IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON

FOR THE COUNTY OF THURSTON

NATIONAL ASSOCIATION OF CHAIN DRUG STORES; WASHINGTON STATE PHARMACY ASSOCIATION; NATIONAL COMMUNITY PHARMACISTS ASSOCIATION,

Petitioners,

vs.

WASHINGTON STATE HEALTH CARE AUTHORITY; Dorothy Frost Teeter, not individually, but solely in her official capacity as Director of the WASHINGTON STATE HEALTH CARE AUTHORITY,

Respondents.

No. 17-2-01489-34
[Clerk's Action Required]

PETITION FOR DECLARATORY RELIEF AND EMERGENCY STAY

PETITION FOR DECLARATORY RELIEF AND EMERGENCY STAY

NOW COME the Petitioners the NATIONAL ASSOCIATION OF CHAIN DRUG STORES ("NACDS"), the WASHINGTON STATE PHARMACY ASSOCIATION ("WSPA"), and the NATIONAL COMMUNITY PHARMACISTS ASSOCIATION ("NCPA"), (collectively, the "Petitioners"), and for their Petition for Declaratory Relief and Emergency Stay (the "Petition") pursuant to the Washington Administrative Procedure Act, RCWA § 34.05 *et seq.*, against the WASHINGTON STATE HEALTH CARE AUTHORITY and Dorothy Frost Teeter, not individually, but solely in her official capacity

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as Director of the WASHINGTON STATE HEALTH CARE AUTHORITY (collectively, "Respondents"), state as follows:

INTRODUCTION

1. In less than 48 hours, Washington's Medicaid program will implement a new rule that unlawfully and significantly reduces the total reimbursement it pays to pharmacies that serve the State's most vulnerable residents. As described in more detail, *infra*, the State will effectuate this total reimbursement rate cut by reducing the amount it pays pharmacies for their ingredient costs to purchase drugs, while leaving the amount it pays pharmacies for their cost of dispensing unchanged (a reimbursement rate that *already* does not cover the pharmacies' cost of dispensing).

2. Washington's WSR 17-07-001 is a new rule governing the reimbursement of pharmacies that participate in the State's Medicaid program (the "New Rule"). The State has adopted substantial amendments in the New Rule, the effect of which will significantly cut Medicaid reimbursement to Petitioners' members, which are pharmacies that provide services to disadvantaged Medicaid patients.

3. Washington, like other states, administers its own Medicaid program and must comply with federal and state law. State Medicaid actions that do not comply with the standards and regulations established under federal law are illegal.

4. Federal law requires state Medicaid programs to establish reimbursement rates that cover pharmacies' costs to purchase prescription drugs ("ingredient cost reimbursement") and cover costs associated with dispensing those drugs to Medicaid patients ("professional dispensing fee") (collectively, "total reimbursement"). Although the State's

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New Rule cuts pharmacies' ingredient cost reimbursement rates, the State failed to increase professional dispensing fees to cover the costs of dispensing that pharmacies incur when they provide medications and services to Medicaid patients. All the available evidence, including the State's own study, indicates that the State's professional dispensing fees are far below pharmacies' cost of dispensing. This failure to reimburse pharmacies for their costs not only violates federal law, but the manner in which the State promulgated the New Rule violates Washington's statutory rule-making procedures as it disallowed pharmacies from making meaningful comment on the unchanged professional dispensing fee.

5. The New Rule goes into effect on April 1, 2017. Accordingly, unless stopped, there will be a significant negative change affecting numerous Washington Medicaid pharmacy providers.

6. For these reasons, the New Rule and related agency actions must be declared invalid. Petitioners seek an emergency stay of the State's New Rule pending the outcome on the merits of the declaratory judgment action to prevent imminent harm to their members.

JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to RCW § 34.05.510 *et seq.* The Washington Administrative Procedure Act ("APA") "establishes the exclusive means of judicial review" of an agency rule. *Id.* RCW § 34.05.570(2)(b)(i) specifically applies to judicial review of rules and provides that a rule may be reviewed by a petition for declaratory judgment. RCW § 34.05.550(2) provides that "[a]fter a petition for judicial review has been filed, a party may file a motion in the reviewing court seeking a stay or other temporary remedy."

8. Venue is proper in this County pursuant to RCW § 34.05.570(b)(i).

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PARTIES

9. Petitioners are non-profit associations of pharmacies that will be affected by the implementation of the total reimbursement rate reduction to be paid to Washington's Medicaid pharmacy providers. Each of the Petitioners have members that participate in the State's Medicaid program and who will be injured by the New Rule and associated agency actions. Therefore, Petitioners have associational standing to bring this suit as: (1) Petitioners' member pharmacies would otherwise have standing to sue in their own right; (2) the interests that Petitioners seek to protect are germane to their purpose as pharmacy associations that advocate in favor of the rights and interests of pharmacies; and (3) neither the claims asserted nor the relief requested requires the participation of Petitioners' individual members.

10. The National Association of Chain Drug Stores ("NACDS") is a non-profit organization incorporated and based in Arlington, Virginia. NACDS' purpose is to represent the interests of traditional drug stores, supermarkets and mass merchants with pharmacies, and supplier partners. NACDS' members operate over 40,000 pharmacies, which include regional chains with at least four stores as well as national companies, employ more than 3.2 million people, including 178,000 pharmacists, and operate 932 pharmacies and employ over 72,000 people in Washington State. Many of NACDS' members participate in Washington's Medicaid program.

11. The Washington State Pharmacy Association ("WSPA") is a non-profit organization incorporated and established under the laws of the State of Washington. The WSPA represents pharmacists, technicians, and interns practicing within community

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pharmacies, as well as clinics, nursing homes, and hospitals. Many of WSPA's members participate in Washington's Medicaid program.

12. The National Community Pharmacists Association ("NCPA") is a non-profit organization incorporated and based in Alexandria, Virginia. NCPA represents the interests of the owners, managers, and employees of more than 22,000 independent community pharmacies across the United States (hereinafter, "Independent Pharmacies"). Together, Independent Pharmacies employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescriptions. NCPA's members operate in Washington and participate in Washington's Medicaid program.

13. In 2011, the State Health Care Authority ("HCA") replaced the State Department of Social and Health Services ("DSHS") as Washington State's Medicaid single state agency.

14. The HCA is charged with administering the State's Medicaid program and implementing Medicaid reimbursement rates for pharmacies.

15. Dorothy Frost Teeter is named in this petition solely in her official capacity as Director of the HCA.

BACKGROUND

16. Medicaid is a joint federal and state program created under Title XIX of the Social Security Act to provide health care to indigent and otherwise disadvantaged individuals and families. The Medicaid program is commonly known as the "payor of last resort" because Medicaid patients often lack resources to pay for medical treatment or pharmacy services.

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17. A state's participation in Medicaid is voluntary; however, a state's Medicaid program must comply with federal Medicaid laws and regulations, and be approved by the Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS") in order to receive federal funds.

18. The Washington Medicaid Plan is the HCA's comprehensive written statement submitted to CMS that describes the nature and scope of the State Medicaid program and gives assurances that HCA will administer the State Plan in conformity with the specific requirements of the Social Security Act. In order to comply with federal law, Washington's Medicaid program must comply with Section 1902(a)(30)(A) of the Social Security Act which provides, in relevant part:

> A State plan for medical assistance must … assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

42 U.S.C. § 1396a(a)(30)(A).

19. Pharmacies such as the Petitioners' members who participate in a state's Medicaid program, including Washington's program, receive reimbursement for providing prescription drugs and services to Medicaid patients. Medicaid reimbursement to pharmacies includes two basic components: (i) an *ingredient cost reimbursement* to pay for the drug, and (ii) a *professional dispensing fee* to cover the costs of preparing and dispensing the drug to Medicaid patients and providing related professional services. The focus of this lawsuit is on both components of the State's Medicaid reimbursement rate methodology.

20. Currently, under WAC 182-530-1000 *et seq*., Washington's Medicaid reimbursement rate methodology for fee-for-service prescriptions for ingredient cost is based

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on estimated acquisition cost, which is often calculated as 16% to 50% less than a benchmark price known as Average Wholesale Price ("AWP"). The professional dispensing fee for Medicaid fee-for-service prescriptions is $4.24 to $5.25 (based on 3-tiered pharmacy volume). These reimbursement rates have not been updated since at least July 1, 2009.[1]

21. In February 2016, CMS promulgated a new regulation that significantly changed the way in which States must reimburse pharmacies in the Medicaid program (the "CMS Rule"). 81 Fed. Reg. 5170 (Feb. 1, 2016). The CMS Rule requires states to adopt total reimbursement rates that cover the costs incurred by pharmacies as they purchase and dispense prescription drugs to Medicaid patients.

22. With regard to ingredient cost reimbursement for the cost of purchasing drugs, the CMS Rule requires States to move from reimbursement based on "Estimated Acquisition Cost" to "Actual Acquisition Cost" ("AAC"). 42 C.F.R. §§ 447.502, 447.512(b), 447.518(a)(2). In addition, the CMS Rule requires each State Medicaid agency to establish a new professional dispensing fee that is sufficient to cover a long list of specified pharmacy costs associated with operating pharmacies and employing pharmacists to provide services to Medicaid patients. 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1). The CMS Rule requires States to issue findings and assurances that their ingredient cost reimbursement is sufficient to cover pharmacies cost to purchase drugs, and that their new professional dispensing fee is sufficient to cover pharmacy costs associated with dispensing drugs to Medicaid patients. 42 C.F.R. § 447.518(b).

[1] Health and Recovery Services Administration (HRSA), *Prescription Drug Program: Billing Instructions*, Washington State Health Care Authority (October 20, 2008), https://www.hca.wa.gov/assets/billers-and-providers/prescription_drug_program_bi_01012010-05082010.pdf at pp. H.2-4.

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23. The CMS Rule further provides, in relevant part, that "[w]hen proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of [subpart d] …" 42 C.F.R. § 447.518(d). Subpart (d) requires States to "consider **both** the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes" and to "**provide adequate data** such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to … the components of the reimbursement methodology." *Id.* (emphasis added).

24. Under Washington's New Rule, the State has decreased the Medicaid reimbursement rate for fee-for-service prescriptions for ingredient cost by adopting the AAC methodology; however, the State has not adopted any corresponding increase in professional dispensing fees to cover the cost of dispensing incurred by pharmacies as required by the CMS Rule. Moreover, during the rulemaking process, the State did not identify any study or other adequate data to support its decision not to change the dispensing fee that has been in place since at least 2009.

FACTS COMMON TO ALL COUNTS

25. Petitioners restate and incorporate by reference paragraphs 1-24 as paragraph 25, as if fully set forth herein.

26. On June 29, 2016, the State filed Preproposal Statement of Inquiry WSR 16-14-053 (the "Statement of Inquiry") in the Washington State Register. The Statement of Inquiry provided that WAC Chapter 182-530, Prescription drugs (outpatient), and other

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related rules were the subject of a possible rule-making. A true and correct copy of WAC 182-530 is attached hereto as **Exhibit A**.

27. The Statement of Inquiry identified CMS as the only other agency (federal or state) regulating the subject matter of the rule and was silent as to how HCA planned to coordinate with CMS. A true and correct copy of the Statement of Inquiry is attached hereto as **Exhibit B**.

28. On January 4, 2017, the State published notice of its Proposed Rule-Making Order WSR 17-02-083 in the Code Reviser. The Proposed Rule-Making Order identified February 7, 2017 as both the date for the public hearing and the deadline to submit written comments. A true and correct copy of Proposed Rule-Making Order WSR 17-02-083 is attached hereto as **Exhibit C**.

29. On March 1, 2017, the State filed Permanent Rule-Making Order WSR 17-07-001 with the Code Reviser. The Order states that the State Rule is revising WAC Chapter 182-530 "to align with [CMS'] new covered outpatient drug rule, CMS-2345-FC." Despite substantial amendments to the Rule, the State failed to determine if the Rule, as amended, complies with the CMS Rule. A true and correct copy of Permanent Rule-Making Order 17-07-001 is attached hereto as **Exhibit D**.

30. On or about March 2, 2017, the State sent a Medicaid pharmacy provider alert to all pharmacies indicating that the "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's no NADAC available for a drug,

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the Agency will use wholesale acquisition cost or other available price." Importantly, the Agency for the first time notified pharmacies that "[d]ispensing fees are unaffected by this change."[2] A true and correct copy of the E-mail Notice is attached hereto as **Exhibit E**.

31. On March 17, 2017—*after* filing the adopted Rule with the Code Reviser and notifying providers of the decision not to raise the dispensing fee —the State prepared a "Concise Explanatory Statement" ("CES"). The CES outlines and responds to ten comments on the Rule; however, none of which addresses the failure to increase the professional dispensing fee given that the State did not notify pharmacies until after the comment period had ended. A true and correct copy of the CES is attached hereto as **Exhibit F**.

32. Additionally, the CES is silent as to the basis or process that HCA relied upon in developing the Rule. It provides no indication that it considered the Washington Office of the Insurance Commissioner's ("OIC") "Study of the Pharmacy Chain of Supply" (the "Study"), which the legislature required OIC conduct pursuant to SB 5ESSB 5857. The Study finds that states that have adopted the AAC reimbursement methodology for ingredient cost have performed cost of dispensing surveys and currently have dispensing fees that are generally in excess of $10 per prescription. A true and correct copy of OIC's Study is attached hereto as **Exhibit G**.

33. On April 1, 2017, the Rule will become effective for all participating pharmacies in the state according to Permanent Rule-Making Order WSR 17-07-001. As a result, Washington's total reimbursement to pharmacies will not cover Petitioners' member's total costs, as the New Rule adopts the AAC methodology for ingredient cost reimbursement

[2] The current professional dispensing fee for Medicaid fee-for-service prescriptions is $4.24 to $5.25 (based on 3-tiered pharmacy volume).

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but maintains the current professional dispensing fee of $4.24-$5.25 which is significantly below participating pharmacies' cost of dispensing.

COUNT I

DECLARATORY JUDGMENT UNDER THE WASHINGTON ADMINISTRATIVE PROCEDURE ACT (Ingredient Cost Reimbursement)

34. Petitioners restate and incorporate by reference paragraphs 1-33 as paragraph 34, as if fully set forth herein.

35. The New Rule, or its threatened application, interferes with or impairs, or immediately threatens to interfere with or impair, the legal rights or privileges of the Petitioners' member pharmacies.

36. The New Rule was adopted without compliance with statutory rule-making procedures because it failed to provide pharmacies an opportunity to meaningfully participate in the development of the New Rule.

37. Additionally, the New Rule exceeds the statutory authority of the agency because it:

a. fails to increase the professional dispensing fee to cover pharmacies' costs of dispensing, in violation of the CMS Rule; and

b. improperly allows consideration of professional dispensing fees paid by other third-party payers and legislative appropriations in violation of the CMS Rule;

38. Lastly, the rule is arbitrary and capricious because the State failed to:

a. identify a cost of dispensing basis or process relied upon to arrive at its conclusion that the professional dispensing fee should not be increased;

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b. consider the OIC Study and other readily available evidence of the cost of dispensing in making its determination that the professional dispensing fee should not be increased;

c. prepare a small business impact statement; and

d. submit a cost-benefit analysis.

39. Therefore, the Court should enter an order declaring that the State's proposed ingredient cost rate reduction that will become effective April 1, 2017 is invalid because it (i) was adopted without compliance with statutory rule-making procedures and violates Petitioners' due process rights; (ii) exceeds the agency's statutory authority in that it violates the CMS Rule and the provisions of the Social Security Act implemented by the CMS Rule, and (iii) is arbitrary, capricious, and otherwise unlawful in that it violates the CMS Rule and the provisions of the Social Security Act implemented by the CMS Rule.

40. Additionally, the Court should enter an emergency stay preventing the proposed ingredient cost reimbursement rate reduction from going into effect on April 1, 2017 pending the outcome on the merits of the declaratory judgment action to prevent imminent harm to petitioners.

COUNT II

DECLARATORY JUDGMENT UNDER THE WASHINGTON ADMINISTRATIVE PROCEDURE ACT (Professional Dispensing Fee)

41. Petitioners restate and incorporate by reference paragraphs 1-40 as paragraph 41, as if fully set forth herein.

42. The State's professional dispensing fee rate currently set forth in the Provider Manual that will remain effective on April 1, 2017 is invalid because it (i) was adopted

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without compliance with statutory rule-making procedures and violates Petitioners' due process rights; (ii) exceeds the agency's statutory authority in that it violates the CMS Rule and the provisions of the Social Security Act implemented by the CMS Rule, and (iii) is arbitrary, capricious, and otherwise unlawful in that it violates the CMS Rule and the provisions of the Social Security Act implemented by the CMS Rule.

43. The Court should declare that the professional dispensing fee that is set to continue on April 1, 2017 is unlawful or, in the alternative, declare that the professional dispensing fee set to take effect on April 1, 2017 is unlawful, and remand the matter to the agency for further consideration of the appropriate professional dispensing fee.

IN THE ALTERNATIVE
COUNT III

DECLARATORY JUDGMENT UNDER THE WASHINGTON ADMINISTRATIVE PROCEDURE ACT (Professional Dispensing Fee)

44. Petitioners restate and incorporate by reference paragraphs 1-43 as paragraph 44, as if fully set forth herein.

45. The New Rule provides that "the Medicaid agency pays a dispensing fee for each covered, prescribed drug." WAC 182-530-7050(1). The New Rule substantially amends the definition of "dispensing fee" to mean a "professional dispensing fee" that is sufficient to cover a long list of specified costs that pharmacies incur when they dispense medications and provide associated services to Medicaid patients. WAC 182-530-1050. The New Rule further provides that the "agency periodically examines the sufficiency of pharmacy dispensing fees and may adjust the dispensing fee by considering [several factors]." WAC 182-530-7050(3).

46. The professional dispensing fees to be paid by the State Medicaid program

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under the New Rule are entirely insufficient to cover pharmacies' costs of dispensing. As a result, pharmacies will receive insufficient professional dispensing fees in violation of the State's own regulation. WAC 182-530-1050; WAC 182-530-7050.

47. Therefore, the Court should enter an order declaring the State's professional dispensing fee rates, currently set forth in the Provider Manual that are now or will become effective April 1, 2017, are invalid because they (i) exceed the agency's statutory authority in that they violate WAC 182-530-1050 and WAC 182-530-7050, and (ii) are arbitrary, capricious, and otherwise unlawful in that they violate WAC 182-530-1050 and WAC 182-530-7050.

PRAYER FOR RELIEF

Petitioners respectfully request that the Court:

(i) issue an immediate stay of the March 1, 2017 Rule-Making Order entitled WSR-17-07-001 and the imminent amendments to WAC 182-530-1050 *et seq.* (the "Rules");

(ii) declare that the Rules' implementation and threatened application, without any corresponding amendment to the professional dispensing fee to cover pharmacies' cost of dispensing, interferes with or impairs, or immediately threatens to interfere with or impair, the legal rights or privileges of the Petitioners' member pharmacies;

(iii) declare that the Rules and corresponding professional dispensing fee were adopted without compliance with statutory rule-making procedures;

(iv) declare that the adoption of the Rules without a corresponding adjustment of the professional dispensing fee exceeds the statutory authority of the agency; and

(v) declare that the State's action in adopting the Rules without a corresponding adjustment to the professional dispensing fee to cover pharmacy costs is arbitrary, capricious, and unlawful.

Petitioners further request all other appropriate relief deemed just.

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Dated this 29th day of March, 2017.

I declare under penalty of perjury under the laws of the state of Washington that I have read the foregoing complaint, know the contents, and that the foregoing complaint is true and correct to the best of my knowledge.

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By: _____
Virginia R. Nicholson, WSBA # 39601
Jeffrey Eden, WSBA # 19603
Counsel for Petitioners

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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 29th day of March, 2017, I arranged for service of the foregoing PETITION FOR DECLARATORY RELIEF AND EMERGENCY STAY to the parties to this action as follows:

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by:

- ☒ U.S. Postal Service, ordinary first class mail
- ☐ U.S. Postal Service, certified or registered mail, return receipt requested
- ☐ hand delivery
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EXHIBIT A

Last Update: 8/16/16

Chapter 182-530 WAC

PRESCRIPTION DRUGS (OUTPATIENT)

Chapter Listing

WAC Sections

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

182-530-2200 How the medicaid agency develops and maintains the formulary. [Statutory Authority: RCW **41.05.021** and section 1927 of the Social Security Act. WSR 12-18-062, § 182-530-2200, filed 8/31/12, effective 10/1/12.] Repealed by WSR 13-18-035, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW **41.05.021** .

182-530-2300 The medicaid agency's nonformulary justification process. [Statutory Authority: RCW **41.05.021** and section 1927 of the Social Security Act. WSR 12-18-062, § 182-530-2300, filed 8/31/12, effective 10/1/12.] Repealed by WSR 13-18-035, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW **41.05.021** .

182-530-1000
Outpatient drug program—General.

(1) The purpose of the outpatient drug program is to reimburse providers for outpatient drugs, vitamins, minerals, devices, and drug-related supplies according to medicaid agency rules and subject to the limitations and requirements in this chapter.

(2) The agency reimburses for outpatient drugs, vitamins, minerals, devices, and pharmaceutical supplies that are:

(a) Covered. Refer to WAC **182-530-2000** for covered drugs, vitamins, minerals, devices, and drug-related supplies and to WAC **182-530-2100** for noncovered drugs and drug-related supplies;

(b) Prescribed by a provider with prescriptive authority (see exceptions for family planning and emergency contraception for women eighteen years of age and older in WAC **182-530-2000** (1)(b), and over-the-counter (OTC) drugs to promote smoking cessation in WAC **182-530-2000** (1)(g));

(c) Prescribed by:

(i) A provider with an approved core provider agreement;

(ii) A provider who is enrolled as a performing provider on an approved core provider agreement; or

(iii) A provider who is enrolled as a nonbilling provider.

(d) Within the scope of an eligible client's medical assistance program;

(e) Medically necessary as defined in WAC **182-500-0070** and determined according to the process found in WAC **182-501-0165**;

(f) Authorized, as required within this chapter;

(g) Billed according to WAC **182-502-0150** and **182-502-0160**; and

(h) Billed according to the requirements of this chapter.

(3) Coverage determinations for the agency are made by the agency's pharmacists or medical consultants in accordance with applicable federal law. The agency's determination may include consultation with the drug use review (DUR) board.

[Statutory Authority: 42 C.F.R. 455.410, RCW **41.05.021**. WSR 13-19-037, § 182-530-1000, filed 9/11/13, effective 10/12/13. Statutory Authority: RCW **41.05.021** and 42 C.F.R. 455.410. WSR 13-04-095, § 182-530-1000, filed 2/6/13, effective 3/9/13. WSR 11-14-075, recodified as § 182-530-1000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 09-05-007, § 388-530-1000, filed 2/5/09, effective 3/8/09. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-1000, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-1000, filed 9/26/07, effective 11/1/07; WSR 06-24-036, § 388-530-1000, filed 11/30/06, effective 1/1/07. Statutory Authority: RCW **74.09.080**, **74.04.050** and 42 C.F.R. Subpart K, subsection 162.1102. WSR 02-17-023, § 388-530-1000, filed 8/9/02, effective 9/9/02. Statutory Authority: RCW **74.08.090**, **74.04.050**. WSR 01-01-028, § 388-530-1000, filed 12/7/00, effective 1/7/01. Statutory Authority: RCW **74.08.090**. WSR 96-21-031, § 388-530-1000, filed 10/9/96, effective 11/9/96.]

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.

"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).

"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 price of a drug product that is calculated from wholesale list prices nationwide 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.

"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 agency-covered prescriptions. The fee is the agency's maximum reimbursement for expenses involved in the practice of pharmacy and is in addition to the agency's reimbursement for the costs of covered ingredients.

"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.

"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 (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)" -** The application of a set of principles and a method for the review of well-designed 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.

"Evidence-based practice center" - 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.

"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.

"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.

"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 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.

"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.

"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.

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

"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.

"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.

"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 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.

"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 paid by a wholesaler for drugs purchased from a manufacturer.

[Statutory Authority: RCW **41.05.021**. WSR 13-18-035, § 182-530-1050, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW **41.05.021** and section 1927 of the Social Security Act. WSR 12-18-062, § 182-530-1050, filed 8/31/12, effective 10/1/12. WSR 11-14-075, recodified as § 182-530-1050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050, 74.08.090, 74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-1050, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050, 74.08.090, 74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-1050, filed 9/26/07, effective 11/1/07. Statutory Authority: RCW **74.08.090, 70.14.050, 69.41.150, 69.41.190**, chapter **41.05** RCW. WSR 05-02-044, § 388-530-1050, filed 12/30/04, effective 1/30/05. Statutory Authority: RCW **74.09.080, 74.04.050** and 42 C.F.R. Subpart K, subsection 162.1102. WSR 02-17-023, § 388-530-1050, filed 8/9/02, effective 9/9/02. Statutory Authority: RCW **74.08.090, 74.04.050**. WSR 01-24-066, § 388-530-1050, filed 11/30/01, effective 1/2/02; WSR 01-01-028, § 388-530-1050, filed 12/7/00, effective 1/7/01. Statutory Authority: RCW **74.08.090**. WSR 96-21-031, § 388-530-1050, filed 10/9/96, effective 11/9/96.]

182-530-1075
Requirements—Use of tamper-resistant prescription pads.

(1) The medicaid agency requires providers to use tamper-resistant prescription pads or paper for written outpatient prescriptions, including over-the-counter drugs, for Washington apple health clients.

(2) This requirement applies to all outpatient prescription drugs, including:

(a) Prescriptions when medicaid is primary or secondary payer (including medicare Part D prescriptions).

(b) Signed hardcopy prescriptions given to a client, whether handwritten or computer-generated.

(3) This requirement does not apply to:

(a) Prescriptions paid for by Washington's healthy options (HO) program or other agency-contracted managed care organizations.

(b) Prescription drugs that are part of the per diem or bundled rate and not reimbursed separately in designated institutional or clinical settings, such as a nursing facility, ICF/MR, dental office, hospice, or radiology. For example, a morphine prescription used to control a hospice client's cancer pain is covered under the hospice per diem rate and therefore the tamper-resistant prescription requirement is not required.

(c) Telephone, fax, or electronic prescriptions.

(d) Refill prescriptions, if the original written prescriptions were presented at a pharmacy before April 1, 2008.

(e) Prescriber or clinic drug samples given directly to the client.

(f) An institutional setting, as defined in WAC **182-500-0050**, where the prescriber writes the order into the medical records and the orders go directly to the pharmacy.

(4) Effective April 1, 2008, the tamper-resistant prescription pads and paper must meet at least one of the following industry recognized characteristics:

(a) One or more features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) One or more features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or

(c) One or more features designed to prevent the use of counterfeit prescription forms.

(5) Effective October 1, 2008, the tamper-resistant prescription pads and paper must contain all of the three characteristics in subsection (4) of this section.

(6) If the written prescription is not on tamper-resistant paper, the pharmacy may provide the prescription on an emergency basis. The pharmacy must verify the prescription with the prescriber by telephone, fax, or electronic communication, or by physical receipt of a tamper-resistant written prescription within seventy-two hours of filling the prescription.

(7) Federal controlled substance laws on controlled substances apply when prescribing or dispensing schedule II drugs.

(8) Record retention requirements under WAC **182-502-0020** remain in effect. Additional documentation is required as follows:

(a) Documentation by the pharmacy of verbal confirmation of a noncompliant written prescription.

(b) Documentation by the pharmacy of verbal confirmation about the authenticity of the tamper-resistant prescription.

(9) To submit a claim for a medicaid client retroactively certified for medicaid, the following applies:

(a) The prescription must meet the tamper-resistant compliance requirement.

(b) Refills that occur after the date on which the client is determined to be eligible require a new, tamper-resistant prescription in compliance with this WAC.

(c) If the original order is not compliant with subsection (4) of this section, the pharmacy must obtain a verbal, faxed, or email confirmation of the prescription from the prescriber.

(d) The pharmacy must reimburse the client under WAC **182-502-0160.**

(10) The pharmacy accepting a prescription transfer from another pharmacy must confirm the authenticity of the prescription by telephone or facsimile from the transferring pharmacy.

[Statutory Authority: RCW **41.05.021** and **41.05.160.** WSR 16-01-046, § 182-530-1075, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-1075, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.08.090**, **74.04.050**, **74.04.057**, **74.09.500** and Section 1903(i) of the Social Security Act (42 U.S.C. Section 1936b (i)(23)); Section 7002(b), U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (Pub.L. 110-28). WSR 08-07-048, § 388-530-1075, filed 3/14/08, effective 4/14/08.]

182-530-2000
Covered—Outpatient drugs, devices, and drug-related supplies.

(1) The medicaid agency covers:

(a) Outpatient drugs, including over-the-counter (OTC) drugs, as defined in WAC **182-530-1050**, subject to the limitations and requirements in this chapter, when:

(i) The drug is approved by the Food and Drug Administration (FDA);

(ii) The drug is for a medically accepted indication as defined in WAC **182-530-1050**;

(iii) The drug is not excluded from coverage under WAC **182-530-2100**;

(iv) The manufacturer has a signed drug rebate agreement with the federal Department of Health and Human Services (DHHS). Exceptions to the drug rebate requirement are described in WAC **182-530-7500**; and

(v) The drug is prescribed by a provider with prescriptive authority. Exceptions to the prescription requirement exist for family planning and emergency contraception in (b) of this subsection, and for OTC drugs that promote smoking cessation in (g) of this subsection.

(b) Family planning drugs, devices, and drug-related supplies per chapter **182-532** WAC and as follows:

(i) OTC family planning drugs, devices, and drug-related supplies without a prescription when the agency determines it necessary for client access and safety;

(ii) Family planning drugs that do not meet the federal drug rebate requirement in WAC **182-530-7500** on a case-by-case basis; and

(iii) Contraceptive patches, contraceptive rings, and oral contraceptives, excluding emergency contraception, when dispensed in a one-year supply only, unless:

(A) A smaller supply is directed by the prescriber.

(B) A smaller supply is requested by the client.

(C) The pharmacy does not have adequate stock.

(c) Vitamins, minerals, and enzymes when prescribed for:

(i) Prenatal vitamins, when prescribed and dispensed to pregnant women;

(ii) A medical condition caused by a clinically documented deficiency;

(iii) A United States Preventive Services Task Force recommendation with an A or B rating;

(iv) Fluoride for clients under age twenty-one; or

(v) A clinically documented medical condition that causes vitamin, mineral, or enzyme deficiencies, and the deficiency cannot be treated through other dietary interventions.

(d) OTC drugs, vitamins, and minerals when determined by the agency to be the least costly therapeutic alternative for a medically accepted indication. The agency will maintain and publish a list of the covered OTC drugs available to clients which have been determined to be the least costly therapeutic alternatives for medically accepted indications. This subsection (1)(d) of this section does not apply to products prescribed for the treatment of cough or cold symptoms. See (1)(i) under this subsection and WAC **182-530-2100** (1)(b)(v) for coverage of products prescribed for the treatment of cough and cold symptoms.

(e) Drug-related devices and drug-related supplies as an outpatient pharmacy benefit when:

(i) Prescribed by a provider with prescribing authority;

(ii) Essential for the administration of a covered drug;

(iii) Not excluded from coverage under WAC **182-530-2100**; and

(iv) Determined by the agency that a product covered under chapter **182-543** WAC related to durable medical equipment and supplies should be available at retail pharmacies.

(f) Preservatives, flavoring, or coloring agents, only when used as a suspending agent in a compound.

(g) OTC drugs, without a prescription, to promote smoking cessation only for clients age eighteen or older and participating in an agency-approved smoking cessation program. Limitation extensions as described in WAC **182-501-0169** are prohibited for the age and counseling requirements in this section.

(h) Drugs prescribed to promote smoking cessation only for clients participating in an agency-approved smoking cessation program, or for clients who are pregnant with a verifiable estimated due date and receiving smoking cessation counseling from the prescribing provider. Limitation extensions as described in WAC **182-501-0169** are prohibited for the age and counseling requirements in this section.

(i) For the treatment of cough and cold symptoms:

(i) Only the following generic, single ingredient formulations:

(A) Guaifenesin 100 mg/5 ml liquid or syrup;

(B) Dextromethorphan 15 mg/5 ml liquid or syrup;

(C) Pseudoephedrine 30 mg or 60 mg tablets;

(D) Saline nasal spray 0.65%; and

(ii) Generic combination product dextromethorphan-guaifenesin 10-100 mg/5 ml syrup, including sugar-free formulations.

(2) The agency does not reimburse for any drug, device, or drug-related supply not meeting the coverage requirements under this section.

[Statutory Authority: RCW **41.05.021**, **41.05.160**. WSR 16-17-071, § 182-530-2000, filed 8/16/16, effective 9/16/16. WSR 11-14-075, recodified as § 182-530-2000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, SSA § 1927 (42 U.S.C. 1396r-8(d)(2)(D)), and 2009 c 564 § 1109. WSR 09-22-005, § 388-530-2000, filed 10/22/09, effective 11/22/09. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 09-05-007, § 388-530-2000, filed 2/5/09, effective 3/8/09. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-2000, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-2000, filed 9/26/07, effective 11/1/07.]

182-530-2100
Noncovered—Outpatient drugs and pharmaceutical supplies.

(1) The medicaid agency does not cover:

(a) A drug that is:

(i) Not approved by the Food and Drug Administration (FDA); or

(ii) Prescribed for a nonmedically accepted indication, including diagnosis, dose, or dosage schedule that is not evidenced-based.

(b) A drug prescribed:

(i) For weight loss or gain;

(ii) For infertility, frigidity, impotency;

(iii) For sexual or erectile dysfunction;

(iv) For cosmetic purposes or hair growth; or

(v) For treatment of cough or cold symptoms, except as listed in WAC **182-530-2000** (1)(i).

