NADAC) in place of the AWP based rates. When there is no NADAC available for a drug, the Agency will use wholesale acquisition cost or other available price.

The Point of Sale AAC will be calculated as the lowest of:

- National average drug acquisition cost (NADAC);
- Maximum allowable cost (MAC);
- Federal upper limit (FUL);
- 340B Actual acquisition cost (340B AAC) for drugs purchased under section 340B of the Public Health Service (PHS) Act.

Dispensing fees are unaffected by this change.

For more information on the Federal Upper Limit (FUL) or the National Average Drug Acquisition Cost (NADAC) please see [Medicaid.gov Pharmacy Pricing](#).

To request a change in reimbursement for a FFS claim, please download the Pharmacy Information Authorization (13-835A) form on the [Pharmacy Reimbursement FFS website](#) and fax the request with an invoice to (866) 668-1214.



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Michael T. Hunter, PharmD
 Pharmacy Management Consultant

michael.t.hunter@milliman.com

August 5, 2016

Ms. Myra Davis
 Manager Pharmacy Rates, Rebate Receipts and Special Programs
 Washington Health Care Authority
 P.O. Box 45510
 Olympia, WA 98504-5510

Re: Prescription Drug Reimbursement and Dispensing Fee Benchmarks

Dear Myra:

At your request, we have summarized retail pharmacy reimbursement levels for brand name, generic, and specialty prescriptions and retail pharmacy dispensing fees for commercial and Medicare markets for informational purposes as directed by the Washington State Health Care Authority (HCA). We understand that this benchmark data will allow HCA to comply with federal laws that require examination of sufficiency of point-of-sale ingredient cost and dispensing fee reimbursement levels. The analysis may not be appropriate for other purposes. The following information details the results of our analysis.

RESULTS

Table 1 below shows the 50th percentile of dispensing costs per script and discount off average wholesale price for Medicare and commercial plans.

Table 1 Washington Health Care Authority 50th Percentile Survey Benchmark				
Metric	AWP Discount		Dispensing Fee per Script	
	Medicare	Commercial	Medicare	Commercial
Retail Generic	78.7%	71.4%	\$1.25	\$1.35
Retail Brand	16.0%	15.1%	\$1.25	\$1.40
Retail Specialty	17.2%	17.0%	\$1.00	\$0.55

Detailed results of our analysis are presented in the attached tables at the end of this report (Appendix A). Table 1a displays average wholesale price (AWP) discounts for generic, brand, and specialty medications for the 20th, 40th, 50th, 60th, and 80th percentile levels within Medicare for plan year 2016 as calculated by Milliman's annual PBM Survey. Table 1b displays retail dispensing fees in the same layout.

Table 2a and 2b displays the same information as Table 1a and Table 1b but utilizes 2015 commercial data for the benchmark. Additionally, the commercial AWP specialty discount and specialty dispensing fee data are separately broken out into brand and generic.

DATA

AWP discount and dispensing fee benchmarks are based on the following datasets:

Milliman's 2016 Medicare PBM Survey

This is a Milliman survey of Medicare Part D pharmacy benefit manager (PBM) arrangements. The 2016 Medicare Part D PBM survey includes input from 12 Milliman offices nationwide and contains a total of 123 data points. It is based on Part D PBM arrangements and bid information for 2016 using information gathered during the most recent bid season.

2015 Proprietary Commercial Aggregated Dataset

This is a collection of approximately 40 bids within the employer and health plan commercial market. The 2015 commercial benchmark data is a collection of approximately 40 bids from the employer and health plan commercial market.

DISCUSSION

Contracts between PBMs and pharmacies are very complex and are generally negotiated in totality. AWP discounts, dispensing fees, and rebates are common levers used to adjust overall contract terms. For example, as one lever is negotiated up, another may be negotiated down. Given this dynamic, it is unlikely that the most aggressive AWP discount paired with the most aggressive dispensing fee be obtainable.

Comparing AWP discounts and dispensing fee benchmarks to other markets should be done with caution due to differences in drug mix and demographics within the populations. It should be recognized that a Medicaid population will utilize a different drug mix than a commercial or Medicare population. It is also important to mention that the benchmark data provided utilizes information from national health plans and are not specific to one geographical area.

One last item of importance is the nuances of each of these markets and how they may be similar or different to the Washington Medicaid market. As HCA evaluates and compares their own AWP discounts and dispensing fees to these other market segments, the following items are important to take into consideration.

Medicare Benchmarks

There are important dynamics that must be understood within the Medicare D market when comparing dispensing fees and AWP discounts to other market segments. One of the most relevant dynamics is the payment of direct and indirect remuneration (DIR) payments by retail pharmacies in exchange for preferred network status. In many cases, these are dollar for dollar discounts on a per-prescription basis that affect the point of sale discounts (AWP discounts) and dispensing fees. We have attempted to normalize this within the benchmark data provided by only including plans that have no preferred networks, which is only a small portion of the overall market because a majority of Prescription Drug Plans (PDP) have a preferred network.

Commercial Benchmarks

There are also important dynamics that should be considered in the commercial market when comparing dispensing fees and AWP discounts to other market segments. One major difference is the prevalence of mandatory mail order programs and 90 day supply penetration rates. Mail order AWP discounts are typically much deeper than retail discounts and dispensing fees are typically \$0.00, therefore mail order penetration rates can have a large impact on 30 day retail price points.



CAVEATS AND LIMITATIONS

This analysis is intended for the use of the Washington Health Care Authority in support of Apple Health programs. We understand that this information may be shared with other parties. To the extent that the information contained in this report is provided to third parties, the document should be distributed in its entirety. Any user of the data must possess a certain level of expertise in actuarial science and health care modeling so as not to misinterpret the data presented.

Milliman makes no representations or warranties regarding the contents of this report to third parties. Similarly, third parties are instructed that they are to place no reliance upon this report prepared for HCA by Milliman that would result in the creation of any duty or liability under any theory of law by Milliman or its employees to third parties.

We have relied upon data derived from two separate data sets; Milliman's 2016 PBM survey and the 2015 proprietary commercial aggregated dataset. We have not audited or verified this data and other information. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete. We performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review was beyond the scope of our assignment.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. I am a member of the American Academy of Actuaries, and meet the qualification standards for performing the analysis in this letter.

The terms of Milliman's contract with the Washington Health Care Authority signed on April 1, 2013 apply to this report and its use.



Ms. Myra Davis
Washington Health Care Authority
August 5, 2016
Page 4 of 4

If you have any questions regarding this analysis, please do not hesitate to call me at (312) 499-5734.

Sincerely,

Michael T. Hunter, PharmD
Pharmacy Management Consultant

MTH/jf

Attachments

DRAFT



THE BURCHFIELD GROUP
Our Expertise. Your Benefit.™

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Prescription Drug Consortium use only.
Not to be distributed to any
other parties or vendors.*

Market Check Evaluation

Moda Health (Consortium Line of Business)

for presentation November 17, 2015
(Updated Version)

Kevin Waite, R. Ph. – Managing Consultant
Joel Sedgeman, J.D. – Consultant & Strategic Services Lead
Steve Anderson – Lead Financial Analyst

Moda Health

Consortium Line of Business

Discussion Objectives

- **Utilization Summary**
 - Building the model
- **Financial Assumptions**
 - Trending the model
- **Market Comparison**
 - Market check results and potential opportunities for financial improvement
- **Summary of Price Points**
 - Sensitivity of price points and areas to focus for financial improvement opportunities

Moda Health

Consortium Line of Business

Considerations

- **Market comparison pricing may differ in key ways:**
 - More recent multi-year contracts
 - Competitive bidding situation
 - Administrative fee comparison not on the same basis
 - Discount card program versus small commercial offers
- **Important to consider an offer as a whole**
 - No single PBM offer will contain the most advantageous pricing at each price point

Moda Health

Consortium Groups

Modeling Assumptions

- Actual Moda Health (Consortium) data from last eight months of 2014 used to create financial model
- Baseline developed using 3.0 million claims to calculate modeling assumptions:
 - Average AWP
 - Drug mix
 - Distribution channel
 - Utilization
- Model baseline trended forward to estimate 2016 total gross drug spend (*AWP inflation, brand/generic mix, utilization increase*)
- Trended baseline lives to the most recent level of Consortium lives from May 2015 of 428,072 lives
- Baseline pricing applied:
 - Discount and dispensing fee: Consortium contract guarantees
 - Administrative fee: \$3.04/Rx blended guarantee from Consortium Contract



Moda Health

Consortium Groups

Market Comparison

- **Market Pricing Applied**
 - Moda Health's (Consortium) current 2016 guarantees vs. market 2016 pricing
 - Similar size clients
 - Seven unique commercial offers
 - Traditional and pass-through offers
 - Quality offers (i.e. 'RFP finalist level') from competitive bidding situations
 - Recently negotiated multi-year offers

Moda Health Consortium Groups Market Comparison

(Continued)

- **Market Check Result**
 - **Discount and Dispensing Fees**
 - Potential financial change: -\$1.0 million to \$25.0 million
 - Opportunity for improvement in retail dispensing fees and retail 90/mail generic discounts
 - **Administrative Fees**
 - Potential financial improvement: \$10.1 million to \$14.7 million
 - Services included in administrative fees vary between PBMs and offers and are best addressed in an RFP situation through close evaluation of each individual PBM offer

Moda Health Consortium Groups Price Point Summary

LOB	Guarantee Type		Moda Health	Market Pricing ⁽¹⁾		Sensitivity ⁽²⁾	Impact with Average Rates	
			Estimated performance	Average Rates	Range (Conservative to Aggressive)			
			2016	2016				
Consortium	Retail	Brand	Discount	16.53%	16.83%	15.75% to 18.50%	1% = \$1.5 million	\$453,000
			Disp. Fee	\$1.22	\$0.60	\$0.85 to \$0.50	\$0.10 / Rx = \$0.05 million	\$287,000
		Generic	Discount	79.42%	79.02%	77.25% to 80.75%	1% = \$3.3 million	(\$1,289,000)
			Disp. Fee	\$1.22	\$0.64	\$0.85 to \$0.55	\$0.10 / Rx = \$0.3 million ⁽³⁾	\$1,784,000
	Retail 90	Brand	Discount	19.50%	21.37%	18.50% to 25.50%	1% = \$0.3 million	\$517,000
			Disp. Fee	\$0.00	\$0.24	\$0.85 to \$0.00	-	(\$10,000)
		Generic	Discount	79.42%	80.95%	78.25% to 86.00%	1% = \$2.0 million ⁽³⁾	\$3,024,000
			Disp. Fee	\$0.00	\$0.23	\$0.85 to \$0.00	-	(\$172,000)
	Mail	Brand	Discount	23.00%	24.07%	23.00% to 25.50%	1% = \$0.4 million	\$430,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
		Generic	Discount	80.00%	82.55%	80.50% to 86.00%	1% = \$0.7 million ⁽³⁾	\$1,666,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
	Specialty Discount (Aggregate Average)			15.07%	15.94%	14.92% to 17.99%	1% = \$2.3 million	\$2,142,000
Administrative Fee ⁽⁴⁾			\$3.04 / Rx	\$0.50 / Rx	\$0.95 / Rx to \$0.00 / Rx	\$0.25 / Rx = \$1.2 million ⁽³⁾	\$10,112,000	
							\$18.9 million (3.8%) over one year time period	

Numbers above reflect Burchfield's impressions of PBM market pricing based on market sample offers and Moda Health's (Consortium) data.

No single PBM offer will contain the most advantageous price point for every pricing component within the market range.

Opportunity Focus:

- Retail dispensing fees
- Retail 90/mail generic discounts
- Administrative fees ⁽⁴⁾

⁽¹⁾ Market pricing consists of Burchfield's experience with similar clients to Moda Health's (Consortium) lines of business through competitive RFP processes involving multi-year deals.

⁽²⁾ Sensitivity represents the dollar value over one year that is improved when pricing is improved by the rate shown in connection with Moda Health's (Consortium) specific utilization.