(c) Drugs used to treat sexual or erectile dysfunction, in accordance with section 1927 (d)(2)(K) of the Social Security Act, unless such drugs are used to treat a condition other than sexual or erectile dysfunction, and these uses have been approved by the Food and Drug Administration.

(d) Drugs listed in the federal register as "less-than-effective" ("DESI" drugs) or which are identical, similar, or related to such drugs.

(e) Outpatient drugs for which the manufacturer requires as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or manufacturer's designee.

(f) A product:

(i) With an obsolete National Drug Code (NDC) for more than two years;

(ii) With a terminated NDC;

(iii) Whose shelf life has expired; or

(iv) Which does not have an eleven-digit NDC.

(g) Over-the-counter (OTC) drugs, vitamins, and minerals, except as allowed under WAC **182-530-2000** (1)(i).

(h) Any drug regularly supplied by other public agencies as an integral part of program activity (e.g., immunization vaccines for children).

(i) Free pharmaceutical samples.

(j) OTC or prescription drugs to promote smoking cessation unless the client is age eighteen or older and participating in an agency-approved cessation program, or is pregnant with a verifiable estimated due date and receiving smoking cessation counseling from the prescribing provider.

(2) A noncovered drug can be requested through the exception to rule process as described in WAC **182-501-0160**.

(3) If a noncovered drug is prescribed through the early and periodic screening, diagnosis, and treatment (EPSDT) process, an authorization request may be submitted indicating that the request is EPSDT related, and the request will be evaluated according to the process in WAC **182-501-0165**. (See WAC **182-534-0100** for EPSDT rules.)

[Statutory Authority: RCW **41.05.021**, **41.05.160**. WSR 16-17-071, § 182-530-2100, filed 8/16/16, effective 9/16/16. Statutory Authority: RCW **41.05.021**. WSR 13-18-035, § 182-530-2100, filed 8/28/13, effective 9/28/13. Statutory Authority: RCW **41.05.021** and section 1927 of the Social Security Act. WSR 12-18-062, § 182-530-2100, filed 8/31/12, effective 10/1/12. WSR 11-14-075, recodified as § 182-530-2100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, SSA § 1927 (42 U.S.C. 1396r-8(d)(2)(D)), and 2009 c 564 § 1109. WSR 09-22-005, § 388-530-2100, filed 10/22/09, effective 11/22/09. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 09-05-007, § 388-530-2100, filed 2/5/09, effective 3/8/09. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-2100, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-2100, filed 9/26/07, effective 11/1/07.]

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.

(1) The medicaid agency's pharmacists and 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.

(2) The drug, device, or drug-related supply is in the 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 promoting safety, efficacy, and effectiveness of drug therapy, 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 of 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.

[Statutory Authority: RCW **41.05.021** and **41.05.160.** WSR 16-01-046, § 182-530-3000, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-3000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-3000, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-3000, filed 9/26/07, effective 11/1/07.]

182-530-3100
How the medicaid agency determines when a drug requires authorization.

(1) The medicaid agency's pharmacists and medical consultants 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 based on quality evidence contained in compendia of drug information and peer-reviewed medical literature.

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

[Statutory Authority: RCW **41.05.021** and **41.05.160.** WSR 16-01-046, § 182-530-3100, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-3100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700.** WSR 07-20-049, § 388-530-3100, filed 9/26/07, effective 11/1/07.]

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 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.

[Statutory Authority: RCW **41.05.021**, **41.05.160**. WSR 16-17-071, § 182-530-3200, filed 8/16/16, effective 9/16/16. WSR 11-14-075, recodified as § 182-530-3200, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.08.090**. WSR 11-11-014, § 388-530-3200, filed 5/9/11, effective 6/9/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-3200, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-3200, filed 9/26/07, effective 11/1/07.]

182-530-4000
Drug use review (DUR) board.

In accordance with 42 C.F.R. 456.716, the medicaid agency establishes a drug use review (DUR) board.

(1) The DUR board:

(a) Includes health professionals who are actively practicing and licensed in the state of Washington and who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of outpatient drugs;

(ii) The clinically appropriate dispensing and monitoring of outpatient drugs;

(iii) Drug use review, evaluation, and intervention; and

(iv) Medical quality assurance.

(b) Is made up of at least one-third but not more than fifty-one percent physicians, and at least one-third pharmacists.

(2) The agency may appoint members of the pharmacy and therapeutics committee established by the agency under chapter **182-50** WAC or other qualified individuals to serve as members of the DUR board.

(3) The DUR board meets periodically to:

(a) Advise the agency on drug use review activities;

(b) Review provider and patient profiles;

(c) Review scientific literature to establish evidence-based guidelines for the appropriate use of drugs, including the appropriate indications and dosing;

(d) Recommend adoption of standards and treatment guidelines for drug therapy;

(e) Recommend interventions targeted toward correcting drug therapy problems; and

(f) Produce an annual report.

(4) The agency has the authority to accept or reject the recommendations of the DUR board in accordance with 42 C.F.R. 456.716(c).

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-4000, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-4000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-4000, filed 9/26/07, effective 11/1/07.]

182-530-4050
Drug use and claims review.

(1) The agency's drug use review (DUR) consists of:

(a) A prospective drug use review (Pro-DUR) that requires all pharmacy providers to:

(i) Obtain patient histories of allergies, idiosyncrasies, or chronic condition or conditions which may relate to drug utilization;

(ii) Screen for potential drug therapy problems; and

(iii) Counsel the patient in accordance with existing state pharmacy laws and federal regulations.

(b) A retrospective drug use review (Retro-DUR), in which the agency provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and individuals receiving benefits.

(2) The agency reviews a periodic sampling of claims to determine if drugs are appropriately dispensed and billed. If a review of the sample finds that a provider is inappropriately dispensing or billing for drugs, the agency may implement corrective action that includes, but is not limited to:

(a) Educating the provider regarding the problem practice or practices;

(b) Requiring the provider to maintain specific documentation in addition to the normal documentation requirements regarding the provider's dispensing or billing actions;

(c) Recouping the payment for the drug or drugs; or

(d) Terminating the provider's core provider agreement (CPA).

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-4050, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-4050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-4050, filed 9/26/07, effective 11/1/07.]

182-530-4100
Washington preferred drug list (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 contracts with evidence-based practice centers for systematic drug reviews.

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

(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.

(4) The appointing authority makes the final selection of drugs included on the Washington 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 therapeutic interchange program (TIP) and dispense as written (DAW) rules under WAC **182-530-4150**.

(6) Drugs in a drug class on the Washington PDL that have not been studied by an evidence-based practice center and have not been reviewed by the P&T committee will be treated as nonpreferred drugs not subject to the dispense as written (DAW) or the therapeutic interchange program (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 PDL may be designated as preferred drugs for special populations or specific indications.

(9) Drugs in a drug class on the Washington PDL may require authorization for safety.

(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 drug has been reviewed by the P&T committee, the agency may immediately designate an available, less expensive, equally effective, generic equivalent 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).

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 15-12-093, § 182-530-4100, filed 6/2/15, effective 7/3/15. WSR 11-14-075, recodified as § 182-530-4100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.09.700**, **74.08.090**, 2009 c 575. WSR 10-06-011, § 388-530-4100, filed 2/19/10, effective 3/22/10. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-4100, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-4100, filed 9/26/07, effective 11/1/07.]

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 agency may require preferred generic drugs on the Washington preferred drug list (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.

(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 DUR board will be subject to authorization to establish medical necessity as defined in WAC **182-500-0070.**

[Statutory Authority: RCW **41.05.021** and **41.05.160.** WSR 15-12-093, § 182-530-4125, filed 6/2/15, effective 7/3/15. WSR 11-14-075, recodified as § 182-530-4125, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.09.700**, **74.08.090**, 2009 c 575. WSR 10-06-011, § 388-530-4125, filed 2/19/10, effective 3/22/10.]

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) applies only to drugs:

(a) Within therapeutic classes on the Washington PDL;

(b) Studied by the evidence-based practice center or centers;

(c) Reviewed by the pharmacy and therapeutics (P&T) committee; and

(d) Prescribed by an endorsing practitioner.

(2) TIP does not apply:

(a) When the P&T committee determines that TIP does not apply to the therapeutic class on the 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) 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) Except as otherwise provided in subsection (11) of this section, for 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) 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 nonpreferred generic drugs for the client's first course of treatment.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-4150, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-4150, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.09.700**, **74.08.090**, 2009 c 575. WSR 10-06-011, § 388-530-4150, filed 2/19/10, effective 3/22/10. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.700**, 2008 c 245. WSR 08-21-107, § 388-530-4150, filed 10/16/08, effective 11/16/08. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-4150, filed 9/26/07, effective 11/1/07.]

182-530-5000
Billing requirements—Pharmacy claim payment.

(1) When billing the medicaid agency for pharmacy services, providers must:

(a) Use the appropriate agency claim form or electronic billing specifications;

(b) Include the actual eleven-digit national drug code (NDC) number of the product dispensed from a rebate eligible manufacturer;

(c) Bill the agency using metric decimal quantities which is the National Council for Prescription Drug Programs (NCPDP) billing unit standard;

(d) Meet the general provider documentation and record retention requirements in WAC **182-502-0020**; and

(e) Maintain proof of delivery receipts.

(i) When a provider delivers an item directly to the client or the client's authorized representative, the provider must be able to furnish proof of delivery including signature, client's name and a detailed description of the item or items delivered.

(ii) When a provider mails an item to the client, the provider must be able to furnish proof of delivery including a mail log.

(iii) When a provider uses a delivery or shipping service to deliver items, the provider must be able to furnish proof of delivery and it must:

(A) Include the delivery service tracking slip with the client's name or a reference to the client's package or packages; the delivery service package identification number; and the delivery address.

(B) Include the supplier's shipping invoice, with the client's name; the shipping service package identification number; and a detailed description.

(iv) Make proof of delivery receipts available to the agency upon request.

(2) When billing drugs under the expedited authorization process, providers must insert the authorization number which includes the corresponding criteria code or codes in the appropriate data field on the drug claim.

(3) Pharmacy services for clients on restriction under WAC **182-501-0135** must be prescribed by the client's primary care provider and are paid only to the client's primary pharmacy, except in cases of:

(a) Emergency;

(b) Family planning services; or

(c) Services properly referred from the client's assigned pharmacy or physician/ARNP.

[Statutory Authority: RCW **41.05.021** and **41.05.160.** WSR 16-01-046, § 182-530-5000, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-5000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700.** WSR 07-20-049, § 388-530-5000, filed 9/26/07, effective 11/1/07.]

182-530-5050
Billing requirements—Point-of-sale (POS) system/prospective drug use review (Pro-DUR).

(1) Pharmacy claims for drugs and other products listed in the medicaid agency's drug file and billed to the agency by national drug code (NDC) are adjudicated by the agency's point-of-sale (POS) system. Claims must be submitted for payment using the billing unit standard identified in WAC **182-530-5000.**

(2) All pharmacy drug claims processed through the POS system undergo a system-facilitated prospective drug use review (Pro-DUR) screening as a complement to the Pro-DUR screening required of pharmacists.

(3) If the POS system identifies a potential drug therapy problem during Pro-DUR screening, a message will alert the pharmacy provider indicating the type of potential problem. The alerts regarding possible drug therapy problems include, but are not limited to:

(a) Therapeutic duplication;

(b) Duration of therapy exceeds the recommended maximum period;

(c) Drug-to-drug interaction;

(d) Drug disease precaution;

(e) High dose;

(f) Ingredient duplication;

(g) Drug-to-client age conflict;

(h) Drug-to-client gender conflict; or

(i) Refill too soon.

(4) The agency provides pharmacy providers with a list of codes from which to choose in overriding POS system alert messages. These codes come from the National Council for Prescription Drug Programs (NCPDP).

(5) The dispensing pharmacist evaluates the potential drug therapy conflict and enters applicable NCPDP codes representing their professional interaction.

(a) If the resolution to the conflict satisfies agency requirements, the claim will be processed accordingly.

(b) If the resolution to the conflict does not satisfy agency requirements, the agency requires prior authorization. This includes all claims for which an alert message is triggered in the POS system and an NCPDP override code is not appropriate.

(6) The agency requires providers to retain documentation of the justification for the use of payment system override codes as described in subsections (4) and (5) of this section. The agency requires the documentation be retained for the same period as that described in WAC **182-502-0020.**

(7) POS/Pro-DUR screening is not applicable to pharmacy claims included in the managed care capitated rate.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-5050, filed 12/9/15, effective

1/9/16. WSR 11-14-075, recodified as § 182-530-5050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 07-20-049, § 388-530-5050, filed 9/26/07, effective 11/1/07.]

182-530-5100
Billing requirements—Unit dose.

(1) To be eligible for a unit dose dispensing fee from the medicaid agency, a pharmacy must:

(a) Notify the agency in writing of its intent to provide unit dose service;

(b) Identify the nursing facility or facilities to be served;

(c) Indicate the approximate date unit dose service to the facility or facilities will commence; and

(d) Follow agency requirements for unit dose payment.

(2) Under a unit dose delivery system, a pharmacy must bill only for the number of drug units actually used by the client in the nursing facility, except as provided in subsections (3), (4), and (5) of this section. It is the unit dose pharmacy provider's responsibility to coordinate with nursing facilities to ensure that the unused drugs the pharmacy dispensed to clients are returned to the pharmacy for credit.

(3) The pharmacy must submit an adjustment form or claims reversal of the charge to the agency for the cost of all unused drugs returned to the pharmacy from the nursing facility on or before the sixtieth day following the date the drug was dispensed, except as provided in subsection (5) of this section. Such adjustment must conform to the nursing facility's monthly log as described in subsection (7) of this section.

(4) The agency pays a unit dose provider a dispensing fee when a provider-packaged unit dose prescription is returned, in its entirety, to the pharmacy. A dispensing fee is not paid if the returned prescription is for a drug with a manufacturer-designated unit dose national drug code (NDC). In addition to the dispensing fee paid under this subsection, the provider may bill the agency one unit of the tablet or capsule but must credit the agency for the remainder of the ingredient costs for the returned prescription.

(5) Unit dose providers do not have to credit the agency for federally designated schedule two drugs which are returned to the pharmacy. These returned drugs must be disposed of according to federal regulations.

(6) Pharmacies must not charge clients or the agency a fee for repackaging a client's bulk medications in unit dose form. The costs of repackaging are the responsibility of the nursing facility when the repackaging is done:

(a) To conform with a nursing facility's drug delivery system; or

(b) For the nursing facility's convenience.

(7) The pharmacy must maintain detailed records of medications dispensed under unit dose delivery systems. The pharmacy must keep a monthly log for each nursing facility served including, but not limited to, the following information:

(a) Facility name and address;

(b) Client's name and patient identification code (PIC);

(c) Drug name/strength;

(d) National drug code (NDC);

(e) Quantity and date dispensed;

(f) Quantity and date returned;

(g) Value of returned drugs or amount credited;

(h) Explanation for no credit given or nonreusable returns; and

(i) Prescription number.

(8) Upon the agency's request, the pharmacy must submit copies of the logs referred to in subsection (7) of this section.

(9) When the pharmacy submits the completed annual prescription volume survey to the agency, it must include an updated list of all nursing facilities currently served under unit dose systems.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-5100, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-5100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 07-20-049, § 388-530-5100, filed 9/26/07, effective 11/1/07.]

182-530-6000
Mail-order 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.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-6000, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-6000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-6000, filed 9/26/07, effective 11/1/07.]

182-530-7000
Reimbursement.

(1) The agency's total reimbursement for a prescription drug must not exceed the lowest of:

(a) Estimated acquisition cost (EAC) plus a dispensing fee;

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

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

(d) Actual acquisition cost (AAC) plus a dispensing fee for drugs purchased under section 340B of the Public Health Service (PHS) Act;

(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) 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) 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) 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) 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.**

[Statutory Authority: RCW **41.05.021.** WSR 12-16-061, § 182-530-7000, filed 7/30/12, effective 11/1/12. WSR 11-14-075, recodified as § 182-530-7000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7000, filed 9/26/07, effective 11/1/07.]

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 nondrug items, devices, or drug-related supplies.

(3) The agency adjusts 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.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7050, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7050, filed 9/26/07, effective 11/1/07.]

182-530-7100
Reimbursement—Pharmaceutical supplies.

(1) The medicaid agency reimburses for selected pharmaceutical supplies through the pharmacy point-of-sale (POS) system when it is necessary for client access and safety.

(2) The agency bases reimbursement of pharmaceutical items or supplies that are not payable through the POS on agency-published fee schedules.

(3) The agency uses any or all of the following methodologies to set the maximum allowable reimbursement rate for drugs, devices, and drug-related supplies:

(a) A pharmacy provider's acquisition cost. Upon review of the claim, the agency may require an invoice which must show the name of the item, the manufacturer, the product description, the quantity, and the current cost including any free goods associated with the invoice;

(b) Medicare's reimbursement rate for the item; or

(c) A specified discount off the item's list price or manufacturer's suggested retail price (MSRP).

(4) The agency does not pay a dispensing fee for nondrug items, devices, or drug-related supplies. See WAC **182-530-7050**.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7100, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7100, filed 9/26/07, effective 11/1/07.]

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 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 following 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).

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7150, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7150, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7150, filed 9/26/07, effective 11/1/07.]

182-530-7200
Reimbursement—Out-of-state prescriptions.

(1) The medicaid agency reimburses out-of-state pharmacies for prescription drugs provided to an eligible client within the scope of the client's medical care program if the pharmacy:

(a) Contracts with the agency to be an enrolled provider; and

(b) Meets the same criteria the agency requires for in-state pharmacy providers.

(2) The agency considers pharmacies located in bordering areas listed in WAC **182-501-0175** the same as in-state pharmacies.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7200, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7200, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7200, filed 9/26/07, effective 11/1/07.]

182-530-7250
Reimbursement—Miscellaneous.

The medicaid agency reimburses for covered drugs, devices, and drug-related supplies provided or administered by nonpharmacy providers under specified conditions, as follows:

(1) 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) Chapter **182-531** WAC Physician-related services;

(b) Chapter **182-532** WAC Reproductive health/family planning only/TAKE CHARGE; and

(c) Chapter **182-540** WAC Kidney disease program and kidney center services.

(2) Providers who are purchasers of Public Health Services (PHS) discounted drugs must comply with PHS 340b program requirements. (See WAC **182-530-7900**.)

(3) 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 free goods associated with the invoice.

(4) 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.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7250, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7250, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7250, filed 9/26/07, effective 11/1/07.]

182-530-7300
Reimbursement—Requesting a change.

Upon request from a pharmacy provider, the medicaid agency may reimburse at actual acquisition cost (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.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7300, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7300, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7300, filed 9/26/07, effective 11/1/07.]

182-530-7350
Reimbursement—Unit dose drug delivery systems.

(1) The medicaid agency pays for unit dose drug delivery systems only for clients residing in nursing facilities, except as provided in subsections (7) and (8) of this section.

(2) Unit dose delivery systems may be either true or modified unit dose.

(3) The agency pays pharmacies that provide unit dose delivery services the agency's highest allowable dispensing fee for each unit dose prescription dispensed to clients in nursing facilities. The agency reimburses

ingredient costs for drugs under unit dose systems as described in WAC **182-530-7000.**

(4) The agency pays a pharmacy that dispenses drugs in bulk containers or multidose forms to clients in nursing facilities the regular dispensing fee applicable to the pharmacy's total annual prescription volume tier. Drugs the agency considers not deliverable in unit dose form include, but are not limited to, liquids, creams, ointments, ophthalmic and otic solutions. The agency reimburses ingredient costs as described in WAC **182-530-7000.**

(5) The agency pays a pharmacy that dispenses drugs prepackaged by the manufacturer in unit dose form to clients in nursing facilities the regular dispensing fee applicable under WAC **182-530-7050.** The agency reimburses ingredient costs for drugs prepackaged by the manufacturer in unit dose form as described in WAC **182-530-7000.**

(6) The agency limits its coverage and payment for manufacturer-designated unit dose packaging to the following conditions:

(a) The drug is a single source drug and a multidose package for the drug is not available;

(b) The drug is a multiple source drug but there is no other multidose package available among the drug's generic equivalents; or

(c) The manufacturer-designated unit dose package is the most cost-effective package available or it is the least costly alternative form of the drug.

(7) The agency reimburses a pharmacy provider for manufacturer-designated unit dose drugs dispensed to clients not residing in nursing facilities only when such drugs:

(a) Are available in the marketplace only in manufacturer-designated unit dose packaging; and

(b) Would otherwise be covered as an outpatient drug. The unit dose dispensing fee does not apply in such cases. The agency pays the pharmacy the dispensing fee applicable to the pharmacy's total annual prescription volume tier.

(8) The agency may pay for unit dose delivery systems for clients of the developmental disabilities administration (DDA) residing in approved community living arrangements.

[Statutory Authority: RCW **41.05.021** and **41.05.160.** WSR 16-01-046, § 182-530-7350, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7350, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700.** WSR 07-20-049, § 388-530-7350, filed 9/26/07, effective 11/1/07.]

182-530-7400
Reimbursement—Compliance packaging services.

(1) The medicaid agency reimburses pharmacies for compliance packaging services provided to clients considered at risk for adverse drug therapy outcomes. Clients who are eligible for compliance packaging services must not reside in a nursing home or other inpatient facility, and must meet (a) and either (b) or (c) of this subsection. The client must:

(a) Have one or more of the following representative disease conditions:

(i) Alzheimer's disease;

(ii) Blood clotting disorders;

(iii) Cardiac arrhythmia;

(iv) Congestive heart failure;

(v) Depression;

(vi) Diabetes;

(vii) Epilepsy;

(viii) HIV/AIDS;

(ix) Hypertension;

(x) Schizophrenia; or

(xi) Tuberculosis.

(b) Concurrently consume two or more prescribed medications for chronic medical conditions, that are dosed at three or more intervals per day; or

(c) Have demonstrated a pattern of noncompliance that is potentially harmful to the client's health. The client's pattern of noncompliance with the prescribed drug regimen must be fully documented in the provider's file.

(2) Compliance packaging services include:

(a) Reusable hard plastic containers of any type (e.g., medisets); and

(b) Nonreusable compliance packaging devices (e.g., blister packs).

(3) The agency pays a filling fee and reimburses pharmacies for the compliance packaging device and container. The frequency of fills and number of payable compliance packaging devices per client is subject to limits specified by the agency. The agency does not pay filling or preparation fees for blister packs.

(4) Pharmacies must use the CMS-1500 claim form to bill the agency for compliance packaging services.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7400, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7400, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7400, filed 9/26/07, effective 11/1/07.]

182-530-7500
Drug rebate requirement.

(1) The medicaid agency reimburses for outpatient prescription drugs only when they are supplied by manufacturers who have a signed drug rebate agreement with the federal Department of Health and Human Services (DHHS), according to 42 U.S.C. 1396r-8. The manufacturer must be listed on the list of participating manufacturers as published by the Center for Medicare and Medicaid Services (CMS).

(2) The fill date must be within the manufacturer's beginning and ending eligibility dates to be reimbursed by the agency.

(3) The agency may extend this rebate requirement to any outpatient drug reimbursements as allowed or required by federal law.

(4) The agency may exempt drugs from the rebate requirement, on a case-by-case basis, when:

(a) It determines that the availability of a single source drug or innovator multiple source drug is essential to the health of beneficiaries; and

(b) All other rebate exemption requirements of SSA Sec. 1927 (42 U.S.C. 1396r-8)(3) are also satisfied.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7500, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7500, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7500, filed 9/26/07, effective 11/1/07.]

182-530-7600
Reimbursement—Clients enrolled in managed care.

Except as specified under the medicaid agency's managed care contracts, the agency does not reimburse providers for any drugs or pharmaceutical supplies provided to clients who have pharmacy benefits under agency-contracted managed care plans. The managed care plan is responsible for payment.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7600, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7600, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7600, filed 9/26/07, effective 11/1/07.]

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.

(2) Medicare Part D:

(a) Medicare is the payer for drugs covered under 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.

[Statutory Authority: RCW **41.05.021**, 2011 c 5, 2010 2nd sp.s. c 1 § 208 (25), and Section 1902 (n)(3)(B) of the Social Security Act, as modified by Section 4714 of the Balanced Budget Act of 1997. WSR 13-14-052, § 182-530-7700, filed 6/27/13, effective 7/28/13. WSR 11-14-075, recodified as § 182-530-7700, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7700, filed 9/26/07, effective 11/1/07.]

182-530-7800
Reimbursement—Clients with third-party liability.

(1) The medicaid agency requires providers to meet the third-party requirements of WAC **182-501-0200**.

(2) The following definitions apply to this section:

(a) "Closed pharmacy network" means an arrangement made by an insurer which restricts prescription coverage to an exclusive list of pharmacies. This arrangement prohibits the coverage and/or payment of prescriptions provided by a pharmacy that is not included on the exclusive list.

(b) "Private point-of-sale (POS) authorization system" means an insurer's system, other than the agency's POS system, which requires that coverage be verified by or submitted to the insurer for authorization at the time of service and at the time the prescription is filled.

(3) This subsection applies to clients who have a third-party resource that is a managed care entity other than an agency-contracted plan, or have other insurance that requires the use of "closed pharmacy networks" or "private point-of-sale authorization system." The agency will not pay pharmacies for prescription drug claims until the pharmacy provider submits an explanation of benefits from the private insurance demonstrating that the pharmacy provider has complied with the terms of the third party's coverage.

(a) If the private insurer pays a fee based on the incident of care, the pharmacy provider must file a claim with the agency consistent with the agency's billing requirements.

(b) If the private insurer pays the pharmacy provider a monthly capitation fee for all prescription costs related to the client, the pharmacy provider must submit a claim to the agency for the amount of the client copayment, coinsurance, and/or deductible. The agency pays the provider the lesser of:

(i) The billed amount; or

(ii) The agency's maximum allowable fee for the prescription.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7800, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7800, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7800, filed 9/26/07, effective 11/1/07.]

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 are required to submit their valid medicaid provider number(s) 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.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-7900, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-7900, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-7900, filed 9/26/07, effective 11/1/07.]

182-530-8000
Reimbursement method—Estimated acquisition cost (EAC).

(1) The medicaid agency determines estimated acquisition cost (EAC) using:

(a) Acquisition cost data made available to the agency; or

(b) Information provided by any of the following:

(i) Audit agencies, federal or state;

(ii) Other state health care purchasing agencies;

(iii) Pharmacy benefit managers;

(iv) Individual pharmacy providers participating in the agency's programs;

(v) Centers for Medicare and Medicaid Services (CMS);

(vi) Other third-party payers;

(vii) Drug file data bases; and

(viii) 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.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-8000, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-8000, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW

74.04.050 and 74.08.090. WSR 10-24-021, § 388-530-8000, filed 11/19/10, effective 12/20/10. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 07-20-049, § 388-530-8000, filed 9/26/07, effective 11/1/07.]

182-530-8050
Reimbursement—Federal upper limit (FUL).

(1) The medicaid agency adopts the federal upper limit (FUL) set by the Centers for Medicare and Medicaid Services (CMS).

(2) The agency's maximum payment for multiple-source drugs for which CMS has set FULs will not exceed, in the aggregate, the prescribed upper limits plus the dispensing fees set by the agency.

(3) Except as provided in WAC 182-530-7300, the agency uses the FUL as the agency's reimbursement rate for the drug when the FUL price is the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-8050, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-8050, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 07-20-049, § 388-530-8050, filed 9/26/07, effective 11/1/07.]

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 acquisition cost (EAC) 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.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 16-01-046, § 182-530-8100, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-8100, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.04.050, 74.08.090, 74.09.530, and 74.09.700. WSR 07-20-049, § 388-530-8100, filed 9/26/07, effective 11/1/07.]

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) or other nationally accepted pricing source in order to estimate acquisition cost.

(3) The agency sets the percentage discount from AWP 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 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**.

[Statutory Authority: RCW **41.05.021** and **41.05.160**. WSR 16-01-046, § 182-530-8150, filed 12/9/15, effective 1/9/16. WSR 11-14-075, recodified as § 182-530-8150, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW **74.04.050**, **74.08.090**, **74.09.530**, and **74.09.700**. WSR 07-20-049, § 388-530-8150, filed 9/26/07, effective 11/1/07.]

EXHIBIT B

WSR 16-14-040
PREPROPOSAL STATEMENT OF INQUIRY
HEALTH CARE AUTHORITY
(Washington Apple Health)
[Filed June 28, 2016, 11:22 a.m.]

Subject of Possible Rule Making: WAC 182-546-4600 Ambulance transportation—Involuntary substance use disorder treatment—Ricky Garcia Act; and other related rules as appropriate.

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 41.05.021, 41.05.160; ESHB [E3SHB] 1713, chapter 29, Laws of 2016 1st sp. sess.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: The agency is creating WAC 182-546-4600 to implement E3SHB 1713, also known as the Ricky Garcia Act. WAC 182-546-4600 allows for ambulance transportation for involuntary substance use disorder treatment. During the course of this review, the agency may identify additional changes that are required in order to improve clarity or update policy.

Process for Developing New Rule: The agency welcomes the public to take part in developing this rule. If interested, contact the person identified below to receive an early rule draft to review. After the early review, the agency will send a notice of proposed rule making (CR-102) to everyone receiving this notice and anyone who requests a copy.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Amy Emerson, Office of Rules and Publications, P.O. Box 42716, Olympia, WA 98504-2716, fax (360) 586-9727, TTY 1-800-848-5429, e-mail amy.emerson@hca.wa.gov.

June 28, 2016
Wendy Barcus
Rules Coordinator

WSR 16-14-051
PREPROPOSAL STATEMENT OF INQUIRY
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
(Economic Services Administration)
[Filed June 29, 2016, 12:18 p.m.]

Subject of Possible Rule Making: The department is proposing to amend WAC 388-444-0035 Who is exempt from the ABAWD time limits and minimum work requirements?; and other related rules as may be required.

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 74.04.050, 74.04.055, 74.04.057, 74.08.090, 74.04.510, 7 C.F.R. 273.7.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: Amendments proposed under this filing will strike provisions pertaining to food assistance program (FAP) for legal immigrants that are inconsistent with state law for the supplemental nutrition assistance program (SNAP).

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: The United States Department of Agriculture, Food and Nutrition Service (FNS) enforces the provisions of the federal SNAP as enacted in the 2008 Food and Nutrition Act as amended and codified in the Code of Federal Regulations. DSHS incorporates regulations from the federal agencies, exercises state options, and implements approved waivers and demonstration projects by adopting administrative rules for food assistance administered as the Washington basic food program and FAP.

Process for Developing New Rule: DSHS welcomes the public to take part in developing the rules. Anyone interested should contact the staff person identified below. At a later date, DSHS will file a proposal with the office of the code reviser with a notice of proposed rule making. A copy of the proposal will be sent to everyone on the mailing list and to anyone who requests a copy.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Corinna Adams, Community Services Division, P.O. Box 45470, Olympia, WA 98504-4904, phone (360) 725-4640, fax (360) 725-4904, e-mail adamsc2@dshs.wa.gov.

June 28, 2016
Katherine I. Vasquez
Rules Coordinator

WSR 16-14-053
PREPROPOSAL STATEMENT OF INQUIRY
HEALTH CARE AUTHORITY
(Washington Apple Health)
[Filed June 29, 2016, 2:17 p.m.]

Subject of Possible Rule Making: Chapter 182-530 WAC, Prescription drugs (outpatient); other related rules as appropriate.

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 41.05.021, 41.05.160; 42 C.F.R. 447.512 (a) and (b), 447-518(a) [447.518(a)], 447.518(d), and 447.522.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: 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. During the course of this review, the agency may identify additional changes that are required in order to improve clarity or update policy.

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: CMS.

Process for Developing New Rule: The agency welcomes the public to take part in developing this rule. If interested, contact the person identified below to receive an early rule draft to review. After the early review, the agency will send a notice of proposed rule making (CR-102) to everyone receiving this notice and anyone who requests a copy.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before pub-

lication by contacting Amy Emerson, P.O. Box 42716, Olympia, WA 98504-2716, fax (360) 586-9727, TTY 1-800-848-5429, e-mail amy.emerson@hca.wa.gov.

June 29, 2016
Wendy Barcus
Rules Coordinator

WSR 16-14-079
PREPROPOSAL STATEMENT OF INQUIRY
WASHINGTON STATE LOTTERY
[Filed July 1, 2016, 2:19 p.m.]

Subject of Possible Rule Making: The lottery commission is considering updates to Title 315 WAC as it applies to the payment options available to licensed retailers.

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 67.70.040(1) and 67.70.050 (1), (8).

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: The lottery commission is considering changes to the instant ticket and draw game retailer settlement rules in order to offer additional payment options to its licensed retailers.

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: None.

Process for Developing New Rule: Negotiated rule making.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Jana Jones, Director of Legal Services, P.O. Box 43000, Olympia, WA 98504-3000, phone (360) 664-4833; or Jennifer McDaniel, legal assistant, phone (360) 664-4834.

July 1, 2016
Jana L. Jones
Director of Legal Services

WSR 16-14-087
PREPROPOSAL STATEMENT OF INQUIRY
DEPARTMENT OF LABOR AND INDUSTRIES
[Filed July 5, 2016, 9:27 a.m.]

Subject of Possible Rule Making: Chapter 296-46B WAC, Electrical safety standards, administration, and installation.

Statutes Authorizing the Agency to Adopt Rules on this Subject: Chapter 19.28 RCW.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: The electrical program is proposing to increase the fees in chapter 296-46B WAC by the fiscal-growth factor of 4.32 percent for fiscal year 2017 (OFM's maximum allowable fiscal growth rate). The program's budget and projected revenue indicate a fee increase is necessary to cover the program's operating expenses.

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: None.