⁽³⁾ Highlighted sensitivities are areas where Burchfield recommends Moda Health (Consortium) focuses during future negotiations.

⁽⁴⁾ Administrative fees do not necessarily represent the identical services provided and contains pass-through as well as traditional arrangements.

Moda Health

Consortium Discount Cards

Modeling Assumptions

- Actual Moda Health (Consortium) data from last eight months of 2014 used to create financial model
- Baseline developed using 300,000 claims to calculate modeling assumptions:
 - Average AWP
 - Drug mix
 - Distribution channel
 - Utilization
- Model baseline trended forward to estimate 2016 total gross drug spend (*AWP inflation, brand/generic mix, utilization increase*)
- Trended baseline lives to the most recent level of Consortium lives from May 2015 of 516,008 lives
- Baseline pricing applied:
 - Discount and dispensing fee: Consortium contract guarantees
 - *Note: performance levels in data significantly above guarantee levels*
 - Admin. fee per Rx: OPDP (ODS11) \$1.20, WPDP (ODS12) \$0.60 (\$0.98/Rx avg.)



Moda Health

Consortium Discount Cards

Market Comparison

- **Market Pricing Applied**

- Moda Health's (Consortium) current 2016 guarantees vs. market 2016 pricing
 - Seven unique small-client commercial offers
 - Traditional and pass-through offers
 - Quality offers (i.e. 'RFP finalist level') from competitive bidding situations
 - Recently negotiated multi-year offers
 - Discount card pricing difficult to compare due to unique type of benefit

Moda Health

Consortium Discount Cards

Market Comparison

(Continued)

- **Market Check Result**
 - **Discount and Dispensing Fees**
 - Potential financial change: -\$0.9 million to \$0.7 million
 - Opportunity for improvement in retail dispensing fees and retail 90 generic discounts
 - **Administrative Fees**
 - Potential financial improvement: -\$0.6 million to \$0.5 million
 - Services included in administrative fees vary between PBMs and offers and are best addressed in an RFP situation through close evaluation of each individual PBM offer

Moda Health Consortium Discount Cards Price Point Summary

LOB	Guarantee Type		Moda Health	Market Pricing ⁽¹⁾		Sensitivity ⁽²⁾	Impact with Average Rates	
			Estimated Performance	Average Rates	Range (Conservative to Aggressive)			
			2016	2016				
Discount Card Program	Retail	Brand	Discount	16.53%	16.16%	15.30% to 17.00%	1% = \$0.4 million	(\$13,000)
			Disp. Fee	\$1.22	\$0.94	\$1.37 to \$0.50	\$0.25 / Rx = \$0.01 million ⁽³⁾	\$5,000
		Generic	Discount	79.42%	77.81%	76.25% to 79.65%	1% = \$0.33 million	(\$527,000)
			Disp. Fee	\$1.22	\$0.94	\$1.37 to \$0.50	\$0.25 / Rx = \$0.08 million ⁽³⁾	\$87,000
	Retail 90	Brand	Discount	19.50%	20.03%	18.97% to 22.50%	1% = \$0.004 million	\$2,000
			Disp. Fee	\$0.00	\$0.38	\$0.90 to \$0.00	-	(\$1,000)
		Generic	Discount	79.42%	80.18%	78.25% to 82.75%	1% = \$0.2 million ⁽³⁾	\$152,000
			Disp. Fee	\$0.00	\$0.38	\$0.90 to \$0.00	-	(\$29,000)
	Mail	Brand	Discount	23.00%	23.10%	18.97% to 25.25%	1% = \$0.002 million	\$1,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
		Generic	Discount	80.00%	80.82%	77.00% to 83.00%	1% = \$0.03 million	\$21,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
Specialty Discount (Aggregate Average)			16.82%	16.47%	12.48% to 22.76%	1% = \$0.004 million	\$1,000	
Administrative Fee ⁽⁴⁾			\$0.98 / Rx	\$0.38 / Rx	\$1.65 / Rx to \$0.00 / Rx	\$0.25 / Rx = \$0.12 million ⁽³⁾	\$285,000	
							-\$16,000 (-0.1%) over one year time period	

Opportunity focus:

- Retail dispensing fees
- Retail 90 generic discounts
- Administrative fees ⁽⁴⁾

(1) Market Pricing consists of Burchfield's experience with small commercial clients through competitive RFP processes involving multi-year deals.

(2) Sensitivity represents the dollar value over one year that is improved when pricing is improved by the rate shown in connection with Moda Health's (Consortium) specific utilization.

(3) Highlighted sensitivities are areas where Burchfield recommends Moda Health (Consortium) focuses during future negotiations.

(4) Administrative fees do not necessarily represent the identical services provided and contains pass-through as well as traditional arrangements.

Numbers above reflect Burchfield's impressions of PBM market pricing based on market sample offers and Moda Health's (Consortium) data.

No single PBM offer will contain the most advantageous price point for every pricing component within the market range.

Moda Health

Consortium Line of Business

Market 2017 versus 2016 Pricing Observations

- **Overall Change**
 - Based on our market samples, 2017 rates improve in aggregate by an average 0.7%.
 - Moda (Consortium) 2017 rates change in aggregate by ~0.4%, so the net improvement of the market over Moda (Consortium) from 2016 to 2017 is ~0.3%.
 - Ability to forecast this far forward is subject to a lot of variance.
 - Overall observation is the result is in line with 2016 analysis.
- **Price Point Tiering/Changes**
 - There may be slight improvement in retail generic discounts and dispensing fees, but modeling 2014 utilization into 2017 becomes less relevant due to drug mix changes and variability.
 - Specialty will likely experience the most growth in both utilization and cost, which is difficult to predict into 2017.

Moda Health

Consortium Line of Business

Executive Summary

- **Market check analysis shows potential 3-4% gap**
 - Consortium network rates appear to be:
 - Groups: in the middle of the market range for groups
 - Discount cards: in the middle of the market range for small groups
 - Limited opportunities exist in AWP discounts and dispensing fees
 - Retail dispensing fees
 - Retail 90/mail generic discounts
 - Administrative fees are higher than expected *as compared with PBM market administrative fees*
 - Administrative services received may be significantly different than market comparators

Moda Health Assumptions

Additional Modeling Assumptions

- Mail claims defined as claims from OHSU Mail Order Pharmacy (*ODS21 only*), Postal Prescription Services for all other HQs.
- Retail 90 claims defined as all retail claims with days of supply greater than 84 days of supply. Choice90 was not implemented until September 2014.
- Specialty claims defined by Moda Health's custom specialty drug lists.
- Specialty Pharmacy claims defined as specialty claims dispensed at Salem Hospital (*ODS14 only*), OHSU Outpatient (*ODS21 only*), OHSU Mail Order (*ODS21 only*), Ardon Health, or Diplomat Specialty Pharmacy.
- Based on benefit codes and 2014 data, assumed 79.3% of Consortium claims are covered under a 3-tier qualifying benefit.
- Market Check analysis is based on a 2016 calendar year. Where applicable Burchfield blended Moda Health's May 1, 2015 to April 30, 2016 and May 1, 2016 to April 30, 2017 contract guarantee rates to calculate a 2016 calendar year rate.
- Market pricing not applied to non-drug item, paper, and non-traditional pharmacy (LTC, HIF, ITU, VA, Military) claims. Performance discount and dispensing rates passed through on these claims.
- COB, vaccine, and onsite pharmacy claims are included in analysis and are bucketed as a normal claim.



Moda Health Caveats & Limitations

Caveats & Limitations

- Information in this report is intended to assist Moda Health in evaluating and assessing pharmacy benefit management options in the marketplace. Other uses of this information may not be appropriate. In addition, the information contained in this report is not intended to benefit any third party;
- Burchfield relies on the information provided by Moda Health or Moda Health's PBM vendor including claims data, contracts, plan, and plan design information, but has not independently verified the information. Any additional information not previously provided may change the outcome of Burchfield's analysis. If the data provided is not accurate or incomplete, then Burchfield's analysis may be similarly impacted;
- Burchfield may have trended data elements such as utilization, AWP inflation, and drug mix using historical experience and future known industry changes such as new generic introductions. Actual experience will not match trended data assumptions used for this analysis. Burchfield recommends Moda Health monitor actual experience;
- Burchfield is providing analysis and descriptions to Moda Health of vendor and plan options. The ultimate choice of a particular vendor or plan option will be made by Moda Health and Burchfield is not recommending nor requiring that Moda Health select any particular vendor or plan option; and,
- It is possible to see projected savings and still experience plan cost increases year to year. Savings is not illustrative of a reduction in plan costs over current plan costs, but is instead reflective of the difference between new PBM pricing versus PBM current pricing based on modeling assumptions trended throughout the time period of the new contract.



To: Northwest Prescription Drug Consortium

DRAFT 3/29/16

From: Moda Health, Inc.

Re: 2015 Market Check Study

This memorandum summarizes the project scope, methodology, findings and recommendations resulting from the Northwest Prescription Drug Consortium (“Consortium”) 2015 “market check” study conducted by The Burchfield Group (“Burchfield”), a pharmacy benefit consulting practice, on behalf of Moda Health.

1. PROJECT SCOPE

Pursuant to terms of Attachment 4, Paragraph 8, Program Analysis and Market Check of the Third Restated Contract for Comprehensive Services for Pharmacy Benefit Administration for the Oregon Prescription Drug Program and the Washington Prescription Drug Program (“Agreement”), Moda Health is required to undertake an annual comprehensive market check to compare the aggregate value of the Consortium's current pricing terms with the aggregate value of the pricing terms currently available in the marketplace. Moda Health contracted with Burchfield, an experienced and mutually agreed upon third party, to conduct this market check. The study began in May 2015 and concluded with a presentation of results to Moda and the Consortium in November 2015. Pursuant to the terms of the Consortium agreement, Moda assumed the costs for completing the study.

The objective of the study was to evaluate the Consortium’s aggregate pricing terms (AWP discounts, dispensing fees, administrative fees) compared to pricing terms that are available in the pharmacy benefit manager marketplace for similar groups for the same time period to determine if Consortium pricing terms are competitive. The study evaluated marketplace pricing that would be available for 2016. It did not evaluate the financial performance for claims that were paid in 2015.

The study assessed pharmacy prescription drug reimbursement pricing at 30-day retail, 90-day retail, mail order and specialty pharmacy networks, as well as PBM program administrative fees. The study prepared market ranges for each pharmacy channel and established benchmark market averages within each channel. As a final component of the study, Consortium prices for each pharmacy channel were compared with these market averages to establish variances which could be used to determine whether Consortium pricing required updating.

Based on the results of this market check, a determination was made that Consortium prices in 2016 required adjustment to remain at or ahead of the market in the current and subsequent years. The Consortium and Moda Health proceeded to negotiate new terms and discussions successfully concluded in January 2016 with updated pricing to become effective July 1, 2016.

2. METHODOLOGY

Burchfield used the following comprehensive methodology for conducting the market check study:

- Reviewed current Consortium contract to ensure understanding of network, brand and generic definitions, pricing and guarantees;
- Received May-December 2014 claims data totaling approximately 3 million claims for Consortium Participating Programs and approximately 300,000 claims for WPDP and OPDP discount cards;

- Created a baseline financial model using this claims experience and trended it (claims, lives, AWP, utilization, contract guarantees) forward to estimate 2016 drug spend;
- Gathered market pricing, using recent PBM benefit procurements it managed, as well as other marketplace intelligence it accumulated;
- Compared Consortium group pricing to pricing for similarly sized clients using seven unique recent commercial multi-year best and final offers (including both traditional and pass-through pricing arrangements);
- Compared Consortium discount cards to seven unique recent small-client commercial multi-year best and final offers (including both traditional and pass-through pricing arrangements), noting that discount card pricing is difficult to analyze because of the type of benefit and lack of data about other cards; and
- Provided both a PowerPoint slide set and oral presentation of the study results.