Process for Developing New Rule: Parties interested in these rules may contact the individual listed below. The public may also participate by commenting after amendments are proposed by providing written comments and/or testimony during the public hearing and comment process.

Interested parties can sign up for e-mail updates at http://www.lni.wa.gov/Main/Listservs/Electrical.asp.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Sally Elliott, Field Services Operations Manager, Department of Labor and Industries, Specialty Compliance Services Division, P.O. Box 44400, Olympia, WA 98504-4400, phone (360) 902-6411, fax (360) 902-5292, e-mail sally.elliott@lni.wa.gov.

July 5, 2016
E. LaPalm
for Joel Sacks
Director

WSR 16-14-112
PREPROPOSAL STATEMENT OF INQUIRY
DEPARTMENT OF LICENSING
[Filed July 6, 2016, 11:07 a.m.]

Subject of Possible Rule Making: WAC 196-27A-010 Purpose and applicability and 196-29-110 Land surveying practice standards.

Statutes Authorizing the Agency to Adopt Rules on this Subject: Chapter 18.43 RCW.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: Housekeeping change to both WAC to remove reference to RCW 18.43.105(11), which no longer exists.

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: None.

Process for Developing New Rule: Negotiated rule making.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Shanan Gillespie, Board of Registration for Professional Engineers and Land Surveyors, P.O. Box 9025, Olympia, WA 98507-9025, phone (360) 664-1575, fax (360) 570-7098, e-mail Engineers@dol.wa.gov.

Comments may be submitted through regular mail, fax or e-mail.

Draft language of rule amendments will be distributed to the board's list of interested persons (listserv).

July 6, 2016
Damon Monroe
Rules Coordinator

EXHIBIT C

PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Health Care Authority, Washington Apple Health

☒ **Preproposal Statement of Inquiry was filed as WSR** 16-14-053 & 16-15-087;**or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR _____**
☐ **Continuance of WSR _____**

Title of rule and other identifying information:
182-530-1050 Definitions, 182-530-3000 When the medicaid agency requires authorization, 182-530-3100 How the medicaid agency determines when a drug requires authorization, 182-530-3200 The medicaid agency's authorization process, 182-530-4100 Washington preferred drug list (PDL), 182-530-4125 Generics first for a client's first course of treatment, 182-530-4150 Therapeutic interchange program (TIP), 182-530-6000 Mail order services, 182-530-7000 Reimbursement, 182-530-7050 Reimbursement – Dispensing fee determination, 182-530-7150 Reimbursement – Compounded prescriptions, 182-530-7250 Reimbursement -- Miscellaneous, 182-530-7300 Reimbursement – Requesting a change, 182-530-7700 Reimbursement – Dual eligible clients/medicare, 182-530-7900 Drugs purchased under the Public Health Service (PHS) Act, 182-530-8000 Reimbursement method – Estimated acquisition cost (EAC), 182-530-8100 Reimbursement – Maximum allowable cost (MAC), 182-530-8150 Reimbursement – Automated maximum allowable cost (AMAC)

Hearing location:
Health Care Authority
Cherry Street Plaza Building; Sue Crystal Conf Rm 106A
626 - 8th Avenue, Olympia WA 98504

Metered public parking is available street side around building. A map is available at:
http://www.hca.wa.gov/documents/directions_to_csp.pdf
or directions can be obtained by calling: (360) 725-1000

Date: **February 7, 2017** Time: **10:00 a.m.**

Submit written comments to:
Name: HCA Rules Coordinator
Address: PO Box 45504, Olympia WA, 98504-5504
Delivery: 626 – 8th Avenue, Olympia WA 98504
e-mail arc@hca.wa.gov
fax (360) 586-9727

by **5:00 pm on February 7, 2017**

Date of intended adoption: Not sooner than February 8, 2017
(Note: This is **NOT** the **effective** date)

Assistance for persons with disabilities: Contact Amber Lougheed by February 3, 2017
e-mail: amber.lougheed@hca.wa.gov or (360) 725-1349

TTY (800) 848-5429 or 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

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.

Reasons supporting proposal: See "purpose" statement above.

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Statute being implemented: RCW 41.05.021, 41.05.160

Is rule necessary because of a:

Federal Law?	☒ Yes	☐ No
Federal Court Decision?	☒ Yes	☐ No
State Court Decision?	☒ Yes	☐ No

If yes, CITATION: CMS-2345-FC

DATE
January 4, 2017

NAME
Wendy Barcus

SIGNATURE
Wendy Barcus

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 04, 2017
TIME: 9:48 AM

WSR 17-02-083

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: Health Care Authority

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Amy Emerson	PO Box 42716, Olympia WA 98504-2716	(360) 725-1348
Implementation....	Myra Davis	PO Box 45510, Olympia WA 98504-5510	(360) 725-1847
	Donna Sullivan	PO Box 45506, Olympia WA 98504-5506	(360) 725-1564
Enforcement....	Myra Davis	PO Box 45510, Olympia WA 98504-5510	(360) 725-1847
	Donna Sullivan	PO Box 45506, Olympia WA 98504-5506	(360) 725-1564

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:
Name:
Address:

phone ( )
fax ( )
e-mail

☒ No. Explain why no statement was prepared.

The agency has determined that the proposed filing does not impose a disproportionate cost impact on small businesses or nonprofits.

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:

phone ( )
fax ( )
e-mail

☒ No: Please explain:

RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

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 agency-covered prescriptions. The fee is the agency's maximum reimbursement for expenses involved in the practice of pharmacy and is in addition to the agency's reimbursement for the costs of covered ingredients.~~

~~**"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.~~)) 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)"** - The application of a set of principles and a method for the review of well-designed 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.

((~~**"Evidence-based practice center"** - 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.~~)) **"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 determined by the agency. 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 the DUR board.

"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 Ad-~~

~~ministration (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 ((~~of~~)) 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~~)) 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~~)) vendor.

(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 only but 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 nonpreferred 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 nonpreferred generic drugs for the client's first course of treatment.

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

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 contract 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.

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

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 following 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 of-

fice 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);

(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 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 ac-

quisition 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.

EXHIBIT D

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

NAME (TYPE OR PRINT)
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

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 _____

The number of sections adopted in the agency's own initiative:

New _____ Amended _____ Repealed _____

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

New _____ Amended 18 Repealed _____

The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	18	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 evidenced-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 agency-covered prescriptions. The fee is the agency's maximum reimbursement for expenses involved in the practice of pharmacy and is in addition to the agency's reimbursement for the costs of covered ingredients.~~

~~**"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 ((~~of~~)) 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 nonpreferred 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) Anticepileptic;~~

~~(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 nonpreferred generic drugs for the client's first course of treatment.

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

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.

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

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.

EXHIBIT E

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

Washington State Health Care Authority

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.

If you have any questions other than for reimbursement corrections please contact us at pharmacyrates@hca.wa.gov.

Thank you,

Medicaid Program
Health Care Authority

EXHIBIT F

STATE OF WASHINGTON

HEALTH CARE AUTHORITY

626 8th Avenue, SE • PO Box 42716 • Olympia, Washington 98504-2716

March 17, 2017

TO: Interested Persons

FROM: Amy Emerson, Program Manager
Rules and Publications
Division of Legal Services

SUBJECT: **CONCISE EXPLANATORY STATEMENT** *(RCW 34.05.325)*
For Rules Not Considered Significant
For Rules Proposed as WSR 17-07-001

WAC(s): 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

REASON FOR ADOPTION: 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.

CHANGES MADE SINCE THE RULE WAS PROPOSED: (check one)

☐ The text being adopted does not differ from the text of the proposed rule.

☐ The text being adopted contains only editorial changes from the proposed rule.

☒ The text of the adopted rule varies from the text of the proposed rule. The changes (other than editing changes) follow:

The changes were made because:

SUMMARY OF COMMENTS RECEIVED	THE AGENCY CONSIDERED ALL THE COMMENTS. THE ACTIONS TAKEN IN RESPONSE TO THE COMMENTS, OR THE REASONS NO ACTIONS WERE TAKEN, FOLLOW.
Comment 1 A stakeholder noted that in the proposed revisions to WAC 182-530-1050 (Definitions), WAC 182-530-7000 (Reimbursement), and WAC 182-530-7900 (Drugs purchased under the Public Health Services Act), reference to professional dispensing fees are eliminated. The effect appears to be that in Apple Health fee-for-service, 340B covered entities may bill HCA only for the acquisition cost of the covered outpatient drug and may not bill a professional dispensing fee. For the vast majority of Washington Federally Qualified Health Care Centers (FQHCs) this does not present a problem. However, a small number of FQHCs do not include the costs general covered by a professional dispensing fee in their costs reports, meaning that the elimination of a professional dispensing fee could have substantial negative impact on their costs and their ability to provide services to this population. The stakeholder believes that a system disadvantaging some health centers but not others is untenable.	**Response to Comment 1** The agency is not removing the professional dispensing fee for 340B billers. Please see WAC 182-530-7000(1). The agency pays a professional dispensing fee regardless of what is billed as a dispensing fee up to the provider's usual and customary charge. **No changes will be made to the rule as a result of this comment.**
Comment 2 A stakeholder commented that the agency's professional dispensing fee methodology should recognize the higher costs incurred by 340B providers.	**Response to Comment 2** The rule has been changed, which makes the comment no longer pertinent. The agency asked the Centers for Medicare and Medicaid Services (CMS) to clarify if the covered outpatient drug rule (CODR) implementation requires Washington Medicaid to change the current family planning clinic 340B methodology. The agency received e-mail confirmation from CMS affirming that the agency is to rely upon the instructions given in the State Medicaid Directors' letter dated February 11, 2016, and Sections 447.502 and 447.518 (d) of the CODR with comment (CMS-2345-FC). These texts are silent on the issue of family planning clinic reimbursements. For the elements that do apply to 340B drugs, the agency is already in compliance. CMS did not respond with an affirmative instruction that the agency is required to change the family planning clinic reimbursement methodology. As Washington Medicaid is already compliant with acquisition cost requirements for participating 340B providers, the agency will reverse the WAC changes related to paying the 340B ceiling rate and a professional dispensing fee. At this time, the agency will not implement any change to family planning clinic 340B reimbursements. *The agency made the following change to 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.~~
Comment 3 A stakeholder commented that the agency should clarify that physician-administered drugs purchased under section 340B of the Public Health Services Act are also subject to the 340B ceiling price and will continue to receive insertion fees instead of professional dispensing fees.	**Response to Comment 3** Washington Fee for Service Medicaid already requires Actual Acquisition Cost billing of 340B discounted products and will be compliant with 340B ceiling price limits. Insertion, injection, and administration fees associated with professional services are not impacted by these WAC changes. **No changes will be made to the rule as a result of this comment.**
Comment 4 A stakeholder commented that the state should codify in regulation the existing per-unit dispensing fee when dispensing multiple cycles of contraceptives in one encounter, which was established based on provider costs to acquire, stock, and dispensing drugs in order to reduce patient barriers to contraception.	**Response to Comment 4** The per-unit dispensing fee will not be codified in WAC. See response to Comment 2.
Comment 5: A stakeholder encourages the agency consistently use "professional dispensing fee" instead of "dispensing fee" throughout the regulation.	**Response to Comment 5** *The agency made the following change based on this comment:* The agency added "Means professional dispensing fee" to the definition of dispensing fee in WAC 182-530-1050.
Comment 6 *Evidence based practice center – WACs 182-530-1050, -3100, 04100* A stakeholder commented that coverage standards for prescription drugs and any conditions that are placed on their operation must be informed by a full and current assessment of the research regarding medical conditions and the drugs that are approved to treat them. To this end, when the agency makes decisions regarding what drugs will be covered in state-administered health programs, it's rules require it contract with 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 conditions" (an "evidence-based practice center") to guide the creation of the agency's drug coverage standards. The agency can consult with an evidence-based practice center when it decides whether a drug's coverage requires authorization. And, an evidence-based practice center assessment must be obtained whenever the agency or the Drug Use Review (DUR) Board makes decisions and recommendations that the coverage of drugs or drug classes for Washington Apple Health Beneficiaries. These requirements constitute a sensible attempt	**Response to Comment 6** *The agency made the following changes based on this comment:* 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 **"Evidence-based drug reviews"** ~~and evidenced-based~~

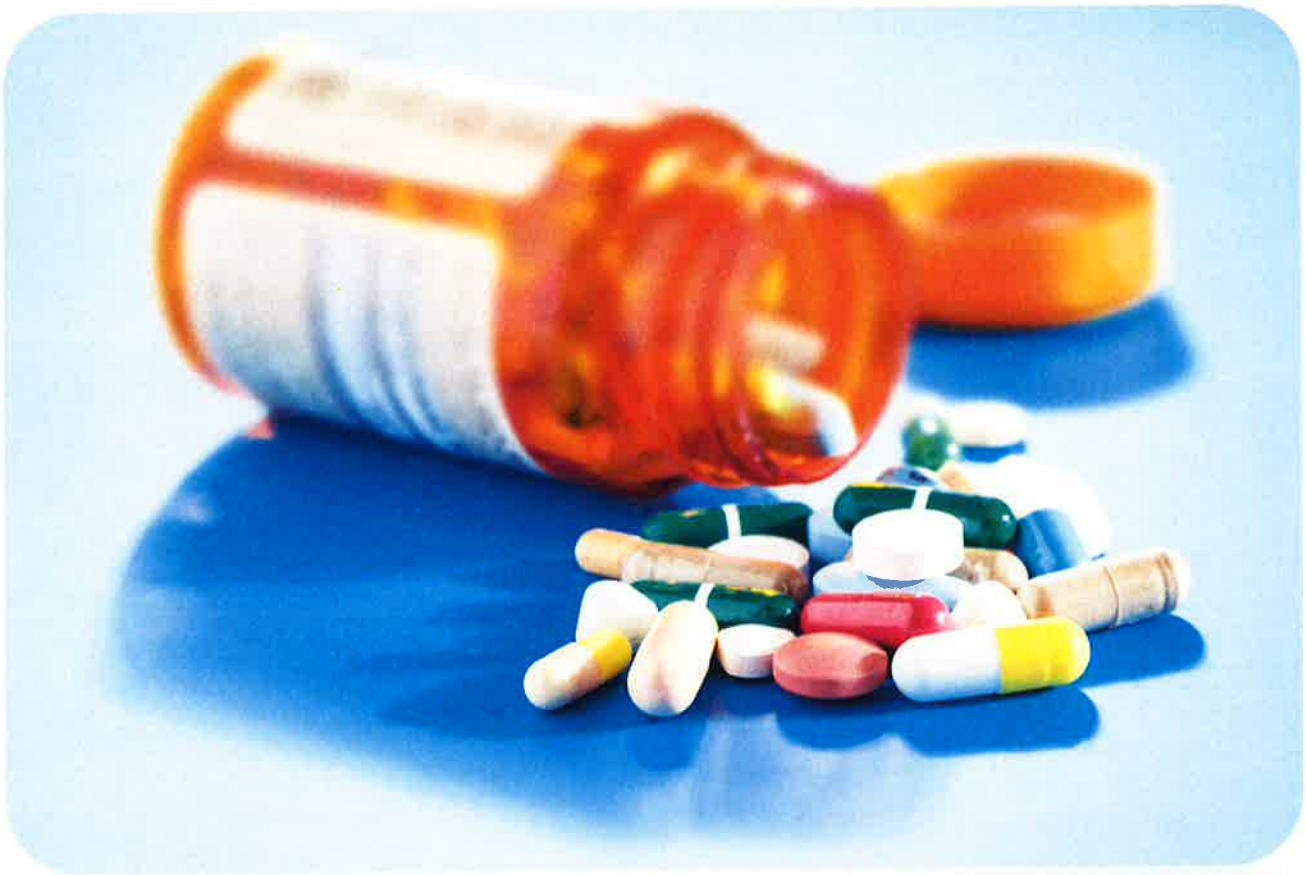
to ensure that the agency and the DUR Board will have an independent assessment of the relevant research from a competent source when making policies regarding what drugs are covered for Apple Health patients and under what conditions. It is this surprising that the agency has sought to unmoor the creation of these coverage standards from the evidentiary basis provided by the evidence-based practice center assessments. More concerning, the proposed amendments would allow the agency to forgo obtaining as assessment from an evidence-based practice center to inform its and the DUR Board's decisions about the drugs to be included in the preferred drug list, with any associated limitations and conditions, so long as it seeks an alternate assessment from a "vendor." Notably, the draft amendments place no requirements on what type of vendor must be used to provide such assessments, or what kinds of certification or qualifications it must have. While there is nothing talismanic about the AHRQ designation, it at least provides some assurance that the evidence-based practice center has been independently recognized by a noncommercial entity for its competence to provide evidence-based systematic assessments of health conditions and their treatments. Consequently, unless there is a substantial reason why evidence-based practice centers have been unable to provide the services required of them, the rules should remain as written regarding using evidence-based practice centers as drug coverage consultants to the agency and the DUR Board.	~~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~~ 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 182-530-3100 (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~~.
Comment 7 *Medicaid preferred drug list (PDL) – WACs 182-530-1050, -4100(3) and (4)* A stakeholder commented that there is confusing and conflicting language regarding what drugs are in the Medicaid Preferred Drug List (PDL) but not on the Washington PDL, and how these additional drugs are selected for inclusion in the Medicaid PDL.	**Response to Comment 7** *The agency made the following changes based on this comment:* 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 182-530-4100 (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.
Comment 8 *Grounds for requiring authorization – WACs 182-530-3000 (3)* A stakeholder commented that the draft amendments broadly expand the justification for requiring authorization for a medication. The new formulation, "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" could easily be read as to give the agency nearly unrestrained discretion to require authorization as a condition of coverage, as it would permit the agency to impose such requirement any time it articulates a general concern regarding the safety, efficacy, or effectiveness of a drug, as well as any tie it believes that a client or clients "would benefit from further clinical review," seemingly for any reason at all.	**Response to Comment 8** The agency is required by federal law to ensure safe and effective use of prescription drugs for Medicaid members and to prevent fraud and abuse of the benefits. Therefore, the agency needs broad authority to determine when it is appropriate to require authorization for certain drugs or clients. **No changes will be made to the rule as a result of this comment.**
Comment 9 *Preferred generic drugs required for a client's first course of treatment – WAC 182-530-4125* The proposed amendments would strike the requirement that the DUR Board approve any specific generics first coverage restrictions, though it is unclear why. Removing the requirement that the DUR Board approve any specific generics first requirements is likely to save little resources on the frontend while increasing the agency's backend expenditures. It will increase agency costs by requiring the agency staff to duplicate in part or in whole the DUR Board's existing assessments of drug classes for which the agency is considering generic first policies. Or, if the agency chooses not to conduct as full and effective assessment as the DUR Board would, to avoid the extra expenditures, it runs the risk if creating inapt generics first policies that result in inappropriate treatment decisions, to the detriment of patients' health, and increasing the costs needed to care for them.	**Response to Comment 9** The change does not make any operational changes. The revised WAC allows for the generics first program according to RCW 69.41.190. This statute requires that the Drug Use Review (DUR) Board reviews and provides recommendations as to the appropriateness of the generic first requirement. The intent of the change to the WAC was to point to the law that dictates the policy, therefore if the law changes the WAC is not misaligned with the agency's legal obligations. **No changes will be made to the rule as a result of this comment.**
Comment 10 A stakeholder appreciates the agency's moves to clarify state rules and eliminate confusing differences between governing state and federal law. However, the stakeholder says that other changes currently under consideration are not obviously needed to conform with federal law, nor is it clear how they will "increase the number of drug classes available for supplemental rebates" - the other purpose to these rule amendments listed in the draft's CR-102 cover sheet.	**Response to Comment 10:** Not all changes made to the WAC were to comply with changes to federal regulations. The former WAC limited the agency's ability to expand supplemental rebates as it limited the information that the Pharmacy and Therapeutics Committee could use to develop the Washington Preferred Drug List (PDL)

	to drug class reviews performed by an Evidence Based Practice Center (EPC). EPCs do not review enough drug classes to develop a comprehensive PDL as only about 35 of the over 200 drug classes have been reviewed. This limits the agency's ability to obtain supplemental rebates on the majority of the drugs it covers for its Medicaid members. **No changes will be made to the rule as a result of this comment.**

cc: HCA Rules Coordinator

EXHIBIT G



STUDY OF THE PHARMACY CHAIN OF SUPPLY

HMA
HEALTH MANAGEMENT ASSOCIATES

OFFICE of the
INSURANCE
COMMISSIONER
WASHINGTON STATE

Table of Contents

Executive Summary

In 2016, the Washington legislature passed 5ESSB 5857, which required the Washington Office of the Insurance Commissioner (OIC) to conduct a Study of the Pharmacy Chain of Supply (Study). The legislation specified that the Study must include at least the following elements:

- Review the entire drug supply chain including plan and pharmacy benefit manager reimbursements to network pharmacies, wholesaler or pharmacy service administrative organization prices to network pharmacies, and drug manufacturer prices to network pharmacies.
- Discuss suggestions that recognize the unique nature of small and rural pharmacies and possible options that support a viable business model that do not increase the cost of pharmacy products.
- Review the availability of all drugs on the maximum allowable cost list or any similar list for pharmacies and provide analysis of the differences in wholesale prices of pharmaceuticals and reimbursement prices.
- Review data submitted to the Department of Revenue under RCW 19.340.100(4)(b), if any, for patterns and trends in the denials of internal pharmacy benefit manager appeals involving pharmacies with fifteen or more *(sic)* [1] retail outlets within the state of Washington, under their corporate umbrellas.
- Review the telephone contacts and standards for response times and availability for telephone inquiries and appeals by pharmacies and providers to pharmacy benefits managers.
- Review the pharmaceutical acquisition cost from national or regional wholesalers that serve pharmacies in Washington, and consider when or whether to make an adjustment and under what standards. The review may assess the timing of pharmacy purchases of products and the relative risk of PBM list price changes related to the timing of dispensing the products.

OIC contracted Health Management Associates (HMA) to conduct the Study. HMA subcontracted Mercer LLC and Gorospe Solutions to provide supplemental subject matter expertise and data analysis when necessary.

OIC identified six PBMs that provide pharmaceutical management services to 98% of the enrollees in Washington State's fully insured commercial market.[2] Elements of the Study required analysis of complex data sets that contained confidential and sensitive information. It is rare that these data are shared outside PBM organizations; however, 5ESSB 5857 required pharmacy benefit managers (PBMs) to provide all information needed to conduct the Study. As a result, HMA and its subcontractor received unprecedented access to claims, proprietary maximum allowable cost (MAC) reimbursement lists, and appeals data from the PBMs. Because of the sensitivity of the data, the names of the PBMs are blinded throughout the study. Each PBM is assigned a number and is referred to in the report as PBM 1, PBM 2, etc.

[1] Senate Bill XXX athe secondary appeal rights of OIC applies to pharmaices with fewer than 15 stores, not greater.
[2] Note, through the Washington Attorney General Office's review, only fully insured commercial payers are subject to the secondary appeals process; therefore, data capture was restricted to those PBMs.

It should be noted that conducting dispensing and actual acquisition cost studies were out of scope for this project; therefore, industry benchmarks were used as proxies for Washington-specific drug acquisition cost and cost of dispensing. Further detail is presented in the methodology section beginning on page ten.

Overviews and key findings for each of the six main sections of the Study are summarized below. In order to achieve a logical flow, and due to overlap across the elements identified in the legislation, the Study was organized differently than the legislative list of required Study elements. Therefore, the six sections of the report summarized below do not align directly to the six elements of the Study outlined in the legislation bulleted above.

The Pharmacy Supply Chain

The pharmacy supply chain is considered by some to be one of the most complex and opaque supply chains in the United States, with thousands of confidential monetary transactions occurring for each unique drug product. Pharmaceutical pricing for commercial insurers is a market established with minimal government regulation. This section of the Study provides descriptions of each segment of the supply chain and how each interacts with one another to provide an overall background on the industry players. The recent EpiPen pricing increase lends itself to be an evocative example of how the various segments of the supply chain impact the pricing of a drug.

Maximum Allowable Cost Reimbursement

The purpose of this section is to understand how Washington state-specific PBM Maximum Allowable Cost (MAC) reimbursement for multi-source generic drugs (generic drugs produced by more than one manufacturer) compares to the National Average Drug Acquisition Cost (NADAC) reimbursement and to two regional benchmark MAC lists. A key objective of the Study is to determine the adequacy of PBM MAC reimbursement to independent pharmacies. In theory, MAC reimbursement adequacy will drive the number of MAC appeals that pharmacies submit to PBMs, thus impacting OIC's decisions on developing the infrastructure to process a secondary-level of appeals.

Key Findings:

- The number of drugs included on PBM MAC lists vary significantly across PBMs.
- Aggregate PBM Wholesale Acquisition Cost (WAC) effective discounts of their MAC lists ranged from WAC -15.5% to WAC-38.0%, while regional benchmarks, and NADAC WAC discounts range from WAC -24.3% to WAC -30.6%. The PBMs demonstrated greater variance (e.g., larger range of effective WAC discounts as compared to national and regional benchmarks) with some PBM MAC lists having reimbursement rates more generous than the national and regional benchmarks (e.g., WAC – 15.5%), and other PBM MAC lists demonstrating more aggressive reimbursement rates (e.g., EAC - 38%) compared to the benchmarks.
- In general, PBM MAC lists result in payments to pharmacies that are higher than the NADAC benchmark price and lower than the regional benchmark prices .
- The fact that the PBM MAC lists result in reimbursements that are higher than the NADAC benchmark is attributable to the fact that NADAC is an average acquisition cost benchmark, whereas MAC lists are designed to reimburse pharmacies more than the lowest available acquisition cost for a drug grouping.
- PBM 3 paid rural pharmacies less than all benchmarks; PBMs 5 and 6 paid more.

- Five of the six PBMs paid independent pharmacies more than chain drug stores in the NADAC analysis.
- PBMs in aggregate paid over 73% of claims to chain pharmacies. Within chain pharmacies there are significant PBM reimbursement variance swings depending on which benchmark (national or regional) the PBM reimbursement is compared to.

PBM MAC List Update Processes

The generic drug market is in a constant state of flux. Prices change as some manufactures enter the market and others leave. There is a direct relationship between the amount of discounts off of the list price and the number of manufacturers distributing a specific drug product. The greater the number of generic manufacturers available for a product, the greater the discount the purchaser will receive. It follows that the drug prices decrease when there is greater competition. Because the availability and pricing of generic drugs changes on a daily basis, pharmacy acquisition costs are changing constantly. In order for reimbursement to keep up with pricing changes, PBMs update their MAC lists on a frequent basis; some report daily updates. To help ensure that MAC reimbursement is fair, some states have passed laws to require PBMs to update their MAC lists on a frequent basis. Washington requires PBMs to update MAC lists weekly.

Key Findings:

- The data varied so much that no conclusions can be drawn regarding timing of MAC list updates, and no trends are found for any of the six PBMs.
- PBMs reacted differently on a drug-by-drug basis with regard to how cost changes were handled.
- PBMs varied in how they reacted to the same cost change on a drug. PBM reimbursement prior to observed acquisition cost changes varied significantly compared to NADAC drug pricing. The PBM ingredient cost reimbursement differed widely, from being equivalent reimbursement to NADAC, to being more than 100% above or below NADAC.
- PBMs appeared to proactively update reimbursement prior to a pricing change on certain drugs. However, the conclusion that PBMs alter reimbursement prior to a known pricing change is merely an inference that cannot be verified as fact through this Study.
- Very rarely did PBMs react on the exact day of a WAC rate change.
- There was no clear pattern in the way different PBMs updated prices, and even individual PBMs seemed to have no consistent method of dealing with price changes.
- During the period reviewed for the Study, some PBMs updated their MAC lists within a week of a cost change, while others made no updates during the period.

Pharmacy Profitability

The Study estimates pharmacy profitability based upon national and regional benchmarks including average wholesale price discounts for drug acquisition costs and cost of dispensing (COD) studies. In addition to assessing overall profitability of Washington pharmacies, the Study includes a case study of independent pharmacies profitability. The profitability of one rural independent and one urban independent was analyzed.

Key Findings:

- In the aggregate, pharmacies showed a positive Gross Profit across the PBMs, but only a positive Gross Profit for PBMs 1 and 4 when considering the cost of dispensing at $10 per prescription.
- Dispensing generic drugs was more profitable than dispensing brand drugs, but that profitability was dependent on an individual pharmacy's cost to dispense.
- The rural independent pharmacy was more profitable than the urban independent pharmacy.
- Profitability decreased when the cost to dispense increased from $10 to $15 per prescription, forcing pharmacies' Net Income as a percent of Gross Income into the negative range.
- The rural independent pharmacy was more profitable at a $10 COD and suffered lower losses at $15 COD than the urban independent pharmacy.
- Pharmacies that relied on prescription drug incomes must obtain higher or expanded fees, or, must maintain a sufficient spread between drug costs and reimbursements in order to remain profitable.

The following table shows pharmacy profitability as a percentage of Gross Income:

Cost to Dispense	Rural Independent Pharmacy Profit	Urban Independent Pharmacy Profit
$10	3.3%	-0.2%
$15	-7.0%	-10.9%

Pharmacy MAC Appeals Analysis

The objective of the appeals analysis was to review data submitted to the Department of Revenue under RCW 19.340.100(4)(b), if any, for patterns and trends in the denials of internal pharmacy benefit manager appeals involving pharmacies with fewer than fifteen retail outlets within the State of Washington, under their corporate umbrellas. In absence of this data from the Department of Revenue, the data was obtained directly from the PBMs.

In order to accomplish the objective, the scope of work for this section included conducting the following:

- An analysis of MAC appeals, the frequency of successful appeals, and the types of pharmacies most likely to generate appeals;
- Establishing an estimate of the percentage of transactions which are likely to generate appeals under the provisions of ESSB 585; and
- An analysis and recommendation for the most useful documents to be submitted by parties when an appeal is filed to OIC to allow for expeditious OIC resolution of submitted appeals.

The analysis separated pharmacies into two designators: SMALL and LARGE. SMALL pharmacies were defined as having fewer than 15 locations in Washington. Since SMALL pharmacies is the subset of pharmacies that will have access to the OIC secondary appeals process, a more granular analysis was conducted for these SMALL pharmacies.

Key Findings

- The Study estimated that OIC is likely to receive 13,500 – 15,500 appeals on average annually. This estimate assumes that PBMs do not change their current business practices, which, if they do, may affect the appeals volume they receive.

- SMALL pharmacies generated a range of appeals, as a percentage of total claims volume, from 0.02% – 2.24% with an overall average of 0.19%.
- 17% (44) of SMALL pharmacies that submitted an appeal generated 80% of the appeals.
- All 44 pharmacies were paid at a higher rate than NADAC, but at a lower rate than all Washington pharmacies except for PBM 2.
- All but one PBM paid the 44 pharmacies' ingredient costs at a higher rate than the statewide pharmacies when comparing to benchmark MAC List 1.
- Four of the six PBMs paid the 44 pharmacies' ingredient cost at a higher rate than the statewide pharmacies when comparing to benchmark MAC List 2.
- Of the 44 pharmacies, 9 were urban locations, 5 were in suburban locations, and 30 were in rural locations. By geography, 12 were in Eastern Washington (east of the Cascade Mountains), 10 were in Central I-5 corridor (defined as King, Pierce, Snohomish, and Thurston Counties), and 22 were in the rest of western Washington.
- 37% (108) of the SMALL pharmacies submitted fewer than 10 appeals over the Study period.
- PBM 4 had 59% of the appeal volume for SMALL pharmacies over the study period, with a notable increase over the study period.
- PBMs denied between 77% and 94% of MAC appeals, with an average of 87%.
- The majority of the appeals were on lower cost drugs. 89% of the appeals came from claims in which the pharmacy was reimbursed less than $50 for the ingredient cost of the drug. Ingredient cost ranged from pennies to over $500 per prescription.
-

PBM MAC-Related Process Review

The Study includes a review of the PBM MAC appeals processes to provide the OIC with baseline information. Areas reviewed include:

- Timeframe for appeals resolution by the PBM (in accordance with RCW 19.340.100(3));
- Provision of an alternative National Drug Code (NDC) for denied appeals (in accordance with RCW 19.340.100(4)(b));
- Updates of the MAC pricing within one day (in accordance with RCW 19.340.100(5)(a));
- PBM telephone contacts for submitting MAC appeals (in accordance with RCW 19.340.100(4)(a)); and
- PBM MAC appeals policy review.

The analysis in this section is intended to be informational only and in no way should be considered a compliance audit. In some cases, the PBM did not provide sufficient data or information to allow the reviewers to gain a full understanding of the PBM's processes. Absence of data does not imply that a PBM is not in compliance with the terms of the regulation, but instead, it is a limitation of the dataset or PBM reporting capabilities. Further, the observations in this report are not intended to be used for enforcement purposes, but merely to show our conclusions based on the information reported.

Further, the appeal data set contains appeal records prior to the enactment of the law, so the data may not reflect compliance practices of the PBMs.

Key Findings

- PBMs reported faster resolution of denied appeals than upheld appeals: 84% of denied appeals were processed in 10 days and 4% were not completed within 30 days; 58% of upheld appeals were processed in 10 days and 10% were not completed within 30 days.
- For SMALL pharmacies, the timeframes were longer: 55% processed within 10 days and 85% processed within 30 days.
- Three of the six PBMs provided the alternate NDC greater than 90% of the time.
- Only three PBMs provided information relating to the requirement to update their MAC list pricing within one day of a pricing change. Of those three, MAC lists updates within the one-day timeframe were made between 87% and 100% from the determination date.
- Each PBM in the Study had a telephone contact number for pharmacies to use to speak with PBM personnel, although direct contact with a live PBM representative was not always available on the first call. The majority of the call center hours of operation observed in the Study were 24 hours a day, seven days per week.
- Each PBM provided policies and procedures or a summary of processes that indicated that the PBM had an appeals resolution timeframe within the requirement of the regulation (30 days).
- The PBMs' response times for appeals ranged from three to 30 days
- The window of time a pharmacy had to submit an eligible MAC appeal varied by PBM.
- The Study found that PBMs have sufficient policies and procedures or processes to fulfill the telephonic contact center requirements of RCW 19.340.100.
- All but one PBM in the Study had specific policies and procedures for handling MAC pricing inquiries and appeals, and response times within the parameters required by regulation. Depending on day of the week and time that a placed a call, live assistance was not always available but callers had the option of leaving a voice message. At the time this report was prepared, not all calls were returned.