The following assumptions were used by Burchfield to complete this market check analysis:

- Mail order pharmacy claims were defined as claims from OHSU Mail Order Pharmacy for one group (OHSU) and Postal Prescription Services for all other groups and discount cards.
- Retail 90 pharmacy claims were defined as retail claims with days of supply greater than 84. Choice90 was not implemented for any participating program until September 2014.
- Specialty pharmacy claims were defined as specialty claims dispensed at Salem Hospital, OHSU Outpatient, OHSU Mail Order, Ardon Health, or Diplomat Specialty Pharmacy. Specialty pharmacy claims were identified using Moda Health’s custom specialty drug lists.
- Non-drug item, paper, and non-traditional pharmacy (LTC, HIF, ITU, VA, Military) claims were omitted from the market check study. Market pricing was not applied to these claims.
- COB, vaccine, and onsite pharmacy claims were included in the market check study and were treated as standard pharmacy claims.
- Limited Distribution Drug claims were included in the claim set provided to Burchfield and the resulting prices counted against the effective discount rates that were calculated for Specialty pharmacy claims. Treatment of these claims in this manner (rather than excluding them from performance guarantees as the current Consortium contract does) negatively impacted the overall specialty discount guarantee that Burchfield included in its baseline financial model.

3. FINDINGS

The tables below, one for participating program groups and one for discount cards, summarize the study results. For each pharmacy distribution channel, these tables show the actual contracted Consortium financial guarantee, the distribution range of market pricing, and the possible dollar value of the difference between the Consortium financial guarantee and the market place average.

Price Point Summary – Consortium Groups

LOB	Guarantee Type		Moda		Market Pricing ⁽¹⁾		Sensitivity ⁽²⁾	Impact with Average Rates
			Current Guarantee*		Average Rates**	Range (Conservative to Aggressive)		
			2016		2016			
Consortium Groups	Retail	Brand	Discount	16.53%	16.83%	15.75% to 18.50%	1% = \$1.5 million	\$453,000
			Disp. Fee	\$1.22	\$0.60	\$0.85 to \$0.50	\$0.10 / Rx = \$0.05 million	\$287,000
		Generic	Discount	79.42%	79.02%	77.25% to 80.75%	1% = \$3.3 million	(\$1,289,000)
			Disp. Fee	\$1.22	\$0.64	\$0.85 to \$0.55	\$0.10 / Rx = \$0.3 million ⁽³⁾	\$1,784,000
	Retail 90	Brand	Discount	19.50%	21.37%	18.50% to 25.50%	1% = \$0.3 million	\$517,000
			Disp. Fee	\$0.03	\$0.24	\$0.85 to \$0.00	-	(\$10,000)
		Generic	Discount	79.42%	80.95%	78.25% to 86.00%	1% = \$2.0 million ⁽³⁾	\$3,024,000
			Disp. Fee	\$0.03	\$0.23	\$0.85 to \$0.00	-	(\$172,000)
	Mail	Brand	Discount	23.00%	24.07%	23.00% to 25.50%	1% = \$0.4 million	\$430,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
		Generic	Discount	80.00%	82.55%	80.50% to 86.00%	1% = \$0.7 million ⁽³⁾	\$1,666,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
	Specialty Discount (Aggregate Average)			15.50%	15.94%	14.92% to 17.99%	1% = \$2.3 million	\$2,142,000
	Administrative Fee ⁽⁴⁾			\$3.04 / Rx	\$0.50 / Rx	\$0.95 / Rx to \$0.00 / Rx	\$0.25 / Rx = \$1.2 million ⁽³⁾	\$10,112,000
								\$18.9 million (3.8%) over one year time period

Price Point Summary – Consortium Discount Cards

LOB	Guarantee Type			Moda	Market Pricing ⁽¹⁾		Sensitivity ⁽²⁾	Impact with Average Rates
				Current Guarantee*	Average Rates**	Range (Conservative to Aggressive)		
				2016	2016	2016		
Discount Card Program	Retail	Brand	Discount	16.53%	16.16%	15.30% to 17.00%	1% = \$0.4 million	(\$13,000)
			Disp. Fee	\$1.22	\$0.94	\$1.37 to \$0.50	\$0.25 / Rx = \$0.01 million ⁽³⁾	\$5,000
		Generic	Discount	79.42%	77.81%	76.25% to 79.65%	1% = \$0.33 million	(\$527,000)
			Disp. Fee	\$1.22	\$0.94	\$1.37 to \$0.50	\$0.25 / Rx = \$0.08 million ⁽³⁾	\$87,000
	Retail 90	Brand	Discount	19.50%	20.03%	18.97% to 22.50%	1% = \$0.004 million	\$2,000
			Disp. Fee	\$0.03	\$0.38	\$0.90 to \$0.00	-	(\$1,000)
		Generic	Discount	79.42%	80.18%	78.25% to 82.75%	1% = \$0.2 million ⁽³⁾	\$152,000
			Disp. Fee	\$0.03	\$0.38	\$0.90 to \$0.00	-	(\$29,000)
	Mail	Brand	Discount	23.00%	23.10%	18.97% to 25.25%	1% = \$0.002 million	\$1,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
		Generic	Discount	80.00%	80.82%	77.00% to 83.00%	1% = \$0.03 million	\$21,000
			Disp. Fee	\$0.00	\$0.00	\$0.00 to \$0.00	-	\$0
	Specialty Discount (Aggregate Average)			15.50%	16.47%	12.48% to 22.76%	1% = \$0.004 million	\$1,000
	Administrative Fee ⁽⁴⁾			\$0.98 / Rx	\$0.38 / Rx	\$1.65 / Rx to \$0.00 / Rx	\$0.25 / Rx = \$0.12 million ⁽³⁾	\$285,000
								-\$16,000 (-0.1%) over one year time period

These notes further explain details that appear in the tables:

- * Current Guarantee represents the blended averages calculated from the current Consortium contract guarantees which span the May 1 contract anniversary dates when financial guarantees change (i.e., calculated using January 1 - April 30, and May 1 –December 31).
- ** Market pricing averages represent the averages of the financial guarantees quoted in the PBM offers that Burchfield surveyed. There is no PBM offer that includes all the averages (i.e., an “average offer” does not exist).
 - (1) Market Pricing consists of best and final prices quoted in Burchfield's experience with similar clients (for the groups table) and small commercial clients (for the discount cards table) through competitive RFP processes involving multi-year deals.
 - (2) “Sensitivity” represents the dollar value over one year that might be improved when pricing is improved by the rate shown in connection with the specific utilization that was applied for the study. Savings is not illustrative of a reduction in plan costs over current plan costs, but is instead reflective of the difference between new pricing versus current pricing based on modeling assumptions trended throughout the time period of the new contract.
 - (3) Administrative fees are not representative of the identical services provided in the various offerings that were evaluated. Administrative fees represent both pass-through as well as traditional pricing arrangements.

Burchfield noted that no single PBM offer will contain the most advantageous price point for every pricing component within the market range. Additionally, Burchfield noted that services included in administrative fees vary among PBMs and the offers they propose. To better compare the similarity of PBM administrative services and the corresponding fees associated with these services, a close evaluation of each individual offer would be required. The market check did not assess the specific scopes of services included in each PBM offer’s administrative fee proposal.

For Participating program groups in the aggregate, the results of the market check study indicate that, given other variables held constant, approximately \$8.8 million in savings may result in achieving ingredient price and dispense fee discounts that approximate the market averages estimated by Burchfield. This potential savings represents approximately 1.8% of the estimated total spending during the assessment period.

An additional \$10 million difference was identified between the current Consortium contracted administration fee and the marketplace average. However, because the administrative fees represented in the proposals evaluated in the market check analysis included both traditional PBM prices, where PBMs keep spread based on differences between the amount billed the client and the amount paid to the pharmacy, as well as traditional pass-through pricing options, an apples to apples comparison of administrative fees was not able to be achieved.

For the discount card pricing comparison of ingredient discounts and dispensing fees, the findings indicate that discount card prices are better than market, representing approximately \$301,000 in value over and above the market prices that were evaluated. When administrative fees are included, the Consortium prices for discount card members continue to outperform the market, but by a much smaller margin, representing only \$16,000 in pricing differential. In summary, then, discount card prices in the aggregate are at market.

At Moda's request, Burchfield attempted to forecast the impact of future changes in Consortium and market pricing. Burchfield concluded that:

- Based on the market offers it included in this study, 2017 market rates improve (compared to 2016) in aggregate by an average 0.7%.
- Consortium financial guarantees for 2017 rates improve in aggregate by approximately 0.4%
- The net improvement of the market over Consortium contract rates from 2016 to 2017 would be approximately 0.3%.
- There may be slight market improvements in retail generic discounts and dispensing fees, but drug mix changes and variability can greatly affect any group's results. As a consequence, accurately projecting the results of this market check survey into a projection for expected savings in future years is problematic and should not be attempted.

4. RECOMMENDATIONS

To optimize the potential to operate at or above market, Burchfield recommended consideration for the following areas of opportunity:

- The study identifies areas where there may be opportunities to review network pricing (reimbursement rates and dispensing fees). Specifically, there are areas where the Consortium guarantee difference from the market average is greater than 1%. These include:
 - Groups:
 - Retail 90 Brand and Generic pricing
 - Mail Brand and Generic pricing
 - Retail Dispensing fees for Generics
 - Discount Cards
 - Retail Generic and Brand pricing
 - Retail Dispensing fees for Generics and Brands

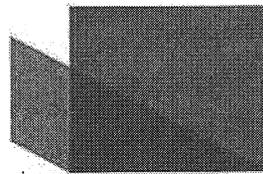
5. EVALUATION AND CONSIDERATIONS FOR SUBSEQUENT MARKET CHECK SURVEYS

As a result of this market check study, Moda offers several observations and recommendations.

- Burchfield did not compare each PBM offering *in toto* to each other offering. For example, neither the Consortium's group business nor either of the Consortium discount cards was compared individually to a single market offer.
- The study did not assess actual financial performance. The study evaluated financial guarantees included in the Consortium contract. Historically, Moda performs significantly better than the Consortium contracted guarantees. As a result, Consortium pricing may be more competitive with the market than study suggests.
- Changes over time in utilization, AWP inflation, drug mix, new drug introductions, and other factors will affect future results. The market survey should not be used to project future savings. Monitoring actual experience and financial performance will be critical to ensuring participating groups and discount cards operate at or above market going forward.
- The PBM proposals (offers) that were included by Burchfield in its analysis do not directly compare with Consortium groups. The PBM offers each apply to a specific single group, whereas the Consortium serves multiples groups with a wide range in size and utilization.



STUDY OF THE PHARMACY CHAIN OF SUPPLY



OFFICE of the
**INSURANCE
COMMISSIONER**
WASHINGTON STATE

The largest PSOs are owned and operated by the three largest drug wholesalers (AmerisourceBergen, Cardinal Health, and McKesson). Although there is no evidence that these entities do not effectively represent their pharmacy clients, informants for the Study have expressed concern regarding a potential conflict of interest.

PBM Pharmacy Reimbursement

The rates of reimbursement are very important to independent pharmacies because more than 90% of their total sales come from prescription drugs.⁴² Nationally, data from PBMs shows that 88% of claims and 32% of reimbursements are for generic drugs. Prescription reimbursement has two specific components: drug ingredient cost (i.e., the cost of the drug) and dispensing fee. The dispensing fee is, in theory, intended to reimburse the pharmacy for the costs not associated with the purchase of the drug. These costs include:

- + pharmacy license fees;
- + delivery expenses;
- + claims processing computer expenses;
- + prescription containers, labels and other packaging material;
- + a portion of facility costs (e.g. rent, utilities, taxes, insurance); and
- + labor costs including professional pharmacy services performed during the provision of the medication to the recipient.

According to a survey of plan sponsors, the average dispensing fees for retail pharmacies in 2015 ranged from \$1.56 to \$2.17.⁴³ 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. The effect of this discrepancy is discussed under the “Maximum Allowable Cost Reimbursement and Pharmacy Profitability” section of the Study.