Overall Observations

PBMs, in theory, design MAC lists to pay pharmacies fairly for multi-source generic and (sometimes) brand drugs. 'Fairly' is generally accepted to mean that a PBM's MAC list reimburses above a pharmacy's ingredient cost in aggregate while at the same time provides value to their payer clients. The results of this Study appear to generally validate this theory both when benchmarked against NADAC and generally accepted AWP brand and generic discounts for drug acquisition pricing. Additionally, independent pharmacies have higher reimbursement rates than chain pharmacies when compared to NADAC. Among independent pharmacies, a case study demonstrated that one rural independent pharmacy fared better than one urban independent pharmacy.

Pharmacy profitability appears to be impacted more by the cost of dispensing than drug cost reimbursement. When cost of dispensing increases, the spread that pharmacies make on ingredient cost reimbursement shrinks. Because the cost of dispensing appears to be the pressure point for profitability based on the data in this Study, the best method of improving pharmacy financial viability without increasing the price of drugs is to address reducing overhead costs or diversifying into profitable non-drug product ("front store") sales.

Pharmacist informants reported wide variability on PBM MAC list updating for drug price inflation, which impacts their profitability. This Study validates that there are no identifiable patterns for

updating MAC lists; however, timing of updating MAC lists does not appear to impact the fairness of the reimbursement in aggregate. Pharmacy informants also stated that PBMs could take 90 days or more to review MAC appeals and pay the pharmacy for upheld appeals. This Study did not validate those statements. PBMs' decision timeframes exceeded 30 days for only 4% of denied appeals and 10% of approved appeals. For PBMs that reported MAC adjustment timelines for approved appeals, one adjusted pharmacy reimbursement was completed within one day 87% of the time, and the other two at 100% of the time.

The Study estimated that OIC could potentially see 13,500 to 15,500 second level MAC appeals based upon current practices. Notably, of the pharmacies with fewer than 15 stores, 44 pharmacies submitted 80% of the appeals to PBMs. OIC has an opportunity to work with these pharmacies individually to understand why they submit a great number of appeals and to see if there are solutions outside of the appeals process. Additionally, nearly 70% of the appeals are driven by one PBM. OIC has another opportunity to work directly with the PBM to determine why it is generating the high percentage of appeals before the law becomes effective.

Methods

Overview

The Study used both qualitative and quantitative data to complete all elements of analysis of the pharmacy supply chain. The data analyses consisted of interviews, research, and analysis of PBM data. The following are the six types of data that were analyzed:

- Qualitative
  - Conducting industry interviews with pharmacy supply chain segments and legislative staff
  - Reviewing PBM MAC pricing and appeals policies and procedures
  - Making secret shopper calls to PBM MAC appeals contact numbers
  - Researching other state MAC transparency laws
- Quantitative
  - Analyzing pharmacy claims and payment data
  - Analyzing MAC list update timeframes
  - Analyzing PBM MAC appeals processing standards

The OIC reviewed the list of carriers in the fully insured commercial market in Washington State and identified the PBMs that provide the pharmacy benefit for their members. Six PBMs administer the pharmacy benefit to 98% of Washington's fully insured population on behalf of the carriers. This Study is limited to the activity of these six PBMs.

OIC sent the PBMs a formal data request for the claims data, appeals data, and policies and procedures (Appendix I). The rest of the data were gathered through interviews and research. As discussed in the Executive Summary, due to the sensitivity of the data received, the PBMs are blinded in the Study and are referred to PBM 1, PBM 2, PBM3, PBM 4, PBM 5, and PBM 6.

Different data and approaches were used in each section of the Study. Because of the variability in data analysis, each section includes a Methods subsection that applies specifically to the scope of the section it is found in. The following is an overview of how the data elements were used across the Study.

Qualitative Analysis

Informant Interviews

OIC and HMA solicited interviews with representatives from the pharmacy supply chain, trade associations, and Washington House and Senate staff. Efforts to secure interviews lasted for three months; all but two stakeholder groups had at least one individual interviewed. The lack of participation is likely due to the current sensitivities related to the pricing of new blockbuster drugs and recent price hikes to established medications, as well as competing positions on how drugs are priced. The general reluctance to be interviewed was probably strengthened by the fact that the controversial and highly publicized EpiPen price increase occurred in the middle of the Study.

The informants were all forthcoming and provided essential background into how each segment of the supply chain interacts with other segments. They also identified their own pressure points including increasing fluctuations in manufacturer pricing, payer pricing strategies, and efforts to keep drugs pricing affordable. Interviews with executive and legislative branch staff were helpful in understanding the environment that led to the initiation of the Study. However, the number of pharmacy supply chain informants was too small to draw definitive conclusions.

The following lists the organizations and categories that agreed to be interviewed, following by the number of interviews in parentheses.

- Washington State Pharmacy Association (2)
- Pharmaceutical Care Management Association (1)
- Drug Manufacturer (0)
- Wholesaler (0)
- Pharmacy Services Administrative Organization (1)
- Pharmacy Benefit Manager (1)
- Washington State Chain Pharmacy (1)
- Washington State Independent Pharmacy (3)
- Industry Consulting Experts (2)
- Washington State Legislative Staff (2)
- Washington DSHS (2)
- Washington Health Care Authority (1)

Policy and Procedure Review

HMA and its subcontractor conducted a desk review of all policies, procedures, provider manuals and other documentation related to MAC appeals processing and related operations. When possible, quantitative data were compared to the policy documents to determine if practice follows policy.

Secret Shopper Calls

A total of 18 secret shopper calls were made (three calls per PBM). Each PBM received calls during regular business hours, after hours, and weekend hours. A process diagram for the secret shopper call is provided as Exhibit 78. The secret shopper presented himself as an assistant calling on behalf of a pharmacist preparing for a MAC appeal. The secret shopper called into the phone number provided by the PBM and verified the hours of operation. The secret shopper was not provided with a pharmacy NCPDP/NPI number, specific RX number for a prescription, or patient number and thus was unable to pursue the call as a complete MAC pricing appeal.

Researching Other State MAC Transparency Laws

Appendix IV contains supplemental research on other states' PBM MAC appeals laws for comparison to Washington's. The data were collected through subject matter knowledge of HMA and its subcontractor, as well as individual research through the firms.

Quantitative Analysis

PBM MAC Reimbursement

The PBMS' ingredient cost reimbursement for multi-source generic drugs (MAC pricing) is compared to three acquisition cost benchmarks to determine the adequacy of MAC reimbursement. Benchmarks were used because the Study's scope did not include an actual acquisition cost survey. The NADAC benchmark is the most reliable because it is based upon actual acquisition cost surveys conducted by CMS and is updated weekly. The two regional benchmarks are Medicaid MAC lists. The first MAC list reimburses pharmacies in a rural region similar to eastern Washington. The second MAC list is used in a state with a similar population to that of Washington State. HMA's subcontractor believes the two benchmark MAC Lists are the best proxies to use for regional acquisition cost.

PBM MAC List Updates

The Study reviewed 60 highly utilized generic drugs which had significant cost increases or decreases in 2015 for a timing analysis of when a drug price changes and when the PBM updates its MAC list. The analysis reviewed each drug's acquisition cost history, inferred from NADAC, in comparison to the PBM MAC lists. The goal was to understand how PBMs reacted once a price change affected the market. NADAC was used because it is based upon acquisition costs and is updated weekly. The Study reviewed the pricing for the drug before the price change, the time of the price change, and the length of time PBMs took to adjust reimbursement so that it is within a reasonable range of the adjusted acquisition cost. A 10% threshold on either side of a NADAC rate was considered reasonable.

Pharmacy Profitability

The pharmacy profitability analysis differs from the PBM MAC Reimbursement analysis because it analyzes profitability for brand and generic drug rather than just generic drugs. The analysis uses national AWP discount benchmarks for drug acquisition costs (18% for brand and 90% for generics), compared to actual PBM reimbursement and then calculates Gross Profit. The cost of dispensing is estimated based upon a national study of cost of dispensing. That figure is then subtracted from the Gross Profit to arrive at estimated Net Income for Washington Pharmacies.[3]

MAC Appeals Processing

PBM MAC appeals and claims data were reviewed to determine the following:

- Number and percentage of appeals submitted by pharmacies in Washington with fewer than 15 pharmacies and those with 15 or more;
- (For SMALL pharmacies) the percentage of pharmacies that generated the greatest number of appeals;
- Timing of approvals and denials by PBMs;
- Whether or not an NDC was provided for denied appeals;
- Timing of a MAC list change for approved appeals; and the
- Dollar amount of pharmacy submitted MAC appeals.

Data Limitations and Cautions to the Reader

All estimates are based on the information available at a singular point in time. Because the data used to make these estimate may reflect unknown or random circumstances that may not be fully reflective of typical conditions, the result of the analysis should be interpreted as only estimates, with the understanding that the actual data point and projections based on that data may vary within a reasonable range around the estimate or the projection. Any estimate or projection may not be used or relied upon by any other party or for any other purpose than for which it was issued by OIC's consultants. HMA and its consultants are not responsible for the consequences of any unauthorized use.

For the analyses in this report, HMA and its subcontractor relied on data, information, and other sources of data as described; the data was not verified by an independent audit. The data was, however, reviewed for reasonableness and consistency to the degree consistent with the scope of the Study. It is

[3] "Cost of Dispensing Study: An Independent Comparative Analysis of U.S. Prescription Dispensing Cost" September 2015. The Washington State estimates range from approximately $10 to $15 per prescription.

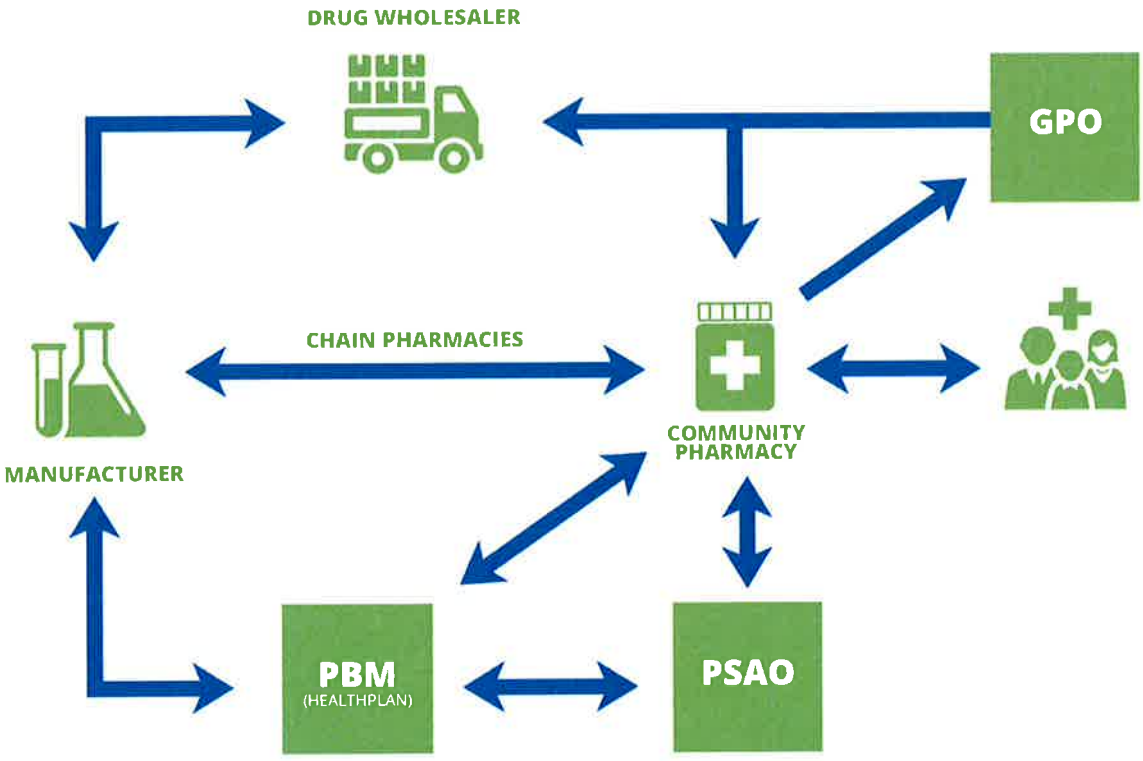
possible that the review of data may not have always revealed some problems or inaccuracies of the data that could affect the results of the Study.

The Pharmaceutical Supply Chain

To understand plan and pharmacy benefit manager reimbursements to network pharmacies, it is important to understand how drugs move through the supply chain from manufacturer to patient and, how prices are influenced by the various members within the chain. At first glance, the pharmaceutical supply chain appears to be a simple, classic commodity design. Manufacturers sell to wholesalers, who in turn sell to retailers, who finally sell to consumers. A closer look at the pharmaceutical supply chain reveals other members who do not handle the product and yet have significant influence over its ultimate distribution to the healthcare consumer. These additional supply chain members are health insurance payers, pharmacy benefit managers (PBMs), group purchasing organization (GPOs),and pharmacy services administrative organizations (PSAOs).

Exhibit 1 illustrates the key players in the pharmaceutical supply chain and their relationships. The interactions each member of the supply chain (represented by blue arrows) has with another impact drug pricing and reimbursement.

Exhibit 1: The Pharmaceutical Supply Chain



Pharmaceutical Supply Chain Acronyms

There are a number of pricing terms and acronyms that occur throughout this report. They are defined below.

Actual Acquisition Cost (AAC) – AAC is defined in federal regulations as the state Medicaid agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. The process used by the federal government to calculate the national AAC proxy, as defined below for NADAC, doesn't factor-in off-invoice discounts, rebates and other reductions to a pharmacy's price for pharmaceutical drugs. See section on Medicaid Reimbursement beginning on page 31.

Average Manufacturer Price (AMP) – AMP is the average price paid by wholesalers to manufacturers for drugs distributed to retail pharmacy class of trade. AMP is used in the federal Medicaid drug rebate program to calculate rebates and to calculate the federal ceiling reimbursement for generic drugs (see **Federal Upper Limit**). The AMP excludes sales to various entities including the federal government (e.g., Department of Defense, the Public Health Service), hospitals, HMOs or MCOs, mail order pharmacies and to clinics).[4]

Average sales price (ASP) – ASP is based on the manufacturer's volume weighted average of average sales prices for a particular drug. ASP is net of rebates, discounts and other price concessions to all classes of trade.[5] ASP is used for reimbursement of drugs under Medicare Part B.

Average Wholesale Price (AWP) – AWP is a price generally used as a reference price for the reimbursement of pharmacies. It is also used by PBMs to establish upper payment rates in contracts with health plans. It is calculated by drug pricing compendia and is equal to 120% of a drug's WAC price. This calculation tends to be more for brand drugs as generic drug companies publish AWPs which can be significantly greater than 120% of WAC.

Federal Upper Limit (FUL) – The FUL is a price calculated by the Centers for Medicare and Medicaid Services (CMS) as the federally required upper payment limit for generic drugs in the Medicaid program. It is calculated based on the weighted average AMP for each generically equivalent drug available on the market.[6] See section on Medicaid Reimbursement beginning on page 31.

Maximum Allowable Cost (MAC) – MAC is the maximum price a PBM or other payer will reimburse a pharmacy for multi-source brand and generic drugs.

National Average Drug Acquisition Cost (NADAC) – NADAC is a national average invoice price derived from retail community pharmacy reports for drug products based on invoices from wholesalers and manufacturers.[7] The NADAC is a national reference that state Medicaid programs can use when determining their AAC reimbursement. It does not measure off-invoice discounts, rebates, or other price concessions. NADAC is calculated for single source, innovator multi-source (i.e., original brand drug for which there are generic equivalent drugs) and generic (non-brand) drugs.

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[4] 42 CFR § 447.504
[5] 42 CFR § 414.904
[6] 42 CFR § 447.514
[7] The NADAC contractor is Myers and Stauffer LC

Rebates – Rebates are supplemental payments to pharmacies, PBMs, and payers for making a drug preferred over others.

Wholesale Acquisition Cost (WAC) – WAC is the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States. WAC is exclusive of prompt pay or other discounts, rebates or other reductions in price. WAC is calculated for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.[8] WAC is used by pricing compendia to calculate average wholesale price. It is also sometimes used to calculate pharmacy reimbursement.

Supply Chain Segment Impact on Drug Pricing and Reimbursement

The following sub-sections describe the members of the supply chain (Exhibit 1) and their unique impact on drug pricing. This larger section closes with an illustration of the recent Epi-Pen price hike as a recent, real-life example of how pricing decisions impact payers, pharmacies, and consumers.

Manufacturer

The supply chain starts with the development and production of a given drug by a manufacturer. Manufacturers of single source (brand name or innovator) drugs research, test, and submit drug products for potential marketing to the federal Food and Drug Administration (FDA) through a New Drug Application (NDA) process.[9] When the FDA approves a NDA, the manufacturer has marketing exclusivity for a period of time determined by either a drug's remaining patent life or a period of exclusivity granted by the FDA.[10]

At the end of patent/exclusivity, other manufacturers are able to submit an Abbreviated New Drug Application (ANDA) to the FDA for the marketing of a generically equivalent drug.[11] As noted by the FDA, generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic drug applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). The first generic approved for marketing typically has a 180-day exclusivity period, during which no other generic may be sold. After this 180-day period, all other approved generic products are allowed onto the market.

Brand Drug Price

Manufacturers of brand name products set their list price based on a number of factors including: development and manufacturing costs; exclusivity period; rebate paid to payers to ensure their drug is preferred on their drug formularies; impact of mandatory discount pricing; rebates to government payers; and estimates of what the market is willing to pay. Not to be overlooked is the impact that brand competition has on initial brand drug pricing. According to the Tufts Center for the Study of Drug Development, the time frame during which competing brand name drugs go to market has become

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[8] 42 USC § 1395w-3a(c)(6)(B)

[9] New Drug Application process at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm

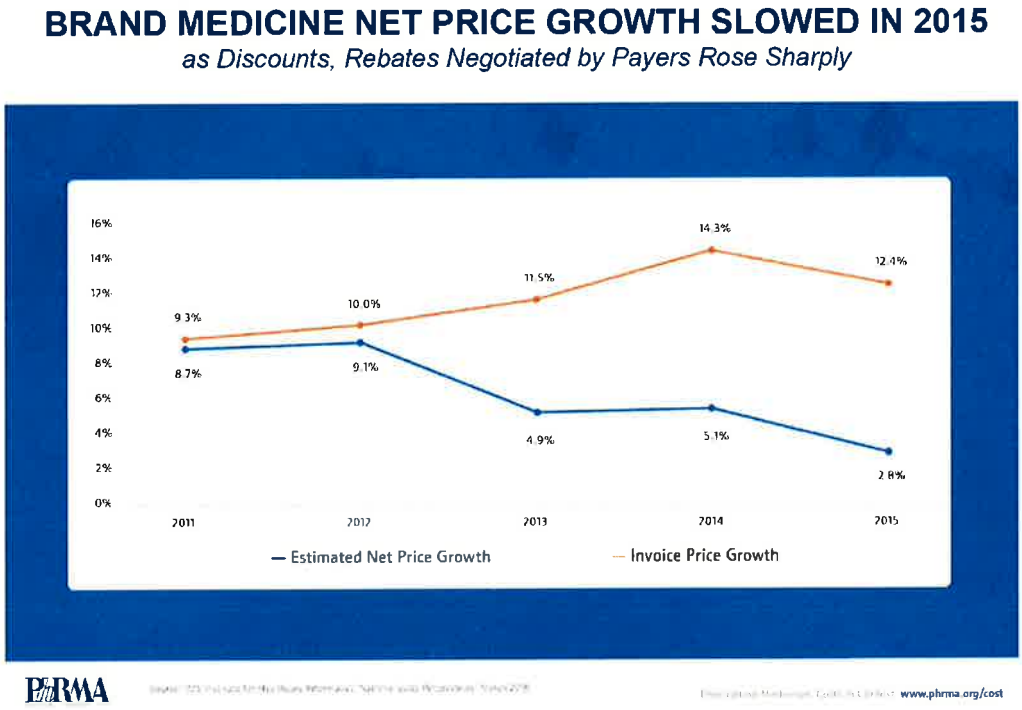
[10] Exclusivity varies depending on the type of drug product and reason for exclusivity. Exclusivity limits are dictated by federal rules. FDA FAQ on Patents and Exclusivity http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm

[11] ANDA process at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm

shorter over the past few years.[12] This type of competition pressure is exhibited, for instance, in the change in pricing and/or discounts for Hepatitis C drugs with the introduction of a lower-priced product.[13] Gilead increased market discounts from 22% to 46% after the introduction of competing products on the market.

Discounts and other price concessions within the brand supply chain also have an impact on how manufacturers price their drugs. The Pharmaceutical Research and Manufacturers of America (PhRMA) indicates that manufacturers are retaining a smaller share of the price increases as evidenced by the divergence between drug invoice price growth and net price. With the exception of federally mandated discounts, such as rebates in Medicaid and lower acquisition costs for federal programs (e.g., Federal Supply Schedule, Veteran's Affairs, and 340B discount program), all other discounts are negotiated by manufacturers as a way to gain market access through preferred status on payer formularies. Exhibit 2 illustrates reduction in net price growth due to these voluntary discounts and price concessions.[14] Mylan justifies its increase in the invoice price of EpiPen by citing the need to offset reductions in the net price, as presented by PhRMA (see Exhibit 12; page 30).

Exhibit 2: Brand Medicine Net Price Growth Slowed in 2015[15]



Source: Pharmaceutical Research and Manufacturers of America

[12] "Nearly all Later Entrants to Drug Classes Were in Clinical Testing or Regulatory Review Before First-in-Class Approval," November 3, 2105, Tufts CSDD, summary at http://csdd.tufts.edu/news/complete_story/pr_ir_november_december_2015

[13] "Merck goes toe-to-toe with Gilead's Hep C goliath, flags discount with blockbuster OK," Fierce Biotech, January 28, 2016 at http://www.fiercebiotech.com/regulatory/merck-goes-toe-to-toe-gilead-s-hep-c-goliath-flags-discount-blockbuster-ok

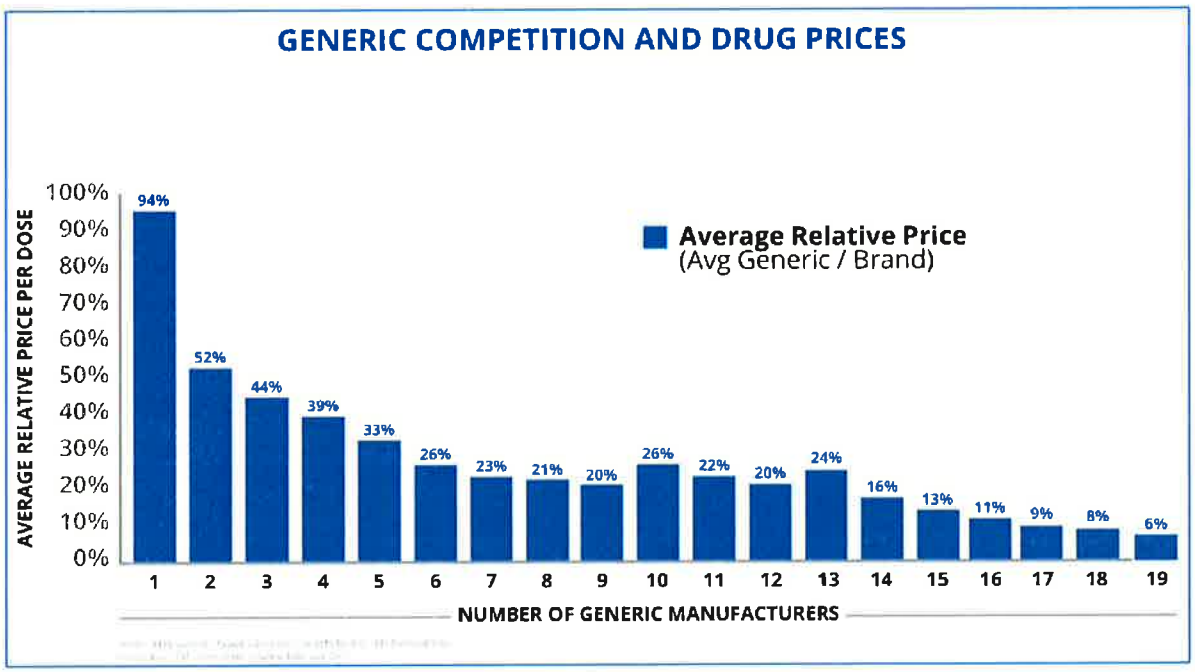
[14] "Prescription Medicines: Cost in Context," PhRMA, August 2016 at http://www.phrma.org/sites/default/files/pdf/prescription-medicines-costs-in-context-extended.pdf

[15] Source: Pharmaceutical Research and Manufacturers of America

Generic Drug Price

Generic drug manufacturers set prices primarily based on two factors: production costs and competition. This is due to the fact that generic companies do not have to bear the burden of research and development costs. Generic drugs also benefit from the fact that a brand name manufacturer has already created a marketplace for the drug. The price of the initial generic drug is near that of the original brand drug, but decreases over time. An FDA analysis of retail sales data between 1999 and 2004 indicated that generic drug prices dropped as generic manufacturers entered into the market, dropping significantly with just three or more generic manufacturers (Exhibit 3).[16] Seen another way, Exhibit 4 shows how the WAC and AWP discounts increase as the number of labelers increases.

Exhibit 3: Generic Competition and Drug Prices[17]



Source: Assistant Secretary for Planning and Evaluation

Exhibit 4: Draft Aggregate Discounts: Generic Legend Drug Groups by Rebating Labeler Count[18]

Draft Aggregate Discounts: Generic Legend Drug Groups by Rebating Labeler Count		
Count of Labelers per Drug Group	Generic Legend Drugs	
	WAC Median	AWP Median
1	-6.0%	-28.9%
2	-14.7%	-36.6%

[16] Office of the Assistant Secretary for Planning and Evaluation Issue Brief, "Expanding the Use of Generic Drugs, "December 1, 2010.

[17] Source: Assistant Secretary for Planning and Evaluation

[18] "State Reimbursement Requirements Webinar, April 28, 2016, CMS Division of Pharmacy

Draft Aggregate Discounts: Generic Legend Drug Groups by Rebating Labeler Count		
Count of Labelers per Drug Group	Generic Legend Drugs	
	WAC Median	AWP Median
3	-20.2%	-43.8%
4	-28.6%	-51.9%
5	-34.5%	-63.2%
6	-43.8%	-73.8%
7	-43.2%	-79.8%
8	-49.2%	-83.8%
9	-48.1%	-88.6%
10	-55.7%	-94.7%
11 or more	-62.2%	-96.8%

Source: Centers for Medicare & Medicaid Services

According to the Generic Pharmaceutical Association (GPhA), 88 percent of all prescriptions in the United States are for generic drugs, accounting for approximately 28 percent of national drug costs.[19] GPhA also notes that generic drugs saved $254 billion in health system costs in 2014, and it anticipates increased savings as new generics are introduced onto the market.

Despite this, the price of generic drugs is significantly increasing. Some of these increases are significantly more than can be explained by increased production costs. The following conclusions are based on a study of 4,421 generic drug groups and their prices from November 13, 2013 to November 13, 2014[20] :

- 222 drug groups increased in price by more than 100%;
- 90 drug groups increased in price by more than 200%;
- 25 drug groups increased in price by more than 500%; and
- 17 drug groups increased in price by more than 1,000%.

Some of the reasons identified for the increases in price by generic manufacturers include the following:

Industry consolidation – Consolidations have reduced the number of manufacturers producing older and less-profitable products. An example of consolidation is the 2012 Watson Pharmaceuticals merger with Actavis under the Actavis name. Actavis then bought Allergan in 2014. In 2015, Teva (after its failed bid to purchase Mylan) purchased Actavis (now the generic arm of Allergan). Teva is now the generic drug market share leader in the United States.

Price competition – When the number of generic manufactures becomes large, the increased competition causes some to leave the market, which reduces the downward pressure on prices.

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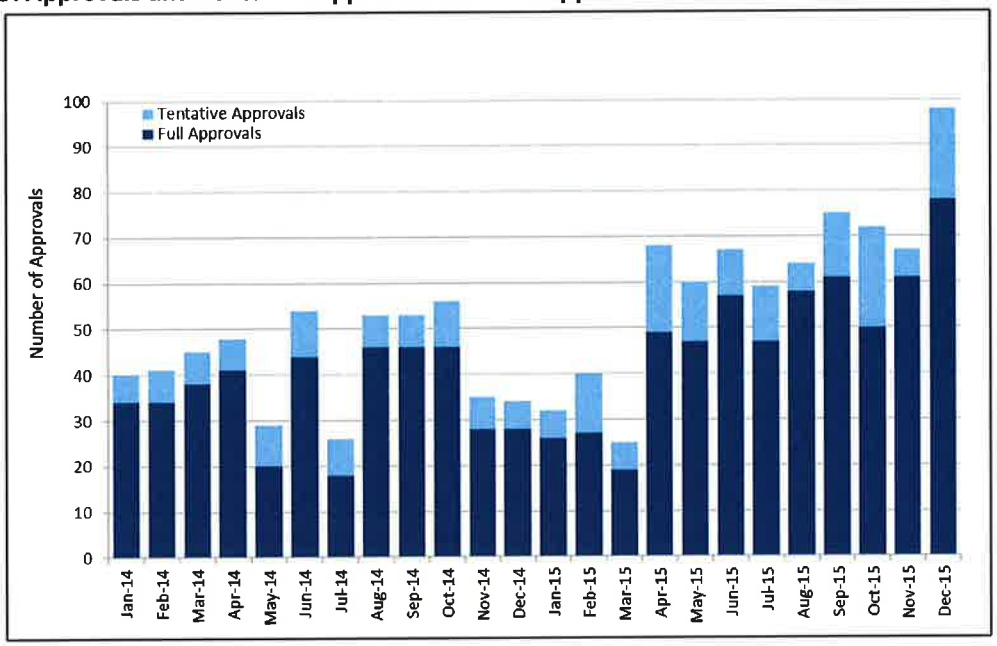
[19] "Generic Drug Savings in the U.S.", Seventh Edition: 2015, GPhA at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf

[20] Analysis by Todd Grover (Glass Box Analytics), as reported in "Generic Drug Price Increases: Causes and Impact," Elsevier Clinical Solutions at https://www.elsevier.com/clinical-solutions/insights/resources/insights-articles/drug-information/whitepapers/whitepaperrising-generic-drug-prices/wpgeneric-drug-prices-form?sq_content_src=%2BdXJsPWh0dHAlM0ElMkYlMkZlbHNjc2Zvcm1zLmNvbSUyRmdlbmVyaWMtZHJ1Zy1wcmljZS1pbmNyZWFzZXMtY2F1c2VzLWFuZC1pbXBhY3QmYWxsPTE%3D

Drug shortages – A lack of raw materials, other manufacturing problems, and declining demand and can lead to limited numbers of manufacturers producing a specific generic drug. This lack of competition (like consolidation) can induce manufacturers to increase prices

Slow FDA ANDA approvals – There has been a backlog of ANDA applications at the FDA. In her testimony before the U.S. House Committee on Oversight and Government Reform, Janet Woodcock, M.D. (Director of the Center for Drug Evaluation and Research), indicated that the FDA would accelerate ANDA reviews with the influx of new staff. The chart (Exhibit 5) provided in her testimony provides supporting evidence.[21]

Exhibit 5: Approvals and Tentative Approvals of ANDA Applications[22]



Source: FDA, CDER

When there is little or no competition, an environment for higher drug prices (especially among generics) is created. Generic companies stop making older, less-used medications due to the lack of profitability, creating the possibility that the remaining one or two manufacturers could establish a monopolistic pricing structure. As recently as November 2016, the United States Department of Justice considered filing criminal charges against several generic drug manufactures for collusion.[23] Price increases impact costs within the entire healthcare market.

[21] Testimony of Janet Woodcock, M.D. at https://oversight.house.gov/wp-content/uploads/2016/02/Woodcock-FDA-Statement-1-26-Prescription-Drugs.pdf

[22] Source: Federal Drug Administration and Center for Drug Evaluation and Research

[23] http://www.wsj.com/articles/generic-drug-makers-shares-drop-on-report-of-possible-probe-1478209036

Manufacturer Wholesaler Interaction

Manufacturers of prescription drugs, both brand and generic, ship their products to primary distributors (e.g. traditional wholesalers), for distribution to pharmacies and other healthcare providers. Approximately 90% of all prescription drug sales are handled through primary distributors.[24] This means only 10% of all drug sales are shipped directly to providers. Approximately 80% of sales go through traditional wholesalers, with 16% (12.8% of all drugs sales) of traditional wholesale drug sales going to independent pharmacies and 45% (36% of all drug sales) going to chain pharmacies (either directly or through the chain's central distribution center).[25] The remaining 39% (31% of all drug sales) is distributed to hospitals, doctors and clinics. Chain warehouses act as centralized distribution points for the chain.

It is important to note that while there may be dozens of drug wholesalers, three companies generate as much as 90% of all drug distribution revenues in the U.S (Exhibit 6).[26]

Exhibit 6: Drug Wholesaler U.S. Revenues

Wholesaler	2015 U.S. Revenues	% Increase from previous year
AmerisourceBergen	$132 billion	12.0%
Cardinal Health	$92 billion	19.5%
McKesson Corporation	$141 billion	16.4%
BIG THREE TOTAL	**$365 billion**	**15.5%**

Source: Pembroke Consulting, Inc. and Drug Channels Institute

When establishing a distribution relationship, each manufacturer enters into agreements related to the purchase and sale of the manufacturer's drug. In the past, wholesalers relied on the "buy-and-hold" model of drug reselling. The wholesaler would invest in drug inventory, with the expectation that drug prices would rise before the drugs were resold. Wholesalers were making about 50% of their profit from investment buying. In this model, manufacturers lost the profit made available through price inflation.[27] If the wholesaler knew that a manufacturer increased its price by 10 percent annually, then purchasing drugs prior to the increase in order to sell after the increase would allow the wholesaler to make not only the amount it normally would have, but to also gain the net profit from the price increase.

For example, a drug has a WAC (list) price of $100 and the wholesaler buys it for $90 (WAC – 10%) and sells it to a pharmacy for $98 (WAC – 2%). If the wholesaler has inventory at the $90 price when the manufacturer increases WAC to $110, then it can sell to the pharmacy at the new WAC – 2% price of $107.80, increasing its profit from $8 ($98 minus $90) to $17.80 ($107.80 minus $90).

The move away from buy-and-hold was largely prompted by a 2004 settlement between the federal Securities and Exchange Commission (SEC) and Bristol-Myers Squibb (BMS). BMS was accused of

[24] Perry Fri presentation to HDMA, "Understanding the Pharmaceutical Supply Chain", July 22, 2015
[25] Perry Fri presentation to HDMA, "Understanding the Pharmaceutical Supply Chain", July 22, 2015
[26] Fein, AJ, "The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies," Pembroke Consulting, Inc., and Drug Channels Institute, January 2016.
[27] Iacocca, K & Zhao, Y; Resell vs. Direct Models: US Branded Drug Distribution in the Future; PharmExec.com, July 17, 2105

perpetrating "a fraudulent earnings management scheme by, among other things, selling excessive amounts of pharmaceutical products to its wholesalers ahead of demand."[28] BMS used this scheme to inflate sales and earnings figures in order to create the appearance that the company had met or exceeded sales and earnings targets and Wall Street analysts' earnings estimates. As part of the settlement, BMS agreed to base the amount of drug sold to wholesalers on demand levels.

With the inability to profit from inflated prices on drugs held within their inventory, wholesalers sought to replace the lost revenue and moved to "fee-for-service" or "distribution service agreements" with manufacturers. In general, these agreements have various performance goals that the wholesaler has to meet. Agreement fees are calculated as a percentage of the drug's list price, allowing the wholesaler's fee to increase whenever a manufacturer increases a drug's list price (typically indexed to the WAC price).[29]

The wholesaler could theoretically profit by selling drugs at the new price if purchased under the old price.[30] However, larger manufacturers have begun to include recapture clauses within the distribution service agreement. These recapture agreements essentially increase the cost of existing wholesaler inventory to the new price.

Historically, generic drugs have been more profitable for wholesalers based on the ability to bargain within a crowded generic market. For example, while only 9% of the revenue for the three largest wholesalers was generated by generic drugs, those same generic drugs generated 56% of the wholesalers' gross profits (Exhibit 7).[31] Fein notes this is due to the enhanced bargaining position wholesalers have with generic manufacturers, requiring generic manufacturers to offer significant price concessions with large wholesalers.

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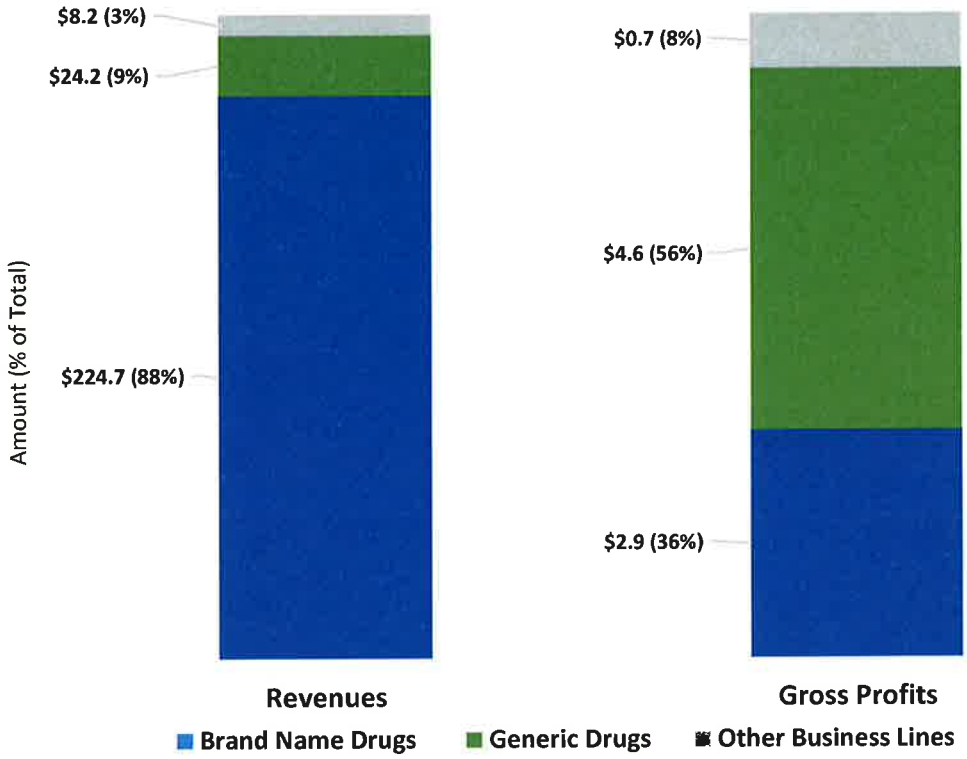
[28] SEC Press Release, August 4, 2004; Bristol-Myers Squibb Company Agrees to Pay $150 Million to Settler Fraud Charges
[29] How Wholesalers Profit from Brand-Name Drug Inflation (But Perhaps Not As Much As You Think), Drug Channels, October 22, 2015.
[30] IBID
[31] "Wholesaler Profits: Brand vs. Generic Drugs", Drug Channels, June 2010.

Exhibit 7: Big Three Wholesaler Revenues and Gross Profits[32]



Manufacturer/Pharmacy and Wholesaler/Pharmacy Interaction

As previously noted, the majority of prescription drug sales occurs through traditional wholesaler distribution channels, with independent pharmacies accounting for 16% of sales and chain stores accounting for 45%. Pharmacies purchase drugs from wholesalers based on discounts calculated off of a drug's WAC price. The percentage discount afforded a pharmacy is typically based on the volume of purchasing and/or any discounts the pharmacy may have negotiated with a manufacturer.

In its Issue Brief, "Paying for Prescribed Drugs in Medicaid: Current Policy and Upcoming Changes,"[33] the Kaiser Family Foundation compared the acquisition costs using NADAC of both brand and generic drugs to AWP and WAC prices. Their study showed that on average, the NADAC price was only slightly lower than WAC for single source (1.35%) and for multi-source brand drugs (1.81%) (Exhibit 8).

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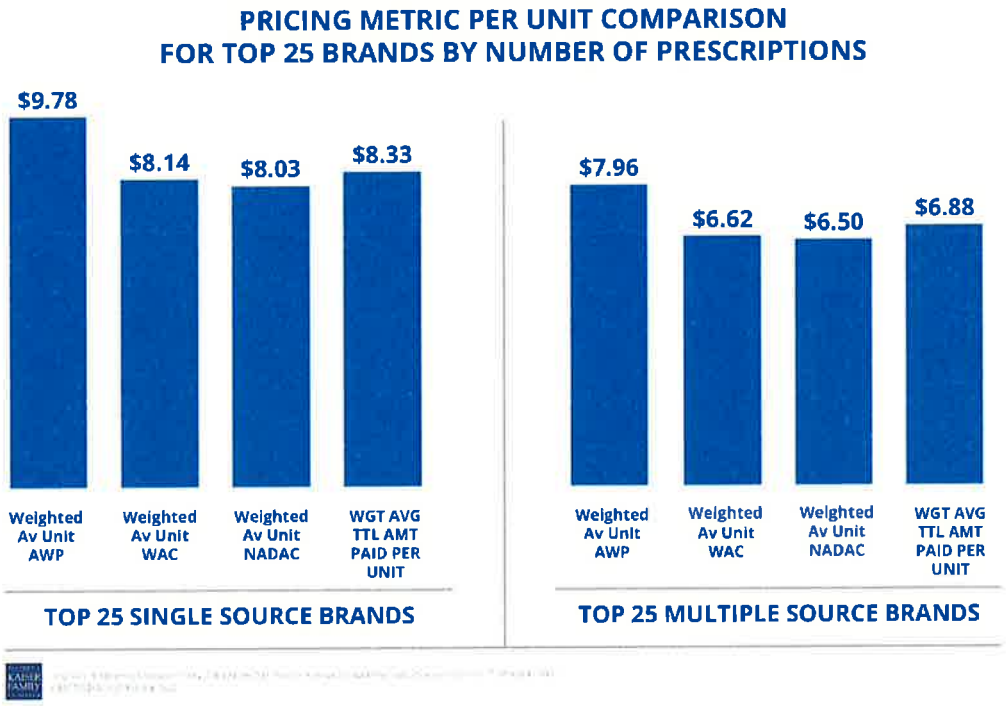
[32] Source Drug Channels: "Wholesaler Profits: Brand vs. Generic Drugs," June 2010

[33] Bruen, B & Young, K, Paying for Prescribed Drugs in Medicaid: Current Policy and Upcoming Changes, The Kaiser Commission on Medicaid and the Uninsured, May 2014 Issue Brief

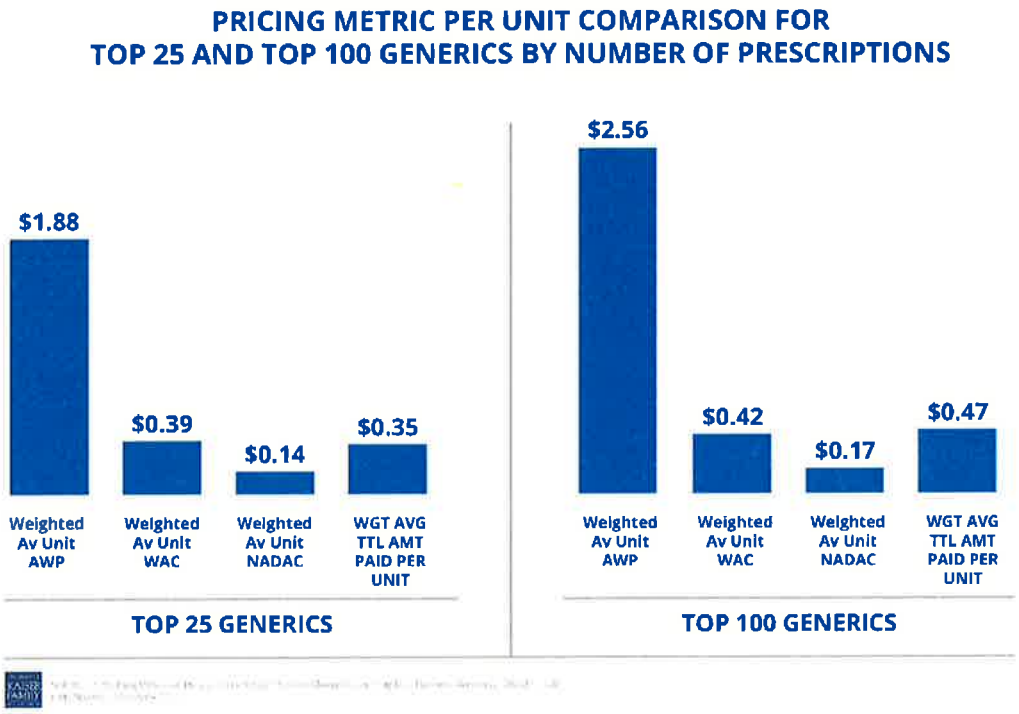
For generic drugs the Kaiser Issue Brief found that there was a significant difference between AWP and the NADAC price, with the difference between NADAC and WAC being much closer. The NADAC average for the top 25 generic drugs was 64% lower than WAC, and for the top 100 drugs, it was 53% lower than WAC (Exhibit 9). The break-out of generics into therapeutic classes shows significant variance, "ranging from 11% less than WAC for the eye, ear, nose, and throat preparations class to 73% less than WAC for the gastrointestinal drugs class."[34]

Exhibit 8: Per Unit Comparison for Top 25 Brand Drugs



[34] IBID

Exhibit 9: Per Unit Comparison for Top 25 Generic Drugs



Source: Kaiser Family Foundation

According to pharmacies interviewed for this report, a significant topic of interaction with drug wholesalers is the minimum purchase requirement language within their agreements. For example, a pharmacy may be required to purchase at least $50,000 in drugs on a monthly basis in order to obtain better discount purchase prices. These purchase minimums play a significant role in a small volume pharmacy's ability to shop around for the best price. National Community Pharmacists Association (NCPA) notes the average annual sales per pharmacy is approximately $3.6 million.[35] According to some independent pharmacies, the inability to shop for the best price can have a significant impact on the pharmacies' profitability when reimbursement is lower than the purchase price of the drug.

Group Purchasing Organizations (GPO)

Independent pharmacies improve their buying power by joining together as a group, generally referred to as Group Purchasing Organizations (GPO). As a GPO member, pharmacies can take advantage of the fact that:

- GPOs aggregate purchasing power to obtain discounts and rebates from manufacturers;
- GPOs facilitate product comparison analysis; and
- GPOs streamline and standardize the purchasing process.

[35] NCPA 2015 Digest, at http://www.ncpa.co/pdf/aaaa-2015-digest-sponsored-by-cardinal-health.pdf

Due to their already large purchasing volume, local and national chain pharmacies may not need to utilize a GPO, opting instead to contract directly with wholesalers, or in some instances, to purchase directly from a manufacturer.

According to some pharmacy informants, another problem is that the high price of specialty drugs makes it impossible for them to stock and dispense those products. Small volume pharmacies may not have the cash flow or credit lines to enable them to purchase and hold high-cost drugs. For example, a small pharmacy with a $40,000 credit line would not be able to purchase $70,000 worth of Hepatitis C drugs to dispense. According to pharmacies, this is compounded by the fact that wholesalers are seeking payment from pharmacies over shorter timeframes as a condition for qualifying for a discount. One pharmacy informant reported payment was required within a week rather than the more common 30 days. There are further complications due to the delay in payment by PBMs and other insurers. PBMs generally pay every two weeks; thus a pharmacy must pay the wholesaler at least a week prior to getting reimbursement from the PBM.

The results of the pharmacy interviews show that only large chain pharmacies can bargain effectively with manufactures. Small independent pharmacies indicate that they do not have the volume to elicit significant discount or rebate contracts from manufacturers.

Pharmacy Benefit Managers

On the "reimbursement" side of the supply chain, there are companies known as Pharmacy Benefit Managers (PBMs). PBMs administer the prescription drug benefit for a variety of third-party payers (e.g., self-insured employers, insurance companies, and HMOs). PBMs administer drug plans for more than 266 million Americans.[36] The top three PBMs, nationally, (Express Scripts, CVS Health, and OptumRx) process 73 percent of all prescription claims; 96 percent of national claims are processed by the top six PBMs.[37]

PBMs are accountable to payers as customers of their services. Third-party payers contract with PBMs to process and pay prescription drug claims submitted by network pharmacies. PBMs contract with a pharmacy network to dispense prescriptions. Much of the value that PBMs bring to their customers is balancing the need to provide adequate network access with providing drugs at the lowest cost. PBMs also obtain discounts (i.e., rebates) to help lower the cost of drugs for payer health plans. In addition to claims adjudication and pharmacy payment, PBMs handle a variety of services for third-party payers, including formulary management, and increasingly, administering clinical programs to improve medication adherence. Many PBMs have sophisticated fraud waste and abuse programs.

PBMs establish their own Pharmacy and Therapeutics (P&T) Committees which recommend how drugs should be covered and which drugs appear on the plan preferred drug list (formulary). Formularies are typically divided into "tiers," with each tier tied to different cost sharing responsibilities for an enrollee in a particular plan. In 2005, approximately 70% of employer-sponsored plans utilized a three-tier

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[36] About PCMA, Pharmaceutical Care Management Association, at http://www.pcmanet.org/about-pcma/about-pcma
[37] Fein, AJ, "The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies," Pembroke Consulting, Inc., and Drug Channels Institute, January 2016.

design, and only 4% used four or more tiers. In 2015, the three-tier design percentage fell to 58% while plans using four or more tiers rose to 23%.[38]

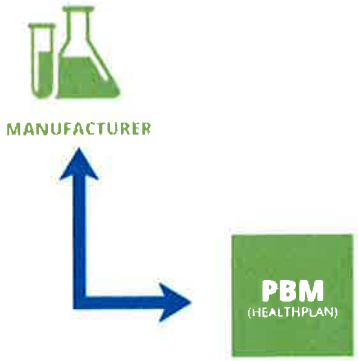
The first and lowest copay tier typically applies to generic drugs. Since generic drugs are less costly, the PBM requires a lower copay to encourage enrollees to utilize a generic drug whenever possible. This helps push generic drug utilization toward 90% of total prescription volume, thus making generic drug reimbursement an important financial factor for network pharmacies. The higher generic volume puts less emphasis on drug rebates or discounts that might be obtained for brand name drugs. Generics can be on a higher tier when the brand drug is lower cost.

PBMs are compensated by payers through two different pricing models: spread pricing and pass-through pricing. Payer clients decide which model will be used in their contracts with PBMs based upon how much risk the payer wants to assume. Under spread pricing the PBM guarantees that reimbursement of network pharmacies will not exceed a predetermined level. The majority of the risk lies with the PBM to meet the guarantee.[39] The PBM then retains the difference between the guaranteed rate and what it actually reimburses network pharmacies. In the pass-through model, the PBM passes everything (reimbursement costs, drug rebates, etc.) through to the plan and is in turn, paid an administrative fee for services rendered by the PBM. In the pass-through model, the payer assumes the majority of the risk.

Spread pricing reduces the plan's risk because the rates are guaranteed, forcing the PBM to absorb any loss when a pharmacy rate is higher than the guaranteed rate. The potential for lost revenue incentivizes the PBM to negotiate lower rates with its pharmacy network and encourages the PBM to structure drug coverage to promote lower-cost (i.e., generic) drugs. Because the PBM is earning revenue via the spread, administrative fees are often lower or eliminated. Payers typically scrutinize PBMs closely to confirm that the PBM is adhering to its guaranteed rates, rebates, and other contractual requirements.

Pass-through pricing does provide for more transparency for the plan, but also increases the risk to the plan by making it absorb the impact of manufacture price increases.

Manufacturer PBM/Plan Interaction



The primary interaction that a PBM has with a manufacturer is in the development of plan formularies and the ability to elicit drug rebates from the manufacturer to establish the manufacturer's drug as a preferred second-tier drug at a lower copayment for plan enrollees. First-tier drugs are almost exclusively multiple source generic drugs. Some single or limited source generic drugs may be placed in either the first or second tier depending on product cost.

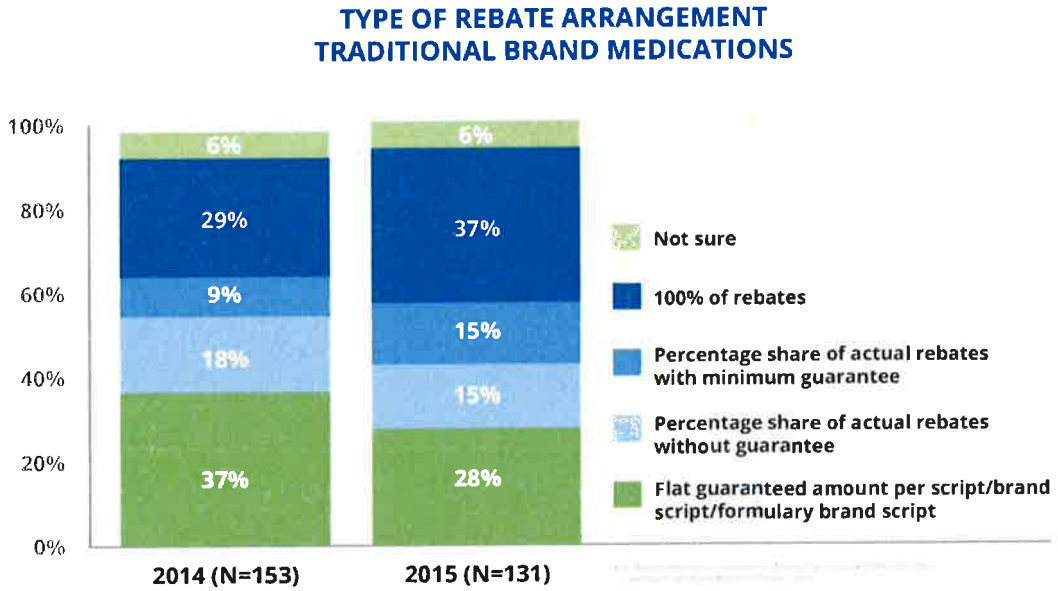
A PBM lowers plan costs by engaging in drug rebate negotiations with brand name drug manufacturers. The amount of cost reduction is dependent on the type of agreement the plan has with the PBM. A PBM may pass 100% of negotiated rebates to the plan, provide a guaranteed amount per prescription, or share a preset amount without any specific guarantee. A survey of employer-based plans revealed

[38] IBID

[39] In this instance risk means fluctuating drug prices which can increase costs.

that 37% of the rebate arrangements in 2015 passed 100% of the rebate through to the plan (Exhibit 10).[40]

Exhibit 10: Type of Rebate Arrangements

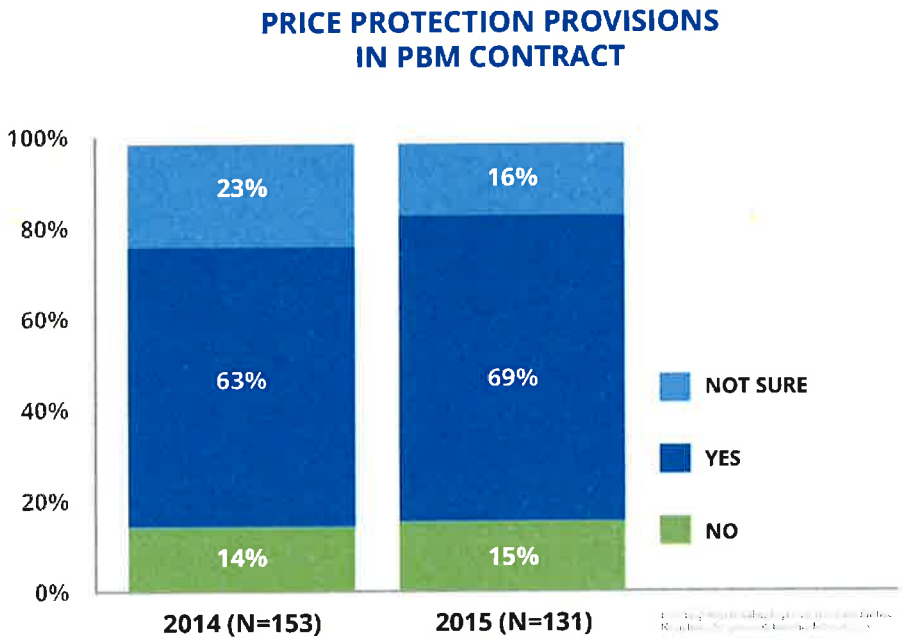


Source: Pharmacy Benefit Management Institute

Some PBMs, in an attempt to protect against clients from inflationary prices, have begun to include price cap guarantees within their contracts with manufacturers, setting a cap on the amount that a manufacturer can increase the cost of a drug. According to Pharmacy Benefit Management Institute (Exhibit 11) only 15% of the responding employer plans have price caps in place.[41]

[40] "2015-2016 Prescription Drug Benefit Cost and Plan Design Report," Pharmacy Benefit Management Institute, 2015
[41] IBID

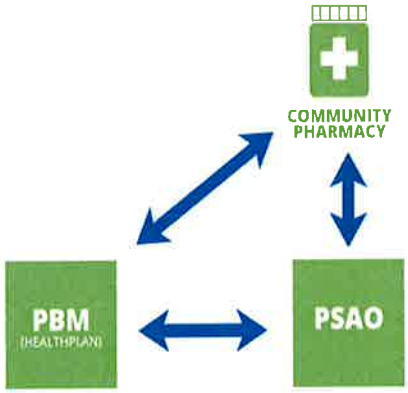
Exhibit 11: Price Protection Provisions in PBM Contracts



Source: Pharmacy Benefit Management Institute

Manufacturers may provide other discounts through the monetary support of clinical programs established by the PBM; however, the amount of support and rebates provided to PBMs and plans is limited by Medicaid Best Price requirements.

Pharmacy, PSAO, and PBM Interactions



Pharmacies profitability is most affected by their relationships with PBMs. As previously noted, the top six PBMs process 96% of all prescription drug claims; therefore, the ability of a pharmacy to cover its costs for goods (drugs) and dispensing is primarily dependent on the reimbursements from PBMs.

PBMs establish networks of pharmacies to meet the access requirements for the health plans they service. These network pharmacies sign contracts agreeing to various network requirements of the PBM. Within these contracts the PBM establishes the reimbursement calculation for brand name and generic drugs.

PSAO/Pharmacy Relationship

Large pharmacy chains have the ability to negotiate with PBMs directly. Small independent pharmacies, on the other hand, have to improve their negotiating influence by participating with other pharmacies in PSAOs. PSAOs can provide important services to the small pharmacy such as PBM relations, contracting, financial intermediary, and other business support activities. The PSAO also acts on behalf of the pharmacies to monitor PBM contract compliance and to submit appeals for reimbursement disputes.

The largest PSAOs 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

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[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

justified because of the increasing amounts of discounts that must be provided to pharmacies and payers. The increase maintains Mylan's EpiPen income at a level that is internally determined to be necessary for the company's business needs.

Exhibit 12 shows Mylan's view of the supply chain, in which they set a list price of $608 and then provide $334 in total price concessions to supply chain partners. The amount of concessions each entity receives is unknown; however, it likely varies considerably within each group. For example, a large chain with high volume may receive larger price concessions than an independent pharmacy. Exhibit 13 shows this in the context of this report's supply chain diagram (Exhibit 1).

Exhibit 12: Mylan Pharmaceuticals Description of Why EpiPen's Price Jumped

Source: Mylan Pharmaceuticals

Exhibit 13: The Money Flow for EpiPen in the Supply Chain

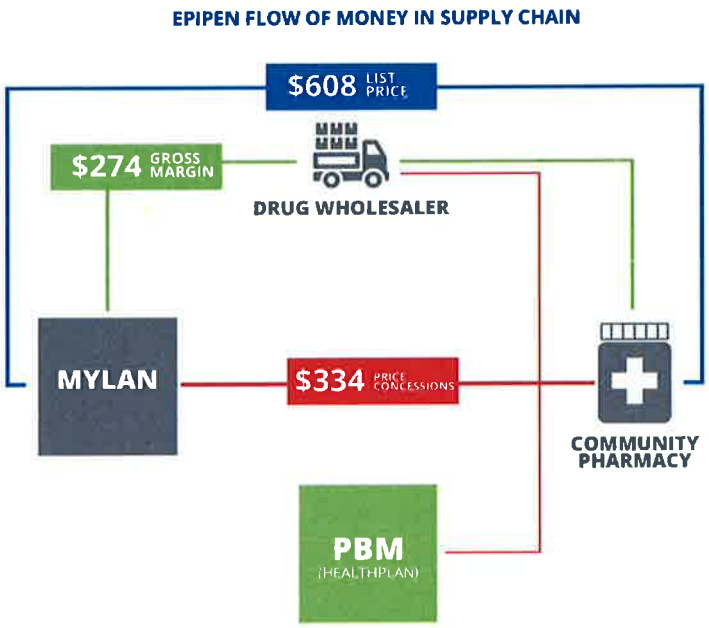

Exhibit 13 provides evidence that Mylan priced the drug in order to reach a specific per-unit revenue amount. The $608 is a list price, which Mylan controls—each of the listed entities do not directly increase the list price. The exhibit shows instead, the level of monetary incentives Mylan provides 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.

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[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.

Maximum Allowable Cost Reimbursement

Overview

The MAC list establishes the maximum price a PBM or other payer will reimburse a pharmacy provider for multi-source generics. MAC list reimbursement is designed to incentivize pharmacies to purchase the lowest-priced drugs for their inventories. PBM MAC lists are composed primarily of multi-source generic drugs, but they can also include brand drugs that have generic equivalents. Multiple manufacturers produce multi-source generic drugs, and they are each priced differently. The maximum price is somewhere in the middle of the range of the manufacturers' drugs prices to provide flexibility to accommodate fluctuations in pricing and drug availability. MAC lists are designed to provide reimbursement to pharmacies to cover at least their drug acquisition cost in aggregate. This means some drugs will be over-reimbursed and other drugs will be under-reimbursed. A key question that this Study addresses in this section is whether PBM MAC lists in the state of Washington are fairly designed.

MAC lists vary in breadth (number of drugs included) and depth (level of discount) across PBMs and even within the multiple MAC lists maintained by a PBM. The specific drugs included on a MAC list can vary widely among PBMs as well. The variation reflects different variables including, but not limited to, the timing of MAC list creation and updates, the PBM's preferred drugs, and their reimbursement methodology. It is clear that the MAC lists reflect individual PBM approaches to pharmacy reimbursement.

An analysis was conducted of the six PBMs' generic MAC list claims for calendar year 2015. In 2015, the PBMs reimbursed pharmacies over $500 million for generic drugs on MAC lists. Using claims information, HMA and its subcontractor compared PBM MAC lists and PBM provider reimbursement for ingredient costs to regional and national generic drug acquisition benchmarks. The analysis included the following components:

- Number of drugs included on the PBM MAC lists compared to national and regional benchmarks;
- Depth of PBM MAC lists' WAC discounts compared to national and regional benchmark;
- Differences in regional (urban/suburban/rural) reimbursement;
- Difference in type of pharmacy class (chain/independent/institutional/clinic) reimbursement; and
- Difference in chain status (chain/independent/PSAO reimbursement.

It is important to note that this report is not a financial audit but rather a data review and description of the Study findings.

Key Findings

- The number of drugs included on PBM MAC lists varied significantly across PBMs.
- Aggregate PBM Wholesale Acquisition Cost (WAC) discounts ranged from -27.0% to -43.5%; regional benchmarks and NADAC WAC discounts ranged from -38.3% to -42.1%
- In general, PBM MAC lists resulted in payments to pharmacies that were higher than what they would have received if the NADAC were used to determine payment, and lower than what they would have received under regional benchmark MAC lists.

- The higher NADAC reimbursement rate is attributable to the fact that NADAC is an average acquisition cost benchmark whereas MAC lists are designed to reimburse pharmacies slightly more than the lowest available acquisition cost for a drug. This incentivizes the purchase of the least costly generic manufacturer's product.
- PBM 3 paid rural pharmacies lower reimbursement than all benchmarks; PBM 5 and 6 paid more.
- All but PBM 2 paid independent pharmacies more than chain drug stores in the NADAC analysis.
- PBMs in aggregate paid over 73% of claims to chain pharmacies. Within chain pharmacies there were significant PBM reimbursement variance swings depending on which benchmark (national or regional) the PBM reimbursement is compared to.

Method

PBM data

OIC requested detailed data from the six PBMs. The complete data request can be found in Appendix I. The request included the following:

Pharmacy paid claims data. Since a claim is generated for each drug sale, the claims data for PBM payments to Washington pharmacies was requested to make it possible to understand reimbursement rates to Washington pharmacies for the period January 1, 2015, through December 31, 2015. Claims data have a tremendous amount of detail on the prescriber, drug, patient, and payer. Elements of the data are enumerated in Exhibit 14 below:

Exhibit 14. Claims Data Requested from PBMs

+ Adjudicated date	+ Amount pharmacy billed
+ Amount pharmacy paid	+ AWP unit cost
+ Basis of cost paid (i.e. AWP, MAC, U&C etc.)	+ Carrier number or other number to indicate Fully insured, Medicaid, and Medicare client
+ Compound code	+ Copay
+ Date of service	+ DAW (dispense as written)
+ Days supply	+ Deductible (if applicable)
+ Dispensing fee	+ Drug indicator (generic, single-source, multi-source)
+ Drug name	+ Formulary indicator
+ GCN or GPI	+ Media (POS/mail/paper)
+ Metric decimal quantity	+ NDC
+ PBM reimbursement unit cost (i.e., MAC unit cost, AWP unit cost, other)	+ Pharmacy chain status (independent, chain)
+ Pharmacy class (pharmacy, mail-order, nursing home)	+ Pharmacy demographic (rural, urban, suburban)
+ Pharmacy ID # (NCPDP, NPI)	+ Pharmacy paid ingredient cost
+ Sales tax (if applicable)	+ Transaction status
+ Usual & customary charge	

MAC Lists. As described in the overview section, the MAC list is a list of multi-source generics that shows the maximum reimbursement for each drug on the list. The data request called for all MAC lists that a

PBM used to pay pharmacy claims from the period January 1, 2015 thru December 31, 2015. The information included effective and termination dates for drugs found on the MAC lists.

MAC List Policies. Policies relating to the construction of MAC list(s) during the same period were also requested. The information should have included frequency of review and update, number of off-cycle updates during the period, and triggers for an off-cycle update.

Ideally, to measure pharmacy profitability, the Study would have benefitted from actual pharmacy drug acquisition cost information to compare those costs to PBM reimbursement. Unfortunately, acquisition cost data specific to Washington pharmacies was not available for this Study. Acquiring actual acquisitions cost data would require reviewing pharmacy drug invoices from each pharmacy provider. Collecting this information was beyond the scope of the Study. Instead, we national and regional acquisition cost benchmarks were proxies for Washington State pharmacy provider drug acquisition costs. NADAC was selected for the national benchmark and two Medicaid MAC lists were selected for the regional benchmark lists.

CMS calculates and publishes the NADAC price list monthly based upon a national survey of retail community drug acquisition costs. The costs are averaged and updated on a weekly basis based on manufacturer price changes and provider inquiries. The NADAC price list is considered the national standard for estimating drug acquisition costs and it serves as the basis of estimated acquisition costs for the analysis presented in the Study.

Since the NADAC price list is based on provider surveys across the nation, two regional MAC lists were included to provide an added level of reimbursement analysis and benchmarking. Benchmark MAC list 1 was chosen for comparison because the region is similar to the makeup of eastern Washington (e.g., rural, independent pharmacy providers).[49] Benchmark MAC list 2 was chosen as a comparison state because the state makeup is similar to the demographics of the entire state of Washington, including urban areas such as King County.

Data limitations

When benchmark data sets did not include a price for a particular drug on a particular date, no variance was calculated.[50] The volume of excluded claims is discussed in the following pages.

Exhibit 15 details missing data by PBM and methods used for the Study to work around the missing fields when possible. Missing fields and indicators resulted in data limitations. The Study notes when data limitations impact the analysis.

[49] Although this was a regional benchmark MAC list, the entire state of Washington payments were compared, not just eastern Washington.

[50] All variances calculated represent a match between drug identifier (GCN) and date of service for the paid claim and effective date on the MAC and NADAC lists.

Exhibit 15: Missing data by PBM and Issue Resolution Where Possible

PBM Data Request	Missing Fields	Pharmacy Chain Status	Pharmacy Class	Pharmacy Demographic
PBM 1	Media, Pharmacy Demographic	Provided	Missing, applied class identifier from PBM 5 based on Pharmacy ID	Missing, applied demographic identifier from PBM 6 based on Pharmacy ID
PBM 2	Formulary Indicator, Pharmacy Chain Status, Pharmacy Class, Pharmacy Demographic	Missing, applied chain status identifier from PBM 6 based on Pharmacy ID	Missing, applied class identifier from PBM 5 based on Pharmacy ID	Missing, applied demographic identifier from PBM 6 based on Pharmacy ID
PBM 3	Pharmacy Chain Status, Pharmacy Class, Pharmacy Demographic	Missing, applied chain status identifier from PBM 6 based on Pharmacy ID	Missing, applied class identifier from PBM 5 based on Pharmacy ID	Missing, applied demographic identifier from PBM 6 based on Pharmacy ID
PBM 4	Copay, DAW, Media, Pharmacy Chain Status, Pharmacy Demographic	Missing, applied chain status identifier from PBM 6 based on Pharmacy ID	Provided	Missing, applied demographic identifier from PBM 6 based on Pharmacy ID
PBM 5	Pharmacy Demographic	Provided	Provided	Missing, applied demographic identifier from PBM 6 based on Pharmacy ID
PBM 6	Adjudicated Date, Basis of Cost Paid, Carrier Number, Compound Code, Copay, DAW, Days Supply, Deductible, Formulary Indicator, Media, NDC, PBM Reimbursement Unit Cost, Pharmacy Class, Sales Tax, Transaction Status	Provided	Missing, applied class identifier from PBM 5 based on Pharmacy ID	Provided

MAC Reimbursement Analysis

The analysis for this section is focused on ingredient cost reimbursement by PBMs. Exhibit 18 summarizes the number of claims paid in 2015 and the dollar value of MAC-reimbursed ingredient cost by PBM. PBM 6 didn't provide the Basis of Cost Paid field in its data file. Therefore, all generic claims, not just MAC-reimbursed claims, are included in PBM 6's data for this portion of the Study. The impact of having to use all of PBM 6's claims is minimal as analysis shows that PBMs 6's pricing variance magnitudes compared to the national and regional benchmarks are within the reasonable variance range of 10% or less of paid ingredient.

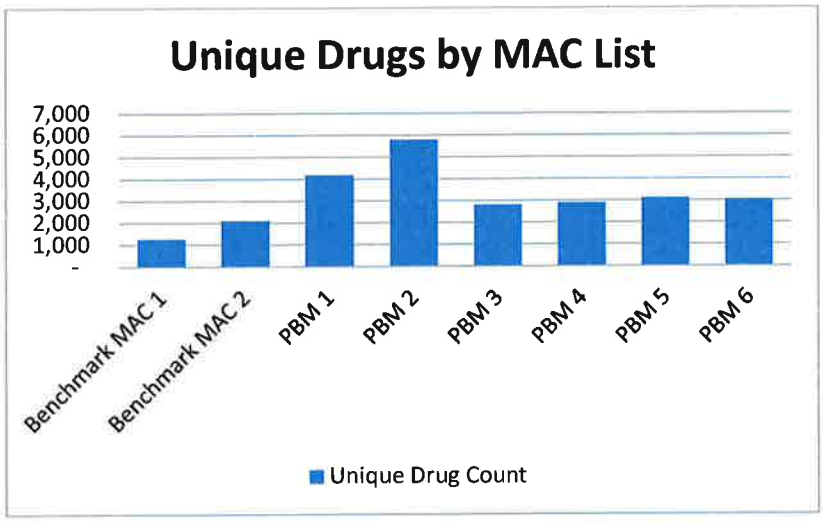
Analysis Findings

The following is a review of the data for five components for this section of the Study, followed by observations.

MAC list breadth analysis

The PBMs' MAC lists were compared to the benchmark regional MAC lists to determine variations in the number of drugs that PBMs included. Each of the PBMs maintained at least one MAC list of generic drug pricing that referenced thousands of individual drugs. Exhibit 16 shows the range of unique drugs on the PBM MAC lists. The range varied from a high of 5,801 individual drugs to a low of 2,814 drugs. Across the board, PBMs had far broader MAC lists than did the benchmarks.

Exhibit 16: Unique Drug Count by MAC List



The PBM MAC lists varied significantly from the benchmark MAC lists. PBM MAC lists were broader than the benchmark lists; for example, between 33% and 82% (1,885 – 4,757) of unique drugs listed on PBM MAC lists were missing from the benchmark MAC lists. The percentage of drugs found on benchmark MAC lists but not on PBM MAC lists ranged from 10% to 29% (292 – 499).

Regional Medicaid benchmark MAC lists used in this Study included a much narrower set of drugs and were typically designed to focus on setting MAC reimbursement rates for high-volume generic products that pharmacy providers frequently dispense rather than on all generic products. Medicaid MAC lists may not include a large variety of Over-the-Counter (OTC) or other products not covered by Medicaid programs.

The analysis revealed that PBMs are reimbursing pharmacies fairly for a large number of drugs, likely both high- and low-volume generics and OTC products. However, rates of reimbursement among PBMs for specific drugs varied widely. PBMs are able to implement different strategies by over- and under-paying on different drugs within their large MAC list portfolio to meet a variety of client guarantees.

MAC List Depth Analysis (WAC Discount)

The MAC list depth analysis compared the level of discounts PBMs applied to their reimbursement to publically available Wholesale Acquisition Cost (WAC) rates, a standard rate list. WAC rates are public information and comparing all of the PBM MAC lists and the benchmark pricing lists to WAC pricing provides a consistent baseline for reimbursement comparison The weighted WAC effective discount for this Study was calculated at the drug level by comparing the difference between the MAC or NADAC list rate to the WAC rate. Each rate was multiplied by the utilization from the largest three PBMs (PBM 3,

PBM 5 and PBM 6) and then the WAC discount was calculated by comparing the differences in aggregate of the total MAC/NADAC list dollars and the WAC dollars. It should be noted that this analysis was conducted for a singular point in time, specifically 07/01/2015, and is not representative of all of 2015.

Exhibit 17 shows the WAC effective discounts applied by the PBMs who participated in this study as well as the WAC effective discount for the regional benchmarks and NADAC list.

Exhibit 17: WAC Discount Analysis by PBM and Benchmark Lists

Weighted WAC Discount Analysis	
PBM	Weighted WAC Discount
PBM 1	-29.4%
PBM 2	-27.0%
PBM 3	-28.0%
PBM 4	-35.3%
PBM 5	-35.2%
PBM 6	-43.5%
Benchmark MAC 1	-38.3%
Benchmark MAC 2	-39.5%
NADAC	-42.1%

The WAC discounts ranged from WAC-27.0% (PBM 2) to WAC-43.5% (PBM 6). The NADAC (WAC-42.1%) and regional MAC list (WAC-38.3%, WAC-39.5%) benchmarks were at the high end of the overall PBM WAC effective discount range. Three of the six PBMs' (PBMs 4, 5, and 6) WAC effective discounts were within 3% of the three benchmark discounts; however, the other three PBMs' (PBM 1 – PBM 3) discounts are approximately 10% lower than the benchmarks. The range of PBM WAC effective discounts showed that there were significant differences in how PBMs approached MAC list reimbursements and that PBM MAC lists varied significantly. PBM 6's WAC effective discount was the most aggressive, but only marginally more aggressive than NADAC. PBM 2 had the lowest WAC effective discount.[51] The NADAC WAC effective discount was expected to be on the high end of the discount range because the NADAC list was based on actual acquisition costs submitted on provider invoices rather than on reimbursement to pharmacies, which in aggregate exceeded acquisition cost. The regional benchmarks included fewer drugs than the PBM MAC lists and NADAC, which was consistent with the fact that the regional benchmark MAC lists were built to provide reimbursement rates for highly utilized generic products, not every drug available in the market. Based on the weighted WAC discount analysis, the regional benchmark WAC effective discounts were not significantly different than NADAC and, were higher than five of the six PBM WAC effective discounts.

PBM Reimbursement Analysis: Overall

Similar to the MAC analysis results, the PBM reimbursement analysis revealed results that varied by PBM. Three PBMs (PBM 3, PBM 5, and PBM 6) represented over 87% of the total MAC-reimbursed generic drug spending in calendar year 2015. Although it is important to understand the discount

[51] PBM 2 included the largest number of unique drugs. PBM 2 MAC lists included a large number of low volume and OTC products on their MAC lists. There were data issues that may have also skewed this effective WAC rate.

variances across all PBMs, the variances of the three largest PBMs were typically less than those for PBM 1 and PBM 2.

Exhibit 18 compares PBM reimbursement to NADAC and the benchmark MAC reimbursement. A positive variance indicates that a PBM paid more to pharmacies than what it would have if it had used NADAC or other benchmark ingredient cost rates. Conversely, a negative variance indicates that a PBM paid less than it would have had it paid the benchmark rate.

Exhibit 18: PBM Generic MAC Data and Reimbursement Variances from NADAC Benchmark

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Total Washington State 2015 Paid Ingredient Cost (PIC): Generic MAC Claims	$45,394,459	$ 9,542,320	$132,439,516	$11,222,203	$107,102,259	$207,281,264
% of Total Washington State 2015 PIC: Generic MAC Claims	8.8%	1.9%	25.8%	2.2%	20.9%	40.4%
Total Number of 2015 Washington State Generic MAC Claims	2,046,704	870,145	7,944,045	517,573	5,100,258	10,612,916
% of Total Washington State 2015 Generic MAC Claims	7.6%	3.2%	29.3%	1.9%	18.8%	39.2%
Variance to NADAC	$6,100,260	$(518,866)	$6,667,203	$438,791	$10,599,002	$8,100,105
Variance to NADAC % of PIC	13.4%	(5.4)%	5.0%	3.9%	9.9%	3.9%
Variance to Benchmark MAC 1	$9,310,374	$(2,465,778)	$(8,969,654)	$(866,349)	$(192,364)	$(21,336,531)
Variance to Benchmark MAC 1 % PIC	20.5%	(25.8)%	(6.8)%	(7.7)%	(0.2)%	(10.3)%
Variance to Benchmark MAC 2	$10,966,741	$(2,993,369)	$(3,596,743)	$(998,197)	$4,755,296	$(18,546,424)
Variance to Benchmark MAC 2 % PIC	24.2%	(31.4)%	(2.7)%	(8.9)%	4.4%	(8.9)%

Observations

- All but one PBM (PBM 2) paid more than what they would have paid had they paid NADAC rates. The variance ranged from 3.9% higher to 13.4% higher.
- PBM 2's data is suspect because of misclassification of generic drugs. See discussion related to Exhibits 41 and 42.
- The variances moved from positive to negative when PBM MAC reimbursement was compared to the benchmark MAC lists, which means that the PBM paid less than it would have had it paid MAC 1 and MAC 2 rates. This is not surprising as the benchmark MAC Lists are Medicaid-

specific. As Exhibit 39 shows, pharmacy gross margin per prescription is higher for Medicaid than commercial payers.[52]

- Only one PBM (PBM1) paid more than what the MAC List 1 would have specified.
- Two of the six PBMs had positive variances compared to MAC List 2.
- The three largest PBMs' (PBM 3, PBM 5, and PBM 6) had a payment variance within a reasonable range[53] of each PBM's Paid Ingredient Cost.

Overall, most PBMs paid pharmacies more compared to NADAC, and less compared to the benchmark MAC lists. Because the NADAC's purpose is to reflect the actual acquisition cost paid by pharmacies, it is not surprising that the majority of the PBMs reimbursed pharmacies with rates greater than actual acquisition cost. The variance from the benchmark lists may be the result of the drugs found on each list and the potential limitations of the data.

PBM Reimbursement Analysis: Pharmacy Demographic

Washington's demographics varied significantly across the state. Though major urban areas exist (Seattle, Spokane, Tacoma), much of the state is rural. The goal of the Pharmacy Demographic analysis was to better understand differences in pharmacy reimbursement across three main demographic regions: urban, suburban and rural.[54]

Exhibit 19 shows how each PBM's total MAC paid ingredient costs break out between regional areas[55].

Exhibit 19: Proportion of PBM Paid Ingredient Costs, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	44.6%	50.3%	38.9%	55.8%	35.1%	23.4%
Suburban	15.3%	20.4%	22.1%	19.3%	17.3%	22.1%
Rural	39.7%	27.9%	37.5%	23.3%	44.5%	26.7%
Not Defined	0.4%	1.5%	1.5%	1.5%	3.0%	27.8%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Observations

- For most PBMs at least 76% of paid ingredient costs were paid in urban or rural areas. The remaining balance is represented by payments to suburban pharmacies and a very low amount of paid ingredient costs were paid to pharmacies with an undefined region.
- PBM 6 had a unique data set with almost 28% of its pharmacies labeled with the Not Defined descriptor.
- PBMs serving primarily King County (Seattle area) residents will likely have a higher proportion of claims paid to urban pharmacies.

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[52] Most of the PBMs couldn't separate Medicaid claims from fully insured claims; thus there are limitations in really understanding if there is a difference between Medicaid MAC reimbursement and fully insured reimbursement.
[53] Based on the analysis conducted a reasonable range is defined as +/- 10% of the Paid Ingredient Cost.
[54] PBM 6 was the only PBM to provide Pharmacy Demographic labels. HMA's subcontractor, Mercer, applied this label by Pharmacy ID to the other PBMs in order to maintain consistency for labeling purposes across PBMs.
[55] PBM Demographic determined based off how PBM 6 identified each pharmacy. PBM 6 was the only PBM to provide a demographic identifier so applying their demographic labels keeps the labels consistent throughout the analysis.

- Four PBMs accounted for a high percentage of payments made to pharmacies in the urban areas.
- PBM 5 and PBM 6 accounted for the majority of payments paid to rural pharmacies.
- The suburban pharmacies accounted for the lowest proportion of costs paid for all the PBMs.

As referenced in the overall PBM reimbursement analysis section, all but one PBM paid the Washington pharmacies more for ingredient costs than they would have had they paid NADAC rates. Exhibit 20 displays the dollar difference by PBM and by type of region.

Exhibit 20: PBM MAC Reimbursement Dollar Variance from NADAC Pricing, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	$2,728,556	$(360,323)	$2,848,997	$249,411	$3,568,311	$1,570,713
Suburban	$947,447	$(109,752)	$1,426,159	$61,876	$1,876,091	$1,584,310
Rural	$2,404,210	$ (54,527)	$2,418,277	$82,693	$4,887,067	$2,370,232
Not Defined	$20,047	$5,735	$ (26,230)	$44,811	$267,533	$2,574,850
Total	**$6,100,260**	**$(518,866)**	**$6,667,203**	**$438,791**	**$10,599,002**	**$8,100,105**

Exhibit 21 shows the percentage of paid ingredient cost for each pharmacy region and the variance between paid rate totals and NADAC rate totals.

Exhibit 21: PBM % of Paid Ingredient Cost Variance from NADAC Pricing, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	13.5%	-7.5%	5.5%	4.0%	9.5%	3.2%
Suburban	13.6%	-5.6%	4.9%	2.9%	10.1%	3.5%
Rural	13.3%	-2.0%	4.9%	3.2%	10.2%	4.3%
Not Defined	11.2%	4.1%	-1.3%	26.5%	8.2%	4.5%
Total	**13.4%**	**-5.4%**	**5.0%**	**3.9%**	**9.9%**	**3.9%**

Observations

- For most of the PBMs, the regional-specific variance percentages did not vary considerably from total variance percentage.
- The Demographic Groups variance was typically within one percentage point of the total variance percentage.
- The PBM with the lowest paid ingredient cost (PBM 2) had slightly more dramatic variation across regions.
- The number of drugs included on PBM MAC lists varied significantly across PBMs.
- Aggregate PBM Wholesale Acquisition Cost (WAC) discounts ranged from -27.0% to -43.5%; regional benchmarks and NADAC WAC discounts ranged from -38.3% to -42.1%
- In general, PBM MAC lists resulted in payments to pharmacies that were higher than they would have been had PBMs paid at NADAC rates, and lower than they would have been had they paid at regional benchmarks MAC list rates.
- The previous observation is explained by the fact that NADAC is an average acquisition cost benchmark, whereas MAC lists are designed to reimburse pharmacies more than the lowest available acquisition cost for a drug grouping.

- PBM 3 paid rural pharmacies at lower rates than all benchmarks, and PBM 5 and 6 paid more.
- All but PBM 2 paid independent pharmacies at higher rates than chain drug stores in the NADAC analysis.
- Exhibits 22 and 23 provide similar analyses as Exhibits 20 and 21 for PBM reimbursement to Benchmark MAC list 1.

Exhibit 22: PBM MAC Reimbursement Dollar Variance from Benchmark MAC 1 Pricing, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	$4,174,880	$(1,346,923)	$(2,377,802)	$(467,336)	$(209,870)	$(5,067,946)
Suburban	$1,493,860	$(518,566)	$(2,107,729)	$(199,786)	$(80,620)	$(4,683,997)
Rural	$3,612,232	$(619,518)	$(3,853,420)	$(240,964)	$167,927	$(5,435,213)
Not Defined	$29,402	$19,229	$ (630,703)	$41,736	$ (69,801)	$(6,149,375)
Total	**$9,310,374**	**$(2,465,778)**	**$(8,969,654)**	**$(866,349)**	**$(192,364)**	**$(21,336,531)**

Exhibit 23: PBM % of Paid Ingredient Cost Variance from Benchmark MAC 1 Pricing, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	20.6%	-28.1%	-4.6%	-7.5%	-0.6%	-10.5%
Suburban	21.5%	-26.7%	-7.2%	-9.2%	-0.4%	-10.2%
Rural	20.0%	-23.3%	-7.8%	-9.2%	0.4%	-9.8%
Not Defined	16.5%	13.7%	-31.6%	24.7%	-2.1%	-10.7%
Total	**20.5%**	**-25.8%**	**-6.8%**	**-7.7%**	**-0.2%**	**-10.3%**

Observations

- Regional specific variances were more extreme than the total variance.
- Only PBM 1's ingredient cost variance was positive compared to the benchmark MAC List 1.
- PBM 2, PBM 5 and PBM 6 paid the rural pharmacies more than other Demographic Groups.

Exhibits 24 and 25 are similar analyses for PBM MAC reimbursement, compared to the Benchmark MAC 2.

Exhibit 24: PBM MAC Reimbursement Dollar Variance from Benchmark MAC 2 Pricing, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	$ 4,842,174	$(1,679,579)	$(616,755)	$(568,308)	$1,617,615	$(4,116,508)
Suburban	$1,735,675	$(662,634)	$(750,632)	$(224,189)	$805,638	$(4,390,663)
Rural	$4,353,234	$(683,220)	$(1,788,473)	$(291,789)	$2,262,612	$(5,044,921)
Not Defined	$35,658	$32,065	$(440,883)	$86,089	$69,431	$(4,994,332)
Total	**$10,966,741**	**$(2,993,369)**	**$(3,596,743)**	**$(998,197)**	**$4,755,296**	**$(18,546,424)**

Exhibit 25: PBM % of Paid Ingredient Cost Variance to Benchmark MAC 2 Pricing, by Pharmacy Region

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Urban	23.9%	-35.0%	-1.2%	-9.1%	4.3%	-8.5%
Suburban	25.0%	-34.1%	-2.6%	-10.3%	4.4%	-9.6%
Rural	24.1%	-25.7%	-3.6%	-11.1%	4.7%	-9.1%
Not Defined	20.0%	22.8%	-22.1%	50.9%	2.1%	-8.7%
Total	**24.2%**	**-31.4%**	**-2.7%**	**-8.9%**	**4.4%**	**-8.9%**

Observations:

- Four of the six PBMs paid lower amounts to pharmacies than they would have had they paid according to benchmark MAC 2 pricing.
- PBM 1 and PBM 2 variances were significantly larger than for the other PBMs: +24.2% to -31.4% versus +4.4% to -8.9%.
- The variances for the benchmark MAC 2 were less than for benchmark MAC 1.
- Compared to benchmark MAC 1, the variances within demographic groups were much larger.

PBM Reimbursement Analysis: Pharmacy Class

The Pharmacy Class describes the type of pharmacy that the PBMs reimburse in Washington. Exhibit 26 shows that community/retail pharmacies accounted from 85.2% to 100% of PBM MAC-reimbursed dollars. Unsurprisingly, the majority of the remaining reimbursement went to long-term care pharmacies, clinical pharmacies, and institutional pharmacies. A similar detailed analysis as seen earlier in this report for Pharmacy Demographic and will be seen later in this report for Pharmacy Chain Status was prepared for Pharmacy Class, which can be referenced in the Appendix. Analyses are located in Appendix II for several reasons: only community/retail pharmacies are in this Study's scope, the findings are unremarkable, and reimbursement arrangements for the other types of pharmacies often differed from those for community/retail pharmacies.

Exhibit 26: Proportion of Paid Ingredient Cost Received by Different Pharmacy Types

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Community/Retail Pharmacy	85.2%	90.4%	93.1%	100.0%	89.8%	93.4%
Long Term Care Pharmacy	6.0%	6.7%	4.1%	0.0%	2.9%	2.4%
Clinic Pharmacy	7.3%	1.6%	1.3%	0.0%	1.9%	2.6%
Not Defined	0.0%	0.1%	0.2%	0.0%	0.0%	0.4%
Indian Health Service /Tribal/Urban (I/T/U)	0.1%	0.1%	0.2%	0.0%	0.3%	0.1%
Non-Pharmacy Dispensing Site	0.0%	0.0%	0.1%	0.0%	0.1%	0.1%
Military/ U.S. Coast Guard Pharmacy	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Durable Medical Equipment (DME)	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Managed Care Organization Pharmacy	0.0%	0.0%	0.2%	0.0%	1.0%	0.0%
Specialty Pharmacy	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Mail Order Pharmacy	0.0%	0.0%	0.2%	0.0%	3.4%	0.0%
Compounding Pharmacy	0.0%	0.1%	0.1%	0.0%	0.1%	0.1%
Department of Veterans Affairs (VA) Pharmacy	0.0%	0.0%	0.1%	0.0%	0.0%	0.1%
Institutional Pharmacy	1.3%	1.0%	0.6%	0.0%	0.4%	0.9%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

PBM Reimbursement Analysis: Pharmacy Chain Status

Pharmacy Chain Status is the third of the three detailed analyses performed for the Study. The Pharmacy Chain Status designated whether the pharmacy was a chain, an independent pharmacy, or a pharmacy that submitted claims through a PSAO. To determine the pharmacy chain status, HMA and its subcontractor relied on the information provided by each of the PBMs in their response to the data request. As with the pharmacy demographic comparison, the accuracy of the pharmacy chain status definitions by PBM depended on the accuracy of their self-reporting. Chains consisted of national chains that spanned the country or regional chains that had a small, or nonexistent, footprint outside the state of Washington. The Independent pharmacy designation included pharmacies labeled as independent by the PBMs. The PSAO analysis included payments made to pharmacies through administrative organizations that provided contract and payment efficiencies for both pharmacies and PBMs.

Chains represented the majority of the generic drug claims paid off of MAC lists in the state of Washington. Exhibit 27 shows that at least 70% of MAC claims are paid to chain pharmacies. The pharmacy chain status group accounted for the second largest proportion of paid claims varied by PBM. Half of the PBMs paid the second largest claims amount to independent pharmacies (PBM 1, PBM 3 and PBM 4) while the other half of the PBMs paid their second largest amount of claims to PSAOs/Associations (PBM 2, PBM 5 and PBM 6). The fact that Pharmacy Chain Status contracting mix varied by PBM should emphasize inconsistencies with PBM reporting on their contracts.

Exhibit 27: MAC Claims Paid Percentages by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	18.5%	7.9%	16.4%	2.5%	2.1%	7.0%
Chain	77.4%	74.1%	80.5%	97.5%	73.8%	73.4%
PSAO/ Association	4.1%	16.5%	3.0%	0.0%	23.9%	19.5%
Not Defined	0.0%	1.5%	0.0%	0.0%	0.2%	0.0%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Exhibits 28 and 29 compare PBM reimbursement to NADAC at a pharmacy chain status level.

Exhibit 28: PBM MAC Reimbursement Dollar Variance from NADAC Pricing –by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	$1,148,919	$41,899	$1,211,916	$48,302	$193,671	$685,896
Chain	$4,713,291	$(682,583)	$5,293,014	$390,489	$7,872,485	$1,890,988
PSAO/ Association	$238,050	$116,083	$162,272	-	$2,536,413	$5,523,220
Not Defined	-	$5,735	-	-	$(3,567)	-
Total	**$6,100,260**	**$(518,866)**	**$6,667,203**	**$438,791**	**$10,599,002**	**$8,100,105**

Exhibit 29: Variance to NADAC % of Paid Ingredient Cost – by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	13.7%	5.6%	5.6%	16.9%	8.6%	4.7%
Chain	13.4%	-9.7%	5.0%	3.6%	10.0%	1.2%
PSAO/ Association	12.8%	7.4%	4.0%	0.0%	9.9%	13.6%
Not Defined	0.0%	4.1%	0.0%	0.0%	-1.8%	0.0%
Total	13.4%	-5.4%	5.0%	3.9%	9.9%	3.9%

Observations

- Five of the six PBMs paid independent pharmacies at higher rates, in some cases significantly higher, than the rates they paid to chains drug stores. This is consistent with HMA's interview with a PBM informant who stated their contracts with independent pharmacies provided for higher reimbursement rates in recognition of higher cost to dispense.
- Only PBM 5 reimbursed chain pharmacies more than other designations; however, the variation across the designations was small.
- The three PBMs (PBM 2, PBM 5, and PBM 6) that paid more claims to PSAOs than to independent pharmacies reimbursed PSAO submitted claims at higher rates than they did for independent pharmacies.

Exhibits 30 and 31 compare PBM reimbursement to the Benchmark MAC 1 at the pharmacy chain status group level.

Exhibit 30: PBM MAC Reimbursement Dollar Variance to Benchmark MAC 1 Pricing – by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	$1,725,773	$(87,241)	$(1,701,642)	$31,834	$(91,483)	$(1,146,071)
Chain	$7,333,729	$(2,212,802)	$(6,720,872)	$(898,183)	$(130,537)	$(20,536,478)
PSAO/ Association	$250,873	$(184,964)	$(547,119)	-	$115,367	$346,018
Not Defined	-	$19,229	$(21)	-	$(85,711)	-
Total	**$9,310,374**	**$(2,465,778)**	**$(8,969,654)**	**$(866,349)**	**$(192,364)**	**$(21,336,531)**

Exhibit 31: PBM % of Paid Ingredient Cost Variance to Benchmark MAC 1 Pricing – by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	20.5%	-11.6%	-7.8%	11.1%	-4.1%	-7.9%
Chain	20.9%	-31.3%	-6.3%	-8.2%	-0.2%	-13.5%
PSAO/Association	13.5%	-11.7%	-13.6%	0.0%	0.5%	0.9%
Not Defined	0.0%	13.7%	-123.2%	0.0%	-43.0%	0.0%
Total	20.5%	-25.8%	-6.8%	-7.7%	-0.2%	-10.3%

Observations

Due to the variability in reimbursement within a PBM and across PBMs, general observations will be made after comparisons to both Benchmark MAC 1 and 2.

Exhibits 32 and 33 summarize a similar analysis for PBM MAC reimbursement compared to Benchmark MAC 2.

Exhibit 32: PBM MAC Reimbursement Dollar Variance to Benchmark MAC 2 Pricing – by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	$ 1,969,559	$ (189,270)	$ (1,190,573)	$ 72,846	$ 1,548	$ (1,054,940)
Chain	$ 8,634,883	$ (2,635,554)	$ (1,902,312)	$ (1,071,043)	$ 3,798,798	$ (18,907,788)
PSAO/Association	$ 362,299	$ (200,609)	$ (503,837)	$ -	$ 1,048,868	$ 1,416,304
Not Defined	$ -	$ 32,065	$ (21)	$ -	$ (93,918)	$ -
Total	**$ 10,966,741**	**$ (2,993,369)**	**$ (3,596,743)**	**$ (998,197)**	**$ 4,755,296**	**$ (18,546,424)**

Exhibit 33: PBM % of Paid Ingredient Cost Variance to Benchmark MAC 2 Pricing – by Pharmacy Chain Status

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Independent	23.4%	-25.2%	-5.5%	25.5%	0.1%	-7.2%
Chain	24.6%	-37.3%	-1.8%	-9.8%	4.8%	-12.4%
PSAO/Association	19.5%	-12.7%	-12.5%	0.0%	4.1%	3.5%
Not Defined	0.0%	22.8%	-123.2%	0.0%	-47.2%	0.0%
Total	**24.2%**	**-31.4%**	**-2.7%**	**-8.9%**	**4.4%**	**-8.9%**

Observations

- It was difficult to draw conclusions based upon these data due the variation in reimbursement within a PBM's MAC list and across PBMs.
- Two of the three PBMs (PBM 5 and PBM 6) who had a higher percentages of reimbursement to PSAOs than to independent pharmacies reimbursed PSAOs higher than benchmark MAC lists 1 and 2, similar to NADAC comparisons.
- In aggregate, the comparison to benchmark MAC 2 was more positive variances that were less dramatic than the comparison to benchmark MAC 1.

PBM MAC List Update Processes

Overview

Price adjustments happen frequently in the generic drug market. How quickly PBMs update their MAC pricing impacts both the pharmacy's and PBM's net incomes. A delay in increasing reimbursement on a drug that has dramatically increased in cost can mean low or negative margins on that drug for a pharmacy. On the other hand, not updating MAC lists when prices decrease will mean over-reimbursement for pharmacies. It is important, again, that MAC lists are designed to reimburse pharmacies for acquisition cost in aggregate. Pursuing that strategy impacts timing of MAC list updates.

A timing study was conducted to understand the PBM reaction to the market shift in price for the Study drugs. Observations of the PBM reaction before, during, and after the price change in the market were documented.

Key Findings

- The data varied so much that no direct conclusions can be drawn, nor trends found for any of the six PBMs.
- Given the analysis that shows that PBMs reimburse above NADAC, the variability appears to have no impact on profitability.
- PBMs reacted differently on a drug-by-drug basis with regard to how cost changes were handled.
- PBMs varied in how they reacted to the same cost change on a drug. PBM reimbursement prior to pricing changes varied significantly compared to NADAC drug pricing. The PBM ingredient cost reimbursement differed widely, from being equivalent reimbursement to NADAC to being more than 100% above and below NADAC.
- PBMs appeared to proactively update reimbursement prior to a pricing change on certain drugs. However, the conclusion that PBMs altered reimbursement prior to a known pricing change was merely an inference that could not be verified as fact through this Study.
- Very rarely did PBMs react on the exact day of a WAC rate change.
- There was no clear pattern in the way different PBMs updated prices, and even individual PBMs seemed to have no consistent way of dealing with price changes.
- The reaction timing of PBM reimbursement updates ranged from one week after a market cost change to no pricing update in the time frame reviewed.

Method

60 highly utilized generic drugs which had significant cost increases or decreases in 2015 were selected for the timing analysis. The drugs were reviewed individually during the timeframe of September 2015 through December 2015 since most of the drugs considered significant for the Study had increases or decreases from third quarter CY 2015 to fourth quarter CY 2015. The PBMs' timing in making MAC list updates was reviewed whenever WAC price increases and decreases were seen in the market during the Study period. Of the 60 drugs selected for review, 35 drugs experienced significant WAC increases, and the remaining 25 drugs experienced significant WAC cost decreases.

Each drug's acquisition cost history, inferred by using NADAC data, was reviewed in comparison to the PBM reimbursement. The goal was to understand how a PBM reacted once a price change affected the

market. NADAC was used because it is based upon acquisition costs and is updated weekly. The Study reviewed the pricing for the drug before the price change, the time of the price change, and the length of time PBMs took to adjust reimbursement within a reasonable range of the adjusted acquisition cost. A 10% threshold on either side of a NADAC rate was considered reasonable.

Data Analysis – Timing Study

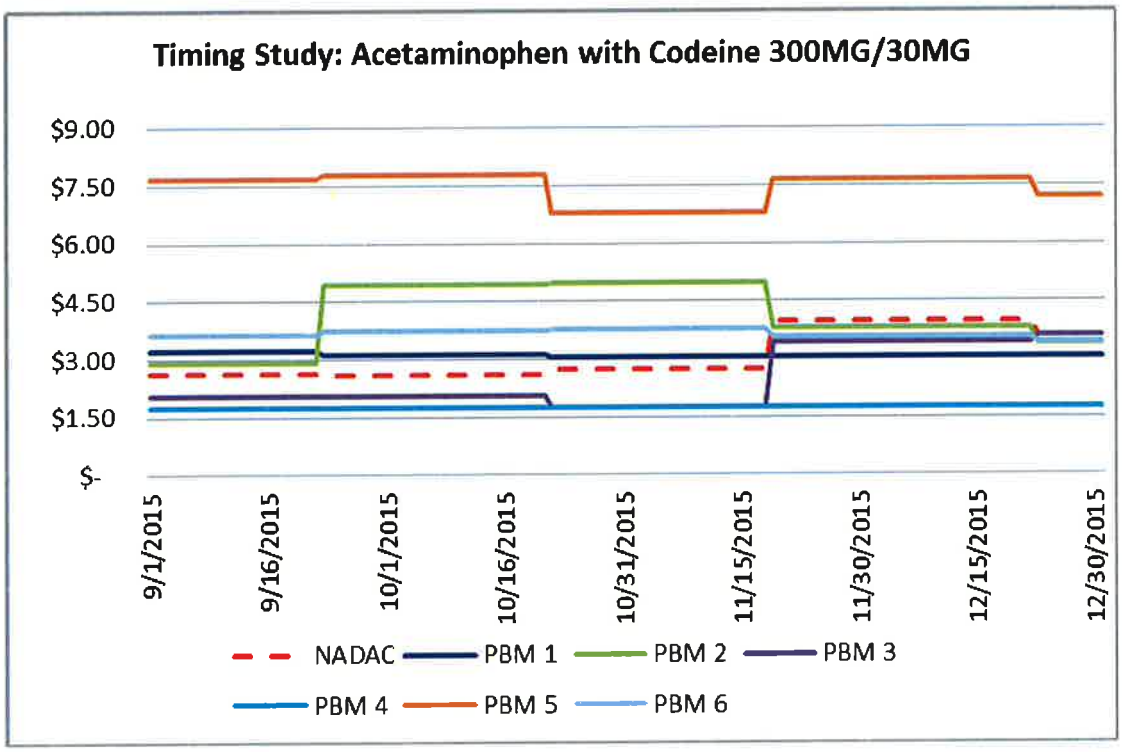
The analysis revealed a data set that would resemble a scatter plot that reflected a lack of consistency in process or reaction time. This could be the result of reviewing a small sample size (60 drugs) of the thousands of generic drugs found in the market at any time. PBM reaction strategies could potentially become more obvious through review of a much larger data set than what was reviewed in this Study.

The analysis was designed to answer the following questions:

- Does the PBM increase/decrease reimbursement prior to a cost increase/decrease by a manufacturer?
- Was reimbursement already significantly higher or lower than the change in ingredient cost, which would possibility affect the PBM reaction time to respond to the pricing change?
- Were there significant differences in PBM MAC list reimbursement prior to the pricing change?

Exhibits 34 and 35 show the reaction time for each of the six PBMs to update their MAC lists. In each Exhibit the per unit average acquisition cost of the drug on the market is represented by the NADAC price (red line). Exhibit 34 represents acetaminophen with codeine 300MG/30MG tablets (dispensing amount of 20) over the time period of September 1, 2015, through December 31, 2015. Acetaminophen with codeine experienced one small (10/22/2015) and one large price increase (11/18/2015) over the time period. The information along the vertical axis represents the dollar range for both NADAC pricing and PBM reimbursements for a dispense count of 20 during the time frame that is labeled on the horizontal axis. Exhibit 35 covers the same time frame and uses the same axis metrics as Exhibit 34 for the drug azithromycin 250MG Pak (dispense amount of 6). Over the time frame, azithromycin Pak experienced two cost decreases (10/20/2015 and 12/22/2015) and the graph evaluates each PBM's reaction.

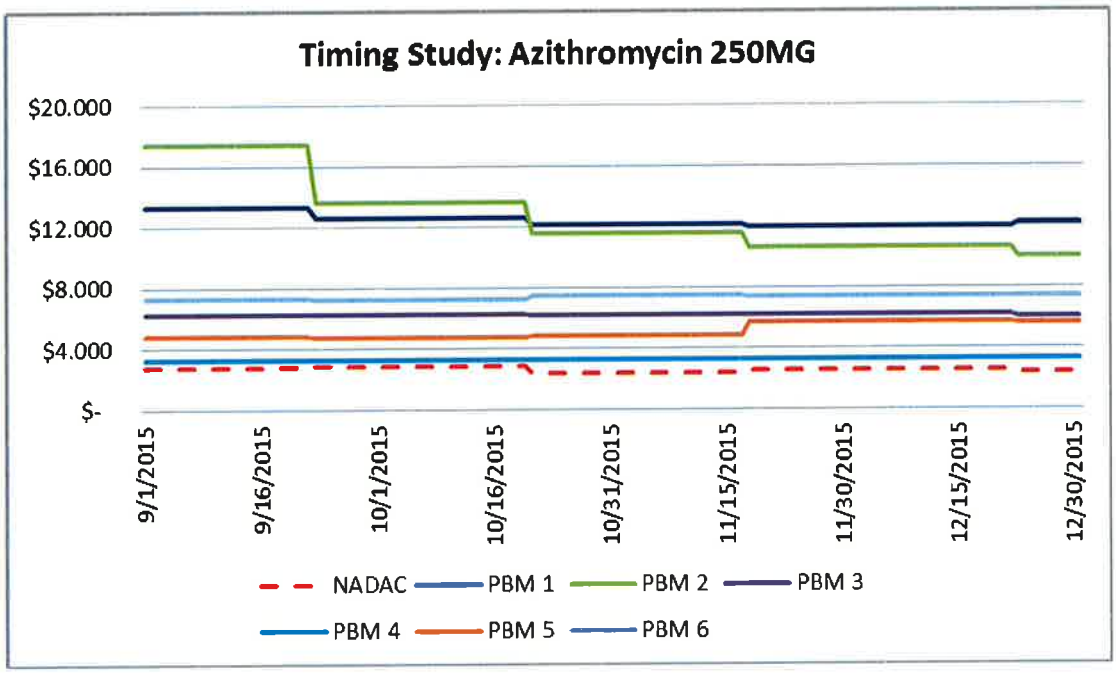
Exhibit 34: Timing Study of Acetaminophen with Codeine 300MG/30MG Tablets – Price Increase Example



Observations

- At the start of the time period reviewed all but two PBMs (PBM 3 and PBM 4) reimbursed more than actual acquisition cost (NADAC)for this particular drug; PBM 5 was paying over two times the NADAC benchmark.
- The NADAC price fluctuated slightly from the middle of September through middle of November, going down slightly in October and then back up again in November.
- The PBMs had similar movement to NADAC during this timeframe with PBM 2 being an outlier, nearly doubling its reimbursement.
- The major price increase took place on November 17. The PBMs at this point reacted very little to the price increase.
- PBM 5 increased its price most significantly, which was expected as it reimbursed the highest amount out of the six PBMs on this drug.
- The other five PBMs reimbursed the ingredient cost close to the NADAC price. Some made little or no adjustment at all (PBM 1 and PBM 4) and end up reimbursing less than the actual acquisition cost (NADAC rate) towards the end of the time frame.

Exhibit 35: Timing Study of Azithromycin 250MG Pak – Price Decrease Example



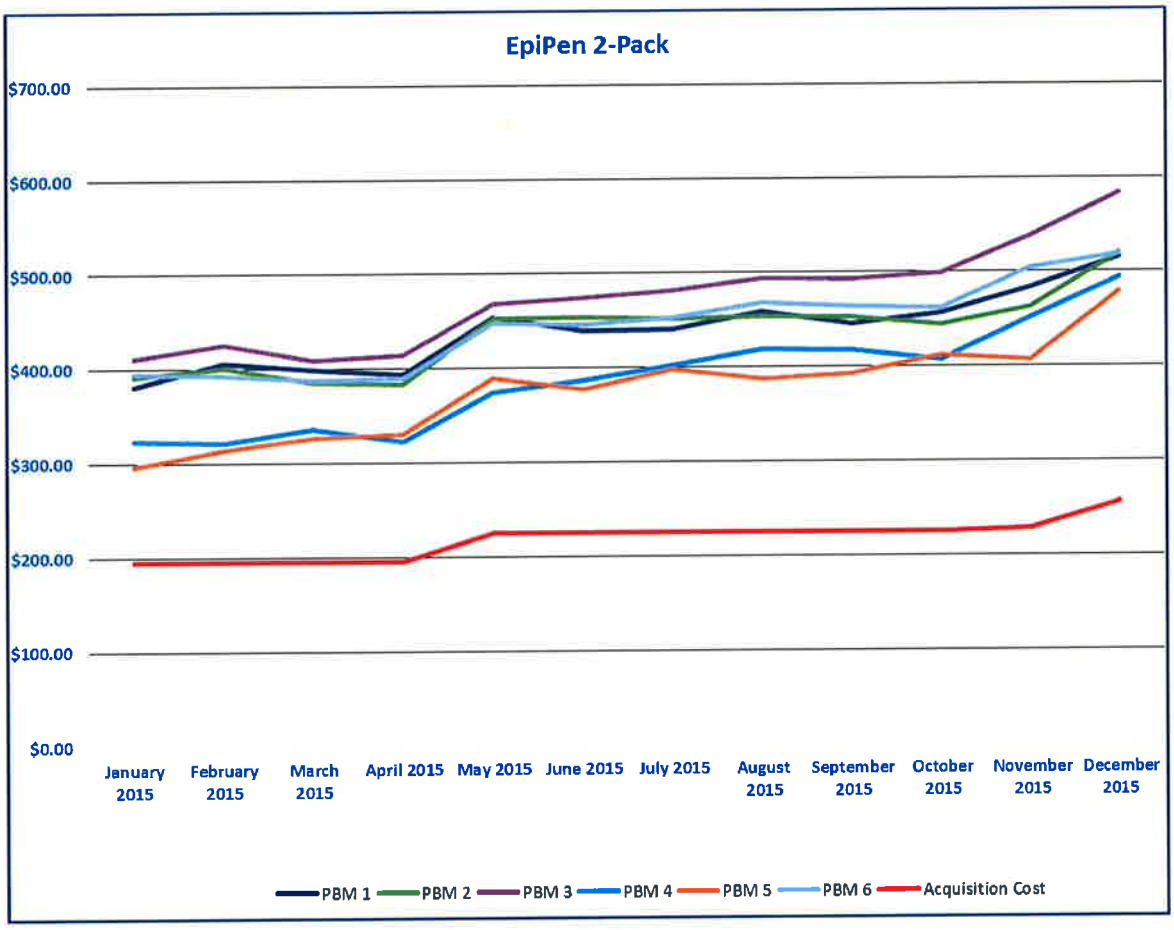
In Exhibit 35 azithromycin 250MG is analyzed as an example of a drug taking a price decrease in the analysis time frame (September 1, 2015 – December 31, 2015).

Observations

- During this time frame the drug took a 17% decrease from a high price ($2.889; from 9/23/15 – 10/20/15) to a low at the end of the time frame ($2.407; as of 12/31/15).
- All of the PBMs analyzed were reimbursing more than the acquisition cost (NADAC) for azithromycin over these four months.
- Four of the six PBMs raised reimbursement levels or held their reimbursement amounts steady.
- PBM 2 took aggressive cuts at its reimbursement for this drug; however, they were still reimbursing more than the actual acquisition cost (NADAC) by a factor of four by the end of the year.
- Azithromycin experienced a 34% decrease in price since Quarter 1 2015 (not seen in this graph). It is unusual that reimbursement by PBMs has not come down further.

Pharmacists interviewed as part of the Study stated that PBMs generally increased the prices of brand name drugs quickly. The Study analyzes EpiPen manufacturer and PBM pricing increases, which validated the informants' statements (Exhibit 36).

Exhibit 36: EpiPen Average Reimbursement and Cost by PBM in 2015



Pharmacy Profitability

Overview

Prescription drug reimbursements to independent pharmacies are vitally important because "92 percent of sales for independent pharmacies" are derived from prescription drugs.[56] Unlike large pharmacy chain stores, independent pharmacies cannot off-set drug reimbursement losses with other store sales (e.g., for cosmetics, food, sundries, etc.). Therefore, to definitively determine pharmacy profitability, access to a pharmacy's actual drug acquisition costs is needed. In the absence of that data (which could be collected in a drug acquisition cost survey which was not included as a part of this Study), this Study addresses the estimated overall profitability of independent pharmacies by comparing actual PBM reimbursements in Washington to national drug acquisition cost benchmarks and to Cost of Dispensing (COD) data reported for Washington.

PBM drug reimbursements to pharmacies have two components: an amount to cover the estimated cost of a drug (the "ingredient cost") and an amount to cover a pharmacy's dispensing cost including, for example, the cost of labor, supplies, and the practice management computer (the "dispensing fee"). Historically, pharmacies have made their profit on the spread between the acquisition cost of a drug and the total reimbursement for a related prescription.

The National Community Pharmacists Association (NCPA) notes that overall independent pharmacy profitability has remained relatively stable over the past 10 years. This is partially evidenced by the fact that the number of independent pharmacies nationwide has remained stable in recent years (Exhibit 37).[57] An analysis of NCPA data in 2015 also indicated that average prescription Gross Margins[58] at independent drugstores did not change significantly during the same timeframe (Exhibit 38).[59]

Exhibit 37: Number of Independent U.S. Pharmacies, 2010-2014[60]

Number of Independent Community Pharmacies					
Year	2010	2011	2012	2013	2014
No. of Pharmacies	23,064	23,106	23,029	22,814	22,478

[56] NCPA 2015 Digest, National Community Pharmacists Association at http://www.ncpa.co/pdf/aaaa-2015-digest-sponsored-by-cardinal-health.pdf

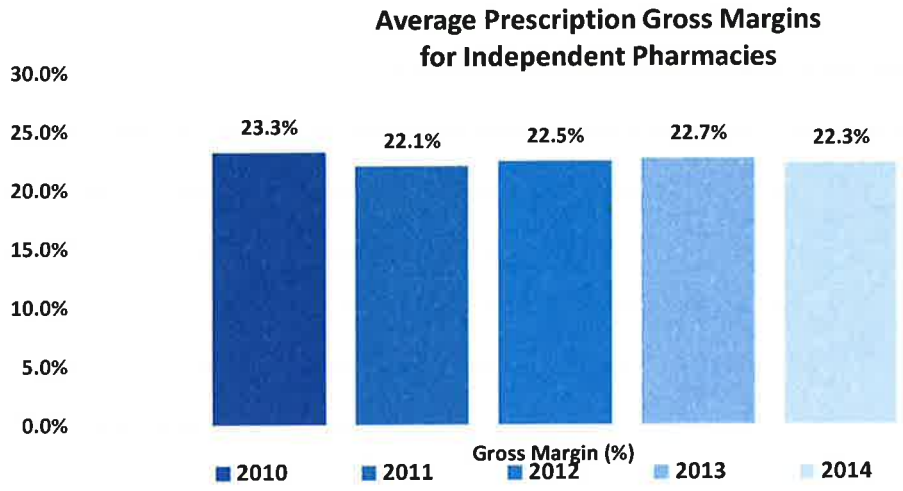
[57] As reported by NCPA in their annual Digest.

[58] Gross Margin is Gross Profit expressed as a percentage of Revenues. Gross profits equal Revenues minus the cost of the drug (net of discounts and returned goods).

[59] Adam J. Fein, Ph.D., "Independent Pharmacy Economics: Profits Steady, but Sales Down (Maybe);" Drug Channels, November 17, 2015.[60] Source: NCPA 2015 Digest.[61] Source: The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies; Pembroke Consulting, Inc. and Drug

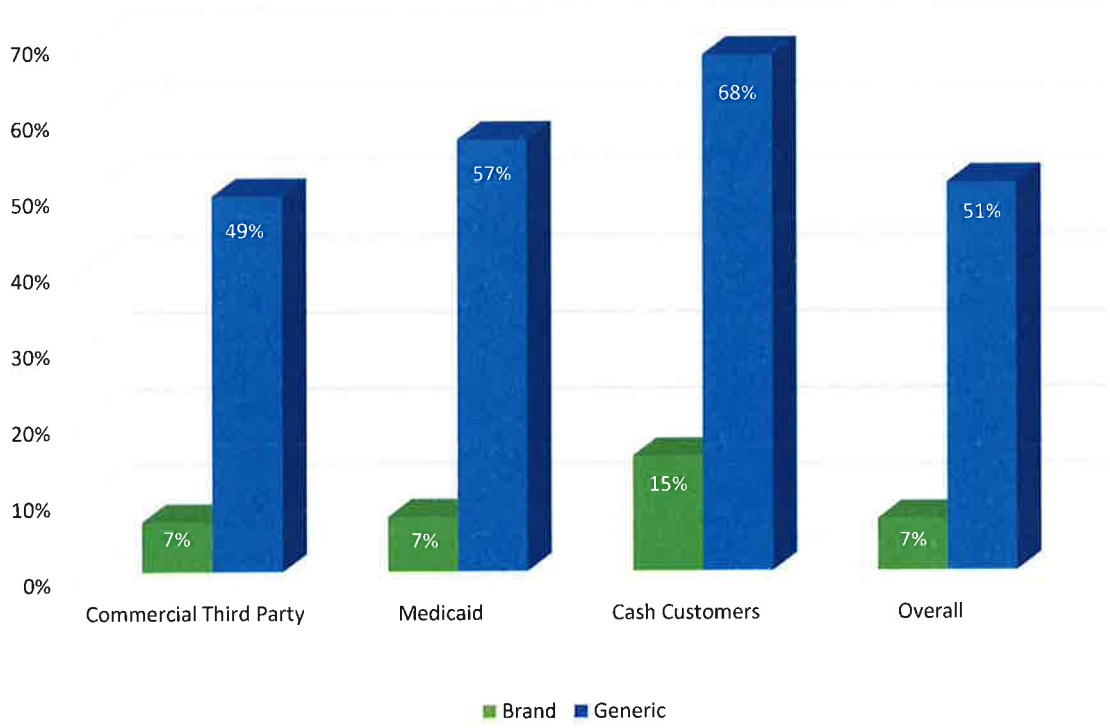
[60] Source: NCPA 2015 Digest.[61] Source: The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies; Pembroke Consulting, Inc. and Drug

Exhibit 38: U.S. Independent Pharmacy Average Gross Margins, 2010-2014



When calculated on a per prescription basis, the average Gross Margin for generic drugs was greater than the average Gross Margin for brand drugs (Exhibit 39).

Exhibit 39: Average U.S. Retail Pharmacy Gross Margin Per Prescription, Brand vs. Generic 2012[61]



[61] Source: The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies; Pembroke Consulting, Inc. and Drug

The remainder of this section provides a detailed analysis comparing PBM payments to Washington pharmacies to national benchmarks. There is also a case study included which applies the benchmark analysis to one rural independent pharmacy and one urban pharmacy.

Key Findings

- In the aggregate, pharmacies showed a positive Gross Profit across the PBMs, but only a positive Gross Profit for PBMs 1 and 4 if a cost of dispensing (COD) of $10 per prescription was assumed.
- Dispensing generic drugs was more profitable than dispensing brand drugs, but that profitability was dependent on an individual pharmacy's COD.
- In the case study provided, the rural independent pharmacy was more profitable than the urban independent pharmacy.
- Profitability decreased when the COD assumption increases from $10 to $15 per prescription, forcing the Net Income of both case study pharmacies as a percent of Gross Income into the negative range.
- The case study showed that the rural independent pharmacy was more profitable at a $10 COD and suffers lower losses at a $15 COD than the urban independent pharmacy.
- Pharmacies that could not off-set losses with other store sales had to: rely primarily on prescription drug income, obtain higher or expanded fees than currently paid by PBMs, or maintain a sufficient spread between drug costs and reimbursement to stay profitable.

Exhibit 40: Rural and Urban Net Income as percent of Gross Income at $10 and $15 cost to dispense for Case Study Pharmacies

Cost to Dispense	Rural Independent Pharmacy Profit	Urban Independent Pharmacy Profit
$10	3.3%	-0.2%
$15	-7.0%	-10.9%

Method

To understand the profitability of filling prescriptions, there must be an understanding of the components that generate a Net Income for a pharmacy. Gross Income related to drugs covered by a PBM is derived from the PBM payment and the patient copayment for any given prescription. Within the PBM reimbursement is an amount allowed by the PBM to cover the cost of the drug and another amount to cover dispensing costs, known as a dispensing fee. This dispensing fee reimbursement and its relationship to a pharmacy's cost of dispensing a prescription is a significant factor, therefore an analysis of the average dispensing fee provided by the PBMs is an important consideration.

On the pharmacy cost side of the equation there is the cost of the drug they dispense and the costs incurred by the pharmacy (labor, supplies, etc.) to dispense the drug. Drug acquisition costs and costs to dispense vary by pharmacy, therefore to analyze profitability, general assumptions are applied to pharmacy drug acquisition and dispensing costs and then compared to the reimbursement data supplied by the PBMs.

Various studies have shown that the average acquisition cost for brand name drugs is generally around AWP minus 18% and for generic drugs around AWP minus 90%.[62] A 2014 Issue Brief from the Kaiser Family Foundation compared the top 25 (in Medicaid) single source and multiple source brand drugs' prescription-weighted, per-unit average AWP, WAC, NADAC and paid amounts.[63] Kaiser found that the NADAC ($8.03) was 18% less than AWP (i.e. AWP minus 18%) for single-source brand drugs and similar ($6.50 NADAC compared to $7.96 AWP) for multiple source brand drugs (Exhibit 8). Kaiser also compared the same pricing metrics for both the top 25 and 100 generic drugs (Exhibit 9). Kaiser information shows that for the top 25 and 100 generic drugs NADAC equaled approximately AWP minus 93% ($0.14 NADAC to $1.88 AWP and $0.17 NADAC to $2.56 AWP).

Based on the Kaiser information and on Cost of Dispensing (COD) data for Washington from a 2015 study,[64] pharmacy profitability calculations were developed using the following assumptions:

- Drug acquisition costs were set at AWP minus 18% for claims data marked as brand and AWP minus 90% for claims data marked as generic.
- The AWP used was that provided in the PBM data for each claim.
- Total pharmacy costs were the sum of the drug acquisition cost plus the COD.
- Multiple COD assumptions were applied ($10, $15 and an amount equal to each PBM's average dispensing fee) to show the effect non-drug costs have on profitability.[65]
- Total income equaled the amount paid by the PBM plus the patient copayment (calculations assumes the patient paid the copayment).
- The number of negative net income claims (brand, generic and total) was counted to show the percentage of claims on which pharmacies lose money. Negative net income occurred when the gross income for a claim was less than the total pharmacy cost (i.e. drug cost plus COD) for the claim.

Data analysis

Aggregate Profitability

An analysis of PBM claims data was performed across all pharmacies attributing a pharmacy dispensing cost for each claim (Exhibits 41 and 42). The results illustrate the difference between Gross Profits (i.e. Gross Income minus Drug Cost) and Net Income (amount remaining after taking into account non-drug COD).

Exhibits 41 and 42 provide estimated net income for Washington pharmacies for each PBM showing an overall Gross Profit of $202,732,929. After applying the COD, however, the overall profit becomes an overall loss of $212,196,941.

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[62] Bruen, B & Young, K, Paying for Prescribed Drugs in Medicaid: Current Policy and Upcoming Changes, The Kaiser Commission on Medicaid and the Uninsured, May 2014 Issue Brief.

[63] Weighted average total paid is for Medicaid programs. NADAC represents the pharmacy acquisition cost.

[64] "Cost of Dispensing Study: An Independent Comparative Analysis of U.S. Prescription Dispensing Cost" September 2015.

[65] This range of dispensing fees is based upon the "Cost of Dispensing Study: An Independent Comparative Analysis of U.S. Prescription Dispensing Cost" September 2015.

Exhibit 41: Total Drug Costs and Income for All Washington Pharmacies Assuming a $10 COD, CY 2015

Metric	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Claims	2,623,315	2,896,412	9,907,024	5,100,849	9,339,630	11,625,757	41,492,987
PBM Paid	$137,983,804	$125,169,121	$430,979,063	$245,215,913	$580,292,420	$548,193,906	$2,067,834,226
Copayment	$1,577,829	$7,046,445	$31,930,224	$64,678,283	$112,968,519	$93,349,287	$311,550,588
Gross Income	$139,561,634	$132,215,566	$462,909,287	$309,894,195	$693,260,939	$641,543,193	$2,379,384,814
Drug Cost	$111,594,558	$245,156,667	$372,204,225	$247,646,886	$662,205,372	$537,844,177	$2,176,651,885
Gross Profit	**$27,967,076**	**($112,941,101)**	**$90,705,062**	**$62,247,309**	**$31,055,567**	**$103,699,016**	**$202,732,929**
Gross Profit % of Gross Income	20%	-85%	20%	20%	4%	16%	9%
Dispensing Cost	$26,233,150	$28,964,120	$99,070,240	$51,008,490	$93,396,300	$116,257,570	$414,929,870
Net Income	**$1,733,926**	**($141,905,221)**	**($8,365,178)**	**$11,238,819**	**($62,340,733)**	**($12,558,554)**	**($212,196,941)**

As illustrated in Exhibit 41, the large negative net income reported for PBM 2 adversely affected the overall net income results. The review of the PBM 2 data indicated a likely inconsistency in the way drugs are identified as either brand or generic. PBM 2 marked many generic drugs as brand, yet the reimbursement was low, comparable to a generic drug. Since the calculations assumed standard AWP discounts that differ between brand and generic drugs, this mismarking of the data caused a large negative income effect. Exhibit 42 presents the same data as Exhibit 41, but excludes the PBM 2 data.

Exhibit 42: Total Drug Costs and Income for All Washington Pharmacies Assuming a $10 COD, CY 2015 – Without PBM 2

Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Claims	2,623,315	9,907,024	5,100,849	9,339,630	11,625,757	38,596,575
PBM Paid	$137,983,804	$430,979,063	$245,215,913	$580,292,420	$548,193,906	$1,942,665,105
Copayment	$1,577,829	$31,930,224	$64,678,283	$112,968,519	$93,349,287	$304,504,142
Gross Income	$139,561,634	$462,909,287	$309,894,195	$693,260,939	$641,543,193	$2,247,169,247
Drug Cost	$111,594,558	$372,204,225	$247,646,886	$662,205,372	$537,844,177	$1,931,495,218
Gross Profit	**$27,967,076**	**$90,705,062**	**$62,247,309**	**$31,055,567**	**$103,699,016**	**$315,674,029**
Gross Profit % of Gross Income	20%	20%	20%	4%	16%	14%
Dispensing Cost	$26,233,150	$99,070,240	$51,008,490	$93,396,300	$116,257,570	$385,965,750
Net Income	**$1,733,926**	**($8,365,178)**	**$11,238,819**	**($62,340,733)**	**($12,558,554)**	**($70,291,721)**

Observations

- All pharmacies, except for PBM 2 (which has significant data anomalies), had a positive Gross Profit (before accounting for the COD). Pharmacies' Gross Profit across all PBM transactions was 14%, which is less than the average prescription Gross Margin for U.S. independent pharmacies illustrated in Exhibit 38.[66]
- In aggregate, the pharmacies had a negative Net Income after applying a $10 COD assumption.
- After subtracting an estimated COD, total pharmacy transactions with only two PBMs (PBM 1 and PBM 4) showed positive Net Incomes. Overall pharmacy Net Income across all PBM transactions was negative.
- In general, if the actual drug acquisition costs for Washington pharmacies had been equal to the national drug acquisition cost benchmarks used in this analysis, PBM reimbursements may not have been adequate to cover pharmacy costs, assuming a $10 COD. If the actual COD was higher than $10, the shortfall would have been greater.

[66] Fein, AJ, "The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies," Pembroke Consulting, Inc., and Drug Channels Institute, January 2016.

The Dispensing Fee

As noted above, the dispensing fee was intended to reimburse the cost of dispensing an individual prescription. According to a 2015-2016 national survey of employer-sponsored plans, retail pharmacy dispensing fees for a 30-day prescription ranged from $1.56 to $2.17 (Exhibit 43). One researcher notes that "for retail, the average dispensing fee declined 37% between 1995 and 2009, from $2.50 to $1.57."[67] Though 37% appears significant, the 93-cent difference is less than two percent of the average drug reimbursement of $54.[68]

Exhibit 43: Average U.S. Dispensing Fees Paid – Employer-Sponsored Plans, 2015-16[69]

Dispensing Fee by Pharmacy Channel				
	Smaller Employers	Larger Employers	Overall Average	Median
Generics	$2.17	$1.56	$1.83	$1.20
Brands	$1.98	$1.67	$1.80	$1.20

The Study analyzed the dispensing fees associated with the PBM claims data to determine how close they were to the referenced national averages. To avoid artificially increasing average dispensing fee results by products that have higher than regular dispensing fees provided for oral dosage forms (i.e. tablets, capsules and liquids) and for claim data with anomalous information, claims were excluded from review if they were: negative paid amounts, compounded drugs, vaccines, claims with erroneous data (i.e. null values or text in numerical fields), and items specifically marked as other than brand or generic. The claims were aggregated by dispensing fee amount for each PBM and then weighted based on claim volume.

The results of the analysis indicated that the six PBMs had average dispensing fees at or below the national average dispensing fees paid by employer-sponsored plans reflected in Exhibit 43. The dispensing fees (Exhibit 44) ranged from zero to as much as $200,[70] but were, on average, below $1.88, with the lowest being $0.66 (PBM 6). It is important to note that, per pharmacist interviews, pharmacies were typically paid a zero dispensing fee when they dispense a 90-day supply. OIC did not have access to PBM network contracts so the mix of prescription types that would generate a higher dispensing fee versus a $0 dispensing fee could not be determined for this analysis. Breaking out the average dispensing fees for brand and generic (Exhibit 45) showed very little difference.

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[67] Berndt, E & Newhouse, P; Pricing and Reimbursement in U.S. Pharmaceutical Markets, Harvard Kennedy School Faculty Research Working Paper, September 2010.

[68] Average reimbursement calculated using PBM data from dispensing fee analysis.

[69] "2015-2016 Prescription Drug Benefit Cost and Plan Design Report," Pharmacy Benefit Management Institute, 2015

[70] The $200 and $17 fees were for a limited number of product claims and had no significant effect on the average dispensing fees.

Exhibit 44: PBM Dispensing Fees Paid to Washington Pharmacies - Ranges and Averages[71]

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Total Claims In Sample	2,623,315	2,896,412	9,907,024	5,100,849	9,339,630	11,625,757
Fee Range	$0 - $5.78	$0 - $2.75	$0 - $200.00	$0 - $5.00	$0 - $17.00	$0 - $3.75
Weighted Avg. Dispensing Fee	$1.88	$1.05	$0.89	$1.26	$1.75	$0.66
Total Reimbursement	$139,561,634	$132,215,566	$462,909,287	$309,894,195	$693,260,939	$641,543,193
Total Dispensing Fees Paid	$4,922,439	$3,044,950	$8,826,128	$6,429,634	$16,341,998	$7,722,606
Total Fees % of Total Reimbursement	3.5%	2.3%	1.9%	2.1%	2.4%	1.2%

Exhibit 45: PBM Dispensing Fees Paid to Washington Pharmacies by Brand and Generic

		PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Brand	Weighted Avg Disp. Fee	$1.83	$1.05	$0.97	$1.25	$2.11	$0.64
	Total Reimbursement	$81,645,272	$118,774,878	$269,003,261	$201,461,973	$449,765,889	$438,065,304
	Total Dispensing Fees Paid	$621,599	$1,996,001	$1,103,990	$816,147	$2,189,333	$979,540
	Total Fees % of Total Reimbursement	0.8%	1.7%	0.4%	0.4%	0.5%	0.2%
Generic	Weighted Avg Disp. Fee	$1.88	$1.05	$0.88	$1.26	$1.70	$0.67
	Total Reimbursement	$57,916,362	$13,440,688	$193,906,026	$108,432,222	$243,495,050	$203,477,889
	Total Dispensing Fees Paid	$4,300,840	$1,048,949	$7,722,138	$5,613,487	$14,152,666	$6,743,067
	Total Fees % of Total Reimbursement	7.4%	7.8%	4.0%	5.2%	5.8%	3.3%

As illustrated in Exhibit 46, brand drugs made up a small percentage of claims but a large percentage of total pharmacy reimbursement. While PBM 2 percentages were notably different, a manual review of the PBM 2 claims suggested that PBM 2 mistakenly coded many generic drugs as brand. In the aggregate for the other five PBMs (excluding PBM 2), generic drugs accounted for 88% of the claims and 34% of the reimbursement.[72]

[71] Total claims and reimbursement is inclusive of all claims (brand and generic) and not limited to those paid using a MAC price list.

[72] In these tables, "Reimbursement" does not include the copayments made by patients. Copayments are used in the assessment of profitability later in this report.

Exhibit 46: Percentage of Total Pharmacy Claims and Reimbursement for Washington Pharmacies by Brand and Generic[73]

		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 study[74]. 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.

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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:

[73]Note: 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.

- Drug acquisition costs were assumed to be AWP minus 18% for claims data marked as brand and AWP minus 90% for claims data marked as generic.
- Varied Cost of Dispensing (COD) assumptions were applied to show the effect non-drug costs have on profitability including dispensing fees of $10 and $15 and an amount equal to each PBM's average dispensing fee.
- Total income equaled the amount paid by the PBM plus the patient copayment (because there is no record of whether the pharmacy collected the patient copayment, the calculations assume the patient paid the copayment as listed in the data).
- The number of negative net income claims were counted as well as the percentage that were brand or generic drugs.

Profitability: $10 versus $15 cost to dispense

Exhibit 47 provides estimated net income for the two pharmacies assuming a per prescription COD of $10. At this amount, only the Rural pharmacy had a positive net income which is approximately 1.4% of gross income.

Exhibit 47: Total Costs and Income by PBM for Case Study Pharmacies

COD $10	Metric	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Claims	2,177	1,124	27,246	1,685	7,037	13,974	53,243
	PBM Paid	$147,944	$69,368	$995,970	$141,993	$331,039	$712,463	$2,398,778
	Copayment	$1,946	$870	$20,950	$16,869	$49,556	$123,059	$213,250
	Gross Income	**$149,890**	**$70,238**	**$1,016,920**	**$158,862**	**$380,594**	**$835,523**	**$2,612,028**
	Drug Cost	$116,521	$107,030	$749,782	$138,638	$286,419	$645,690	$2,044,080
	Dispensing Cost	$21,770	$11,240	$272,460	$16,850	$70,370	$139,740	$532,430
	Total Cost	**$138,291**	**$118,270**	**$1,022,242**	**$155,488**	**$356,789**	**$785,430**	**$2,576,510**
	Net Income	**$11,598**	**($48,032)**	**($5,322)**	**$3,374**	**$23,806**	**$50,093**	**$35,518**
	Net Income % of Gross Income	**7.7%**	**-68.4%**	**-0.5%**	**2.1%**	**6.3%**	**6.0%**	**1.4%**
COD $10	Metric	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	3,115	1,992	19,823	570	825	13,758	40,083
	PBM Paid	$124,808	$89,443	$858,756	$44,794	$28,743	$685,207	$1,831,751
	Copayment	$1,075	$260	$4,145	$7,596	$5,678	$19,359	$38,113
	Gross Income	**$125,883**	**$89,703**	**$862,901**	**$52,389**	**$34,422**	**$704,566**	**$1,869,864**
	Drug Cost	$76,790	$210,851	$670,178	$41,972	$24,738	$588,680	$1,613,209
	Dispensing Cost	$31,150	$19,920	$198,230	$5,700	$8,250	$137,580	$400,830
	Total Cost	**$107,940**	**$230,771**	**$868,408**	**$47,672**	**$32,988**	**$726,260**	**$2,014,039**
	Net Income	**$17,943**	**($141,068)**	**($5,508)**	**$4,718**	**$1,433**	**($21,694)**	**($144,176)**
	Net Income % of Gross Income	**14.3%**	**-157.3%**	**-0.6%**	**9.0%**	**4.2%**	**-3.1%**	**-7.7%**

When PBM 2 was removed from the data (Exhibit 48), net income for both pharmacies increased to $83,550 for the rural pharmacy and resulted in a small $3,108 loss for the urban pharmacy. Because of PBM 2's data anomalies, PBM 2 was excluded from the remaining calculations. It is also important to note that total copayments differed significantly between PBMs as well as between the two pharmacies. Copayments was determined by health plan design, therefore, copayments should not be considered a specific driver of profitability since they are a component of the total reimbursement established by the PBM.

Exhibit 48: Total Costs and Income Assuming a $10 COD (without PBM 2) for Case Study Pharmacies

COD $10	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	$21,770	$272,460	$16,850	$70,370	$139,740	$521,190
	Total Cost	**$138,291**	**$1,022,242**	**$155,488**	**$356,789**	**$785,430**	**$2,458,240**
	Net Income	**$11,598**	**($5,322)**	**$3,374**	**$23,806**	**$50,093**	**$83,550**
	Net Income % of Gross Income	**7.7%**	**-0.5%**	**2.1%**	**6.3%**	**6.0%**	**3.3%**
COD $10	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	$31,150	$198,230	$5,700	$8,250	$137,580	$380,910
	Total Cost	**$107,940**	**$868,408**	**$47,672**	**$32,988**	**$726,260**	**$1,783,268**
	Net Income	**$17,943**	**($5,508)**	**$4,718**	**$1,433**	**($21,694)**	**($3,108)**
	Net Income % of Gross Income	**14.3%**	**-0.6%**	**9.0%**	**4.2%**	**-3.1%**	**-0.2%**

The average generic drug reimbursement (Gross Income) was significantly lower at $20 to $30 per claim when compared to the reimbursement for brand drugs at $200 to $500 per claim (Exhibit 49).

Exhibit 49: Brand and Generic - Percent of Total Claims and Average Gross Income/Claim by PBM for Case Study Pharmacies

		Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	All PBMs
Independent Rural Pharmacy	BRAND	Percent of Total Claims	14%	10%	21%	9%	9%	10%
		Avg. Gross Income per claim	$321	$201	$355	$310	$408	$283
	GENERIC	Percent of Total Claims	86%	90%	79%	91%	91%	90%
		Avg. Gross Income per claim	$26	$20	$25	$30	$24	$23
		Metric	**PBM 1**	**PBM 3**	**PBM 4**	**PBM 5**	**PBM 6**	**All PBMs**
Independent Urban Pharmacy	BRAND	Percent of Total Claims	8%	12%	11%	8%	14%	12%
		Avg. Gross Income per claim	$203	$211	$514	$263	$239	$227
	GENERIC	Percent of Total Claims	92%	88%	89%	92%	86%	88%
		Avg. Gross Income per claim	$27	$21	$39	$23	$21	$22

With apparent slim margins, it is easy to predict that a higher dispensing fee assumption would have a significant negative impact on the pharmacies' net income. As Exhibit 50 shows, increasing the COD assumption from $10 to $15, dropped the total net income of both pharmacies into the red, with net income as a percent of gross income decreasing to negative 7% for the rural pharmacy and negative 11% for the urban pharmacy.

Exhibit 50: Brand and Generic - Percent of Total Claims and Average Gross Income/Claim by PBM for Case Study Pharmacies

COD $15	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	$1,016,920	$141,993	$331,039	$835,523	$2,473,418
	Copayment	$1,946	$20,950	$16,869	$49,556	$123,059	$212,380
	Gross Income	**$149,890**	**$1,037,870**	**$158,862**	**$380,594**	**$958,582**	**$2,685,798**
	Drug Cost	$116,521	$749,782	$138,638	$286,419	$645,690	$1,937,050
	Dispensing Cost	$32,655	$408,690	$25,275	$105,555	$209,610	$781,785
	Total Cost	**$149,176**	**$1,158,472**	**$163,913**	**$391,974**	**$855,300**	**$2,718,835**
	Net Income	**$713**	**($120,602)**	**($5,051)**	**($11,379)**	**$103,282**	**($33,036)**
COD $15	Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	3,115	19,823	570	825	13758	38,091
	PBM Paid	$124,808	$862,901	$44,794	$28,743	$704,566	$1,765,812
	Copayment	$1,075	$4,145	$7,596	$5,678	$19,359	$37,853
	Gross Income	**$125,883**	**$867,045**	**$52,389**	**$34,422**	**$723,925**	**$1,803,664**
	Drug Cost	$76,790	$670,178	$41,972	$24,738	$588,680	$1,402,358
	Dispensing Cost	$46,725	$297,345	$8,550	$12,375	$206,370	$571,365
	Total Cost	**$123,515**	**$967,523**	**$50,522**	**$37,113**	**$795,050**	**$1,973,723**
	Net Income	**$2,368**	**($100,478)**	**$1,868**	**($2,692)**	**($71,125)**	**($170,059)**

Exhibit 51 compares the data in Exhibits 48 and 50 for ease in comparison.

Exhibit 51: Net Income as a Percent of Total Income, Comparison of $10 and $15 COD for Case Study Pharmacies

Independent Rural Pharmacy	Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Cost to Dispense $10	**Total Income**	$149,890	$1,037,870	$158,862	$380,594	$958,582	$2,685,798
	Net Income	$11,598	$15,628	$3,374	$23,806	$173,152	$227,559
	% of Total Income	7.7%	1.5%	2.1%	6.3%	18.1%	8.5%
Cost to Dispense $15	**Total Income**	$149,890	$1,037,870	$158,862	$380,594	$958,582	$2,685,798
	Net Income	$713	($120,602)	($5,051)	($11,379)	$103,282	($33,036)
	% of Total Income	0.5%	-11.6%	-3.2%	-3.0%	10.8%	-1.2%

Independent Urban Pharmacy	Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Cost to Dispense $10	**Total Income**	$125,883	$867,045	$52,389	$34,422	$723,925	$1,803,664
	Net Income	$17,943	($1,363)	$4,718	$1,433	($2,335)	$20,396
	% of Total Income	14.3%	-0.2%	9.0%	4.2%	-0.3%	1.1%
Cost to Dispense $15	**Total Income**	$125,883	$867,045	$52,389	$34,422	$723,925	$1,803,664
	Net Income	$2,368	($100,478)	$1,868	($2,692)	($71,125)	($170,059)
	% of Total Income	1.9%	-11.6%	3.6%	-7.8%	-9.8%	-9.4%

Observations

- The rural pharmacy was profitable and the urban pharmacy was marginally in the red when a $10 COD was assumed.
- Both the rural and urban pharmacies had negative net incomes when the COD assumption increased to $15. The rural pharmacy, however, was still more profitable than the urban pharmacy.
- If a $15 COD was assumed, the rural pharmacy had a positive net income from PBM 1.

- If a $15 COD was assumed, the urban pharmacy had positive net income from PBM 1 and PBM 4.

Profitability: brand versus generic

A separate analysis was performed for the net income derived from brand and generic drugs at these differing COD assumptions. At a $10 COD, brand drugs appeared to be a negative influence on net income while generic drugs were shown to have a positive effect on net income across all but one of the PBMs (PBM 6 for the urban pharmacy) (Exhibits 52 and 53).

Exhibit 52: Brand Drug Costs and Income Assuming a $10 COD for the Case Study Pharmacies

COD $10	Brand Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Claims	314	2,667	354	616	1,300	5,251
	PBM Paid	$100,046	$527,729	$112,765	$163,605	$491,277	$1,395,422
	Copayment	$670	$9,337	$12,804	$27,527	$39,061	$89,398
	Gross Income	**$100,716**	**$537,066**	**$125,569**	**$191,132**	**$530,337**	**$1,484,820**
	Drug Cost	$97,852	$538,650	$122,036	$193,042	$519,899	$1,471,479
	Dispensing Cost	$3,140	$26,670	$3,540	$6,160	$13,000	$52,510
	Total Cost	**$100,992**	**$565,320**	**$125,576**	**$199,202**	**$532,899**	**$1,523,989**
	Net Income	**($276)**	**($28,254)**	**($8)**	**($8,070)**	**($2,562)**	**($39,169)**
	Net Income % of Gross Income	**-0.27%**	**-5.26%**	**-0.01%**	**-4.22%**	**-0.48%**	**-2.64%**
COD $10	Brand Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	235	2,365	64	64	1,928	4,656
	PBM Paid	$47,074	$496,829	$27,026	$13,771	$453,722	$1,038,422
	Copayment	$637	$2,600	$5,846	$3,065	$7,717	$19,864
	Gross Income	**$47,711**	**$499,429**	**$32,871**	**$16,836**	**$461,439**	**$1,058,286**
	Drug Cost	$46,285	$497,550	$31,941	$16,798	$456,079	$1,048,652
	Dispensing Cost	$2,350	$23,650	$640	$640	$19,280	$46,560
	Total Cost	**$48,635**	**$521,200**	**$32,581**	**$17,438**	**$475,359**	**$1,095,212**
	Net Income	**($924)**	**($21,770)**	**$290**	**($602)**	**($13,920)**	**($36,926)**
	Net Income % of Gross Income	**-1.9%**	**-4.4%**	**0.9%**	**-3.6%**	**-3.0%**	**-3.5%**

Exhibit 53: Generic Drug Costs and Income Assuming a $10 COD for the Case Study Pharmacies

COD $10	Generic Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Claims	1,863	24,579	1,331	6,421	12,674	46,868
	PBM Paid	$47,898	$468,242	$29,228	$167,434	$221,187	$933,988
	Copayment	$1,276	$11,613	$4,066	$22,029	$83,999	$122,982
	Gross Income	**$49,174**	**$479,854**	**$33,294**	**$189,462**	**$305,186**	**$1,056,970**
	Drug Cost	$18,669	$211,132	$16,602	$93,377	$125,791	$465,571
	Dispensing Cost	$18,630	$245,790	$13,310	$64,210	$126,740	$468,680
	Total Cost	**$37,299**	**$456,922**	**$29,912**	**$157,587**	**$252,531**	**$934,251**
	Net Income	**$11,874**	**$22,933**	**$3,382**	**$31,875**	**$52,654**	**$122,719**
	Net Income % of	**24.15%**	**4.78%**	**10.16%**	**16.82%**	**17.25%**	**11.61%**
COD $10	Generic Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	2,880	17,458	506	761	11,830	33,435
	PBM Paid	$77,734	$361,927	$17,768	$14,972	$231,484	$703,886
	Copayment	$438	$1,544	$1,750	$2,614	$11,643	$17,988
	Gross Income	**$78,172**	**$363,472**	**$19,518**	**$17,586**	**$243,127**	**$721,874**
	Drug Cost	$30,505	$172,629	$10,030	$7,941	$132,601	$353,706
	Dispensing Cost	$28,800	$174,580	$5,060	$7,610	$118,300	$334,350
	Total Cost	**$59,305**	**$347,209**	**$15,090**	**$15,551**	**$250,901**	**$688,056**
	Net Income	**$18,868**	**$16,263**	**$4,428**	**$2,035**	**($7,774)**	**$33,818**
	Net Income % of	**24.1%**	**4.5%**	**22.7%**	**11.6%**	**-3.2%**	**4.7%**

When, however, the COD assumption was increased to $15 (Exhibits 54 and 55), generic drugs decreased the overall net income more (higher dollar decrease) than brand drugs. For the rural pharmacy, total net income was decreased an additional $26,000 by brand drugs and $234,000 by generic drugs and for the urban pharmacy there was a decrease of $23,000 by brand drugs and $167,000 by generic drugs.

Exhibit 54: Brand Drug Costs and Income Assuming a $15 COD for the Case Study Pharmacies

COD $15	Brand Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Claims	314	2,667	354	616	1,300	5,251
	PBM Paid	$100,046	$527,729	$112,765	$163,605	$491,277	$1,395,422
	Copayment	$670	$9,337	$12,804	$27,527	$39,061	$89,398
	Gross Income	**$100,716**	**$537,066**	**$125,569**	**$191,132**	**$530,337**	**$1,484,820**
	Drug Cost	$97,852	$538,650	$122,036	$193,042	$519,899	$1,471,479
	Dispensing Cost	$4,710	$40,005	$5,310	$9,240	$19,500	$78,765
	Total Cost	**$102,562**	**$578,655**	**$127,346**	**$202,282**	**$539,399**	**$1,550,244**
	Net Income	**($1,846)**	**($41,589)**	**($1,778)**	**($11,150)**	**($9,062)**	**($65,424)**
	Net Income % of Gross Income	**-1.83%**	**-7.74%**	**-1.42%**	**-5.83%**	**-1.71%**	**-4.41%**
COD $15	Brand Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	235	2,365	64	64	1,928	4,656
	PBM Paid	$47,074	$496,829	$27,026	$13,771	$453,722	$1,038,422
	Copayment	$637	$2,600	$5,846	$3,065	$7,717	$19,864
	Gross Income	**$47,711**	**$499,429**	**$32,871**	**$16,836**	**$461,439**	**$1,058,286**
	Drug Cost	$46,285	$497,550	$31,941	$16,798	$456,079	$1,048,652
	Dispensing Cost	$3,525	$35,475	$960	$960	$28,920	$69,840
	Total Cost	**$49,810**	**$533,025**	**$32,901**	**$17,758**	**$484,999**	**$1,118,492**
	Net Income	**($2,099)**	**($33,595)**	**($30)**	**($922)**	**($23,560)**	**($60,206)**
	Net Income % of Gross Income	**-4.4%**	**-6.7%**	**-0.1%**	**-5.5%**	**-5.1%**	**-5.7%**

Exhibit 55: Generic Drug Costs and Income Assuming a $15 COD for the Case Study Pharmacies

COD $15	Generic Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Claims	1,863	24,579	1,331	6,421	12,674	46,868
	PBM Paid	$47,898	$468,242	$29,228	$167,434	$221,187	$933,988
	Copayment	$1,276	$11,613	$4,066	$22,029	$83,999	$122,982
	Gross Income	**$49,174**	**$479,854**	**$33,294**	**$189,462**	**$305,186**	**$1,056,970**
	Drug Cost	$18,669	$211,132	$16,602	$93,377	$125,791	$465,571
	Dispensing Cost	$27,945	$368,685	$19,965	$96,315	$190,110	$703,020
	Total Cost	**$46,614**	**$579,817**	**$36,567**	**$189,692**	**$315,901**	**$1,168,591**
	Net Income	**$2,559**	**($99,962)**	**($3,273)**	**($230)**	**($10,716)**	**($111,621)**
	Net Income % of Gross Income	**5.20%**	**-20.83%**	**-9.83%**	**-0.12%**	**-3.51%**	**-10.56%**
COD $15	Generic Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	Claims	2,880	17,458	506	761	11,830	33,435
	PBM Paid	$77,734	$361,927	$17,768	$14,972	$231,484	$703,886
	Copayment	$438	$1,544	$1,750	$2,614	$11,643	$17,988
	Gross Income	**$78,172**	**$363,472**	**$19,518**	**$17,586**	**$243,127**	**$721,874**
	Drug Cost	$30,505	$172,629	$10,030	$7,941	$132,601	$353,706
	Dispensing Cost	$43,200	$261,870	$7,590	$11,415	$177,450	$501,525
	Total Cost	**$73,705**	**$434,499**	**$17,620**	**$19,356**	**$310,051**	**$855,231**
	Net Income	**$4,468**	**($71,027)**	**$1,898**	**($1,770)**	**($66,924)**	**($133,357)**
	Net Income % of Gross Income	**5.7%**	**-19.5%**	**9.7%**	**-10.1%**	**-27.5%**	**-18.5%**

Observations

- If a $10 COD was assumed, generic drugs were more profitable than brand drugs (consistent with the national data reported in Exhibit 39 above).
- If a $15 COD was assumed, generic drugs generated a greater net loss than brand drugs.
- The significantly lower net income totals that resulted from changing the COD assumption from $10 to $15 were attributable to the lower average reimbursement and larger volume of generic drug claims when compared to brand drugs.
- Generic drugs ranged from 79% to 92% of claims for the case study pharmacies.

Number of negative net income claims

Another examined metric is the number of negative Net Income claims generated at the $10 and $15 COD levels. Without considering the COD (Exhibit 56), i.e. at the gross profit level, generic drugs accounted for almost all negative claims. When adding a COD, the results showed that at a $10 COD (Exhibit 57) both pharmacies took a loss on the majority of their claims. This high negative claim volume (loss) was driven primarily by generic claims.

Exhibit 56: Volume of Negative Net Income Claims (Generic, Brand and Total) for the Case Study Pharmacies – No COD Assumed

No COD		PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	All Claims Total	2,177	27,246	1,685	7,037	13,974	52,119
	No. Negative Generic Claims	243	7,119	453	2,281	2,982	13,078
	% of All Claims	11%	26%	27%	32%	21%	25%
	No. Negative Brand Claims	15	162	21	111	309	618
	% of All Claims	1%	1%	1%	2%	2%	1%
	Total Negative Claims	258	7,281	474	2,392	3,291	13,696
	% of All Claims	12%	27%	28%	34%	24%	26%
No COD		**PBM 1**	**PBM 3**	**PBM 4**	**PBM 5**	**PBM 6**	**Total of PBMs**
Independent Urban Pharmacy	All Claims Total	3,115	19,823	570	825	13,758	38,091
	No. Negative Generic Claims	406	6,313	199	225	4,483	11,626
	% of All Claims	13%	32%	35%	27%	33%	31%
	No. Negative Brand Claims	12	35	4	4	1	56
	% of All Claims	0%	0%	1%	0%	0%	0%
	Total Negative Claims	418	6,348	203	229	4,484	11,682
	% of All Claims	13%	32%	36%	28%	33%	31%

Exhibit 57: Volume of Negative Net Income Claims (Generic, Brand and Total) for the Case Study Pharmacies - $10 COD Assumed

COD $10		PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	All Claims Total	2,177	27,246	1,685	7,037	13,974	52,119
	No. Negative Generic Claims	1,237	20,130	912	4,264	9,436	35,979
	% of All Claims	57%	74%	54%	61%	68%	69%
	No. Negative Brand Claims	227	2,591	204	534	1,016	4,572
	% of All Claims	10%	10%	12%	8%	7%	9%
	Total Negative Claims	1,464	22,721	1,116	4,798	10,452	40,551
	% of All Claims	67%	83%	66%	68%	75%	78%
COD $10	Brand Drugs	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	All Claims Total	3,115	19,823	570	825	13,758	38,091
	No. Negative Generic Claims	1,878	14,193	367	473	9,093	26,004
	% of All Claims	60%	72%	64%	57%	66%	68%
	No. Negative Brand Claims	211	2,359	33	58	1,846	4,507
	% of All Claims	7%	12%	6%	7%	13%	12%
	Total Negative Claims	2,089	16,552	400	531	10,939	30,511
	% of All Claims	67%	83%	70%	64%	80%	80%

By increasing the COD to $15 (Exhibit 58) negative income claims increased, with generic claims primarily responsible for increasing their overall percentage of the total. For example, the rural pharmacy generic negative claims increased from 69% to 75% of all of the pharmacy's claims, a 6 percentage point increase, while the negative brand claim percentage remained unchanged at 9%.

Exhibit 58: Volume of Negative Net Income Claims (Generic, Brand and Total) for the Case Study Pharmacies - $15 COD Assumed

COD $15		PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	All Claims Total	2,177	27,246	1,685	7,037	13,974	52,119
	No. Negative Generic Claims	1,417	21,004	1,011	4,759	8,292	36,483
	% of All Claims	65%	77%	60%	68%	59%	70%
	No. Negative Brand Claims	263	2,437	287	579	453	4,019
	% of All Claims	12%	9%	17%	8%	3%	8%
	Total Negative Claims	1,680	23,441	1,298	5,338	8,745	40,502
	% of All Claims	77%	86%	77%	76%	63%	78%
COD $15		PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Urban Pharmacy	All Claims Total	3,115	19,823	570	825	13,758	38,091
	No. Negative Generic Claims	2,144	15,027	394	565	9,464	27,594
	% of All Claims	69%	76%	69%	68%	69%	72%
	No. Negative Brand Claims	222	2,343	46	58	1,779	4,448
	% of All Claims	7%	12%	8%	7%	13%	12%
	Total Negative Claims	2,366	17,370	440	623	11,243	32,042
	% of All Claims	76%	88%	77%	76%	82%	84%

The impact of a $15 COD showed that generic drug reimbursement was too small to absorb increases in unreimbursed dispensing costs. This can be seen in Exhibit 59, which shows most of the average Net Incomes per claim were at or below $5 if a $10 COD was assumed.

Exhibit 59: Average Net Income per Claim for the Case Study Pharmacies if a $10 COD Assumed

COD $10	Metric	PBM 1	PBM 3	PBM 4	PBM 5	PBM 6	Total of PBMs
Independent Rural Pharmacy	Total Claims	2,177	27,246	1,685	7,037	13,974	52,119
	Net Income	$11,598	($5,322)	$3,374	$23,806	$50,093	$83,550
	Avg. Net Income/Claim	$5.33	($0.20)	$2.00	$3.38	$3.58	$1.60
COD $10	**Metric**	**PBM 1**	**PBM 3**	**PBM 4**	**PBM 5**	**PBM 6**	**Total of PBMs**
Independent Urban Pharmacy	Total Claims	3,115	19,823	570	825	13,758	38,091
	Net Income	$17,943	($5,508)	$4,718	$1,433	($21,694)	($3,108)
	Avg. Net Income/Claim	$5.76	($0.28)	$8.28	$1.74	($1.58)	($0.08)

The impact of COD assumptions on pharmacy profitability were further illustrated by limiting COD as a factor. This was accomplished by setting the COD equal to the average dispensing fee paid by each PBM. If a $10 COD was assumed, the Net Income as a percentage of Gross Income for the target pharmacies was below 10% for most of the individual PBMs as well as in the aggregate for all PBMs in total (Exhibit 60).

Exhibit 60: Net Income as a Percent of Gross Income for the Case Study Pharmacies if a $10 COD Assumed

COD $10	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	$21,770	$272,460	$16,850	$70,370	$139,740	$521,190
	Total Cost	**$138,291**	**$1,022,242**	**$155,488**	**$356,789**	**$785,430**	**$2,458,240**
	Net Income	**$11,598**	**($5,322)**	**$3,374**	**$23,806**	**$50,093**	**$83,550**
	Net Income % of Gross Income	**7.7%**	**-0.5%**	**2.1%**	**6.3%**	**6.0%**	**3.3%**
COD $10	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	$31,150	$198,230	$5,700	$8,250	$137,580	$380,910
	Total Cost	**$107,940**	**$868,408**	**$47,672**	**$32,988**	**$726,260**	**$1,783,268**
	Net Income	**$17,943**	**($5,508)**	**$4,718**	**$1,433**	**($21,694)**	**($3,108)**
	Net Income % of Gross Income	**14.3%**	**-0.6%**	**9.0%**	**4.2%**	**-3.1%**	**-0.2%**

When the cost to dispense was negated by setting the cost to dispense at each PBM's average dispensing fee, the Net Income as a percentage of Gross Income increased significantly (Exhibit 61 below) ranging from 9 to 23 percentage points across the six PBMs. In the aggregate, the rural pharmacy values increased by 18 percentage points and the urban pharmacy values increased by 19 percentage points.

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.

Pharmacy MAC Appeals Analysis

Overview

The objective of the appeals review was to review data submitted to the Department of Revenue under RCW 19.340.100(4)(b), if any, for patterns or trends in the denials of internal pharmacy benefit manager appeals involving pharmacies with fewer than 15 retail outlets within the State of Washington under their corporate umbrellas (hereafter referred to as "SMALL pharmacies"). In absence of this data from the Department of Revenue, the Data was obtained directly from the PBMs for this analysis. The scope of our review included the following components:

- For calendar years 2014 and 2015, Maximum Allowable Cost (MAC) appeals were analyzed aong with the frequency of successful appeals and the types of pharmacies most likely to generate appeals.
- The analysis estimated the percentage of transactions which are likely to generate appeals under the provisions of ESSB 5857.
- The analysis considered and made recommendations regarding what documentation OIC should require from the parties to facilitate the OIC resolution of submitted appeals.

Key Findings

- OIC is likely to receive 13,500 – 15,500 appeals on average annually. This estimate assumes that PBMs do not change their current business practices, which, if they do, could affect the appeals volume they receive.
- SMALL pharmacies generated a range of appeals, as a percentage of total claims volume, from 0.02% – 2.24% with an overall average of 0.19%.
- Of the SMALL pharmacies that submitted an appeal, 17% (44) generated 80% of the appeals.
- These 44 SMALL pharmacies received PBM ingredient cost reimbursement that exceeded NADAC rates in aggregate; however, this variance represented less than 7% of the overall statewide positive variance to NADAC.
- Comparing reimbursement of these 44 SMALL pharmacies to benchmark MAC List 1, five of the six PBMs reimbursed the 44 SMALL pharmacies at a more favorable rate than the statewide average. Comparing reimbursement of these 44 SMALL pharmacies to benchmark MAC List 2, four of the six PBMs reimbursed the 44 SMALL pharmacies at a more favorable rate than the statewide average.
- All but one PBM had reimbursement variances to benchmark MAC List 1 that were significantly more positive for the 44 pharmacies than for all Washington pharmacies. Four of the six pharmacies' reimbursement variances to benchmark MAC List 2 were significantly more positive for the 44 pharmacies than for all Washington pharmacies.
- Of the 44 pharmacies, nine were urban locations, five were in suburban locations, and 30 were in rural locations. By geography, 12 were in Eastern Washington (east of the Cascade Mountains), 10 were in the Central I-5 corridor (defined as King, Pierce, Snohomish, and Thurston Counties), and 22 were in the rest of western Washington.
- Of the SMALL pharmacies that submitted an appeal, 37% (108) submitted fewer than 10 appeals over the Study period.

- PBM 4 accounted for 59% of the appeal volume for SMALL pharmacies over the study period, with a notable increase over the study period.
- PBM denials ranged from 77% to 94% of MAC appeals, with an average of 87%.
- The majority of appeals related to lower cost drugs. The vast majority of appeals (89%) came from claims where the ingredient cost amount reimbursed was less than $50.00. Ingredient cost ranged from pennies to over $500 per prescription.

Method

Data Request

OIC solicited appeals data for calendar years 2014 and 2015 from the six PBMs that account for the largest volume of pharmacy claims for fully-insured health plan enrollees in the state of Washington. The appeals data request was limited to the scope of OIC oversight as specified in WA Senate Bill ESSB 5857 including appeals for MAC multi-source generic drugs dispensed by pharmacies in the state of Washington with utilization limited to fully-insured, commercial health plans.

Exhibit 62 lists the data elements requested and data received by each PBM (see Appendix II for the data request).

Exhibit 62: PBM Appeals Data Request

Appeals Data Type	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
A. A full listing of pharmacy pricing appeals for the January 1, 2014 through December 31, 2015 period. The list should include, but is not limited to:	Provided 7/1/14–12/31/15[1]	X	Provided 6/12/14–12/31/15[1]	X	X	X
i. Explanation of all form fields	X	X	X	X	X	X
ii. Data required from the pharmacy by the PBM[2]	X	X	X	X	X	X
iii. Type of appeal	X	X	X	X	X	X
iv. Appeal determination	X	X	X	X	X	X
v. Appeal comments	X	X	X	X	X	X
vi. Appeal date	X	X	X	X	X	X
vii. Determination date	X	X	X	X	X	No[1]
viii. Determination letter/notification	X	X	X	X	X	X
ix. Pharmacy type	No[1]	X	X	X	X	X
x. If determination was denied, include the reason for the denial and the NDC of the drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the MAC (RCW 19.340.100[4][c])	X	X	X	X	X	X

Appeals Data Type	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
xi. If the appeal was upheld, include verification that an adjustment was made no later than one day after the date of determination and that all similarly situated pharmacies in the state were updated as well (RCW 19.340.100[4][c])	No[1]	X	X	X	X	X
B. Provide a copy of appeals policy, including the process for appeals, the internal timing requirements and the teams that manage the process.	X	X	X	X	X	X

Notes:

[1] Exhibits and analysis were adjusted to account for these discrepancies and noted.

[2] Data was not consistent across PBMs.

Exhibit 63 shows the total number of reported appeals for the Study period.

Exhibit 63. Total Appeals Reported, CYs 2014 and 2015

	PBM 1	PBM 2	PBM 3*	PBM 4	PBM 5	PBM 6	TOTAL
Appeals Submitted	3,048	11,444	9,486	78,015	779	8,944	111,716
Removed claims	379	1,460	0	5,180	0	0	7,019
NET Appeal for Study Set	2,669	9,984	9,486	72,835	779	8,944	104,697

*Note: PBM 3 provided only one MAC list due to the size and complexity of providing all of them. The MAC list they provided is the one that generated the greatest number of appeals.

Upon review, 7,019 of the reported appeals were excluded from our analysis for the following reasons:

- Some PBMs provided "non-MAC" appeals, which were not part of the Study.
- Some PBMs provided duplicate submissions of appeals or appeals on claims that had been reversed. These were viewed as administrative errors and were excluded them from this Study.

To conduct the analysis, the appeals data was partitioned into the following two data sets:

- **SMALL Pharmacies:** Appeals from independent and chain pharmacies with fewer than 15 chain store locations in the state of Washington. This set aligned to the oversight of OIC's authority under ESSB 5857 and the Study focused on these pharmacies through the analysis in this section.
- **LARGE Pharmacies:** Appeals from pharmacy chains with 15 or more pharmacies in the state of Washington. For purposes of this Study, different pharmacy chains with the same ownership were grouped together.

In the submitted appeals data, the PBMs generally identified three types of appeals: independent, Pharmacy Services Administrative Organizations (PSAO), and chains. PSAO appeals appeared to contain both independent and chain pharmacies. The analysis allocated the PSAO appeals based on a best estimate of which pharmacy chains contained more than 15 pharmacies in the state of Washington. Where it was unclear whether a pharmacy chain may contain 15 or more stores in the State of Washington, the pharmacy's website listing of locations was referenced to make the determination.

Other than the excluded appeals described above, all other reported appeals were counted as relevant in this Study, including multiple appeals submitted by a pharmacy relating to a single prescription that includes an initial dispensing and subsequent refills. In these cases, the analysis identified two appeal approaches used by pharmacies:

- For a single prescription (which could include the initial fill and refills), some pharmacies submitted appeals on the initial fill and the subsequent refills, Because each refill did reflect a different date of service (fill date), they were counted as a unique interaction with a PBM and thus a unique appeal
- Some pharmacies submitted multiple appeals for the same prescription and date of service. When provided, these were all treated as unique appeals in the analysis.

Data Analysis

Appeal Types, Frequency, and Estimated Number of Expected OIC Appeals

Control totals

To calculate the rate of appeals as a percent