The drug cost portion of reimbursement is generally identified relative to the list price benchmark of AWP. Historically, AWP was a benchmark price established by the California Medicaid program for pharmaceutical transactions. It was originally based on actual surveyed invoice data. However, it eventually was changed to a calculated figure based on the WAC price established by manufacturers. Today, AWP is equal to 120% of a drug’s WAC price for brand name drugs or the price published by generic manufacturers.

Example of EpiPen Price Increase Across the Supply Chain

The introduction of high-cost drugs and large increases in prices for existing drugs have become significant issues in healthcare. Mylan’s 2016 increase to the cost of EpiPen created a firestorm of interest nationally. As chronicled in the news,⁴⁴ the list price of EpiPen was increased by its manufacturer, Mylan, from \$93.88 (2007) to \$608.61 (2016). Per Mylan, the list price increase was

⁴² NCPA 2015 Digest, at <http://www.ncpa.co/pdf/aaaa-2015-digest-sponsored-by-cardinal-health.pdf>

⁴³ 2015-2016 Prescription Drug Benefit Cost and Plan Design Report,” Pharmacy Benefit Management Institute, 2015.

⁴⁴ <http://www.wsj.com/articles/mylans-epipen-price-increases-highlight-its-grip-on-the-market-1472154769>

Exhibit 13: The Money Flow for EpiPen in the Supply Chain

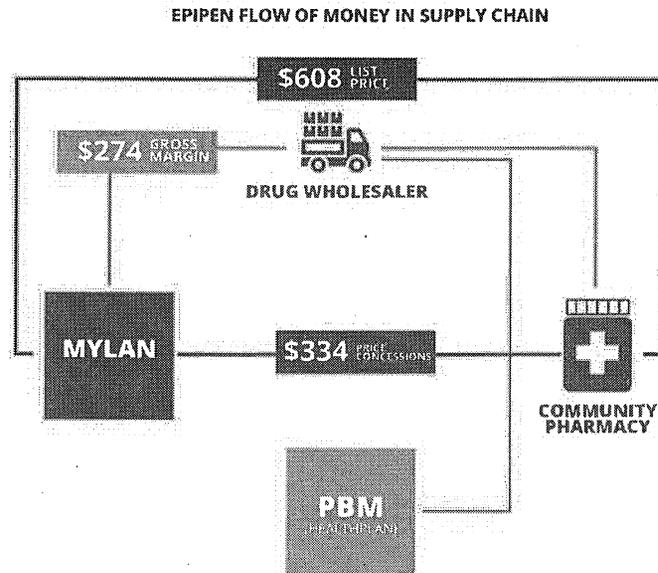


Exhibit 13 provides evidence that Mylan priced the drug in order to reach a specific per-unit revenue amount. The \$608 is a list price, which Mylan controls—each of the listed entities do not directly increase the list price. The exhibit shows instead, the level of monetary incentives Mylan provides to the rest of the supply chain to cover and dispense EpiPen. Mylan, knowing the incentives it was going to provide, increased the price of EpiPen to maintain the target net income. Prior to the EpiPen incident, Mylan pharmaceuticals tried to “corner the market” on two generic drugs in 1999-2000. In that instance, there were willing competitors, but Mylan cut a deal to purchase most or all the raw material for manufacturing. Ultimately, Mylan settled a \$100 million anticompetitive lawsuit filed by the Federal Trade Commission.⁴⁵

Medicaid Reimbursement

Although the Study is focused on aspects of the private sector pharmaceutical supply chain, it is important to also understand the impact that the Medicaid program may have on individual pharmacies and how changes to Medicaid reimbursement mandated by the federal government may or may not spill over into the private sector.

Like other third party payers, Medicaid programs formerly relied on the use of AWP as a reference price. As previously noted, AWP historically originates in the California Medicaid program in the late 1960’s, as a price derived from surveys of major drug wholesalers. AWP has since evolved into a calculated value based on information supplied solely by drug manufacturers. Due to litigation with drug manufacturers over the accuracy of AWP (and by extension WAC), CMS and Medicaid programs searched for a reasonable alternative benchmark.

⁴⁵ <https://www.ftc.gov/news-events/press-releases/2000/11/ftc-reaches-record-financial-settlement-settle-charges-price>

Ultimately, Medicaid Pharmacy Administrators and Medicaid Directors recommended that CMS explore the use of an Actual Acquisition Cost (AAC) model for reimbursement.⁴⁶ Based on these recommendations, CMS issued proposed rules in February 2012 that would adopt AAC as the benchmark for reimbursement of drugs in state fee-for-service (FFS) Medicaid programs. These rules were finalized in February 2016, and state Medicaid FFS programs have until April of 2017 to implement the changes from their current reimbursement methodology. (As of June 2016, 10 states have adopted AAC based reimbursement rates.)

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.⁴⁷ Accordingly, 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.⁴⁸

Because AAC reimbursement relies on surveying provider invoices, pharmacy representatives are concerned that the process may not be broad enough or updated frequently enough to capture changes in AAC.

CMS provides states with an option to use the NADAC price as opposed to doing their own in-state surveys. Because NADAC is a voluntary process (as opposed to the mandatory requirements for pharmacy invoices in some states) the prices may be skewed by the lower costs of large chain pharmacy purchases.

Observations

There is a certain opacity within the supply chain of any commodity. The public rarely gets a glimpse at the specifics of how a product and payments pass from one supply chain member to the other. For example, in the auto industry the public knows that a new automobile goes from the factory to specific authorized dealerships with a sticker price that is a retail reference price used to begin the negotiation on the final purchase price. The pharmaceutical supply chain is much more complex with hundreds of manufacturers selling thousands of products through dozens of wholesalers to thousands of pharmacies, with thousands of different confidential monetary transactions occurring for each unique drug product. Underlying this is the consolidation of the supply chain where corporations own multiple channels in the supply chain.

Pharmacy products are then sold to the consumer with the bulk of the payment coming from a third party who also has confidential agreements with both the consumer's insurance company and the pharmacy. This complex nature of the pharmaceutical supply chain and reimbursement has allowed each member to put blame on other members of the supply chain for the rising cost of drugs or to allege financial injury imposed unto them by other supply chain members.

⁴⁶ "Post AWP Pharmacy Pricing and Reimbursement", National Association of State Medicaid Directors, November 2009

⁴⁷ Section 1902(a)(30)(A) of the Social Security Act

⁴⁸ There is some variation within some states for pharmacy type and preferred vs. non-preferred drugs.

Exhibit 46: Percentage of Total Pharmacy Claims and Reimbursement for Washington Pharmacies by Brand and Generic⁷³

		PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6	All PBMs
Brand	% of Claims	13%	65%	11%	13%	11%	13%	16%
	% of Reimbursement	59%	90%	58%	65%	65%	68%	66%
Generic	% of Claims	87%	35%	89%	87%	89%	87%	84%
	% of Reimbursement	41%	10%	42%	35%	35%	32%	34%

Observations

- + PBM dispensing fees paid to Washington pharmacies were generally lower than national averages.
- + PBM 6 paid the lowest average dispensing fee at \$.66 per claim.
- + The difference in average dispensing fees for brand versus generic drugs was negligible.
- + Current dispensing fees provided by PBMs were significantly lower than the \$11.65 average COD found in the 2015 study⁷⁴. If the ingredient cost reimbursement of drugs were reduced, the spread pharmacies have relied upon to remain profitable would begin to disappear.
- + As the spread disappears, the pharmacy is unable to make up for the discrepancy between their cost to dispense and the dispensing fees paid by the PBMs. Therefore, eliminating the spread for most drugs dispensed by a pharmacy will cause that pharmacy to be less profitable and potentially less viable as a business entity.

Washington State Pharmacy Profitability Case Studies

To further assess the effect of PBM reimbursement on pharmacy profitability, an analysis of PBM reimbursements to two pharmacies randomly selected from the six PBMs' data was conducted. The two pharmacies were both non-chain independent pharmacies, one rural and one urban. Since actual drug acquisition costs and COD costs were not obtained from the pharmacies, the analysis compared actual PBM reimbursements to these pharmacies to the national discounted Average Wholesale Price (AWP) benchmarks (for brand and generic drugs) used in our earlier analysis. The analysis included the following components:

- + Changes in profitability were analyzed under two different COD assumptions: a \$10 dispensing fee and a \$15 dispensing fee.
- + Profitability of dispensing brand versus generic drugs was assessed.
- + The number of negative net income claims was assessed.

As discussed in the Method section above, the assumptions used in the analysis included the following:

⁷³Note: PBM 2's outlier percentages are due to the reporting anomalies.

⁷⁴"Cost of Dispensing Study: An Independent Comparative Analysis of U.S. Prescription Dispensing Cost" September 2015.

Exhibit 61: Net Income as a Percent of Gross Income at PBM Average Dispensing Fee for the Case Study Pharmacies

At Avg. PBM Fee	Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Claims	2,177	27,246	1,685	7,037	13,974	52,119
	PBM Paid	\$147,944	\$995,970	\$141,993	\$331,039	\$712,463	\$2,329,410
	Copayment	\$1,946	\$20,950	\$16,869	\$49,556	\$123,059	\$212,380
	Gross Income	\$149,890	\$1,016,920	\$158,862	\$380,594	\$835,523	\$2,541,789
	Drug Cost	\$116,521	\$749,782	\$138,638	\$286,419	\$645,690	\$1,937,050
	Dispensing Cost	\$4,093	\$23,976	\$2,123	\$12,315	\$9,223	\$51,730
	Total Cost	\$120,614	\$773,758	\$140,761	\$298,734	\$654,913	\$1,988,780
	Net Income	\$29,275	\$243,162	\$18,101	\$81,861	\$180,610	\$553,010
Net Income % of Gross Income	19.5%	23.9%	11.4%	21.5%	21.6%	21.8%	
At Avg. PBM Fee	Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	3,115	19,823	570	825	13,758	38,091
	PBM Paid	\$124,808	\$858,756	\$44,794	\$28,743	\$685,207	\$1,742,308
	Copayment	\$1,075	\$4,145	\$7,596	\$5,678	\$19,359	\$37,853
	Gross Income	\$125,883	\$862,901	\$52,389	\$34,422	\$704,566	\$1,780,160
	Drug Cost	\$76,790	\$670,178	\$41,972	\$24,738	\$588,680	\$1,402,358
	Dispensing Cost	\$5,856	\$17,444	\$718	\$1,444	\$9,082	\$34,544
	Total Cost	\$82,646	\$687,622	\$42,690	\$26,182	\$597,762	\$1,436,902
	Net Income	\$43,237	\$175,278	\$9,700	\$8,239	\$106,804	\$343,258
Net Income % of Gross Income	34.3%	20.3%	18.5%	23.9%	15.2%	19.3%	

Summary

The weighted average dispensing fees (\$0.66 - \$1.88) paid by the six PBMs were significantly lower than the surveyed \$11.65 average actual cost to dispense for Washington pharmacies. Based on the two pharmacy case study profiles, the issue of pharmacy profitability was tied to the declining ability of the spread to compensate for the under reimbursement of pharmacy dispensing costs. This was illustrated by the Average Net Incomes being below \$5.00 in the aggregate for the two target pharmacies at a COD level of \$10. Increased costs cut into these slim margins, making it difficult for pharmacies to maintain profitability.

To compensate for declining profitability, pharmacies had to find ways to improve income levels. However, pharmacies that had to rely heavily on prescription drug income essentially had two choices, they either must obtain higher or expanded fees or they must maintain a sufficient spread on drug costs and reimbursement.

The Office of the Insurance Commissioner can assist on the latter by reviewing PBM reimbursement complaints, but it will be up to the pharmacies and their PSAO representatives to obtain improved cost of delivery (COD) fees. Any actions taken will result in increased costs being passed to the consumer through copayments or increases in premiums.

CERTIFICATE OF SERVICE

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

That on the 25th day of June, 2018, I served the foregoing **OPENING BRIEF OF PETITIONERS** on the following parties and/or counsel of record via *Electronic Court E-Service* as follows:

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s/ Averil Rothrock
Averil Rothrock, WSBA #24248

SCHWABE WILLIAMSON WYATT

June 25, 2018 - 3:16 PM

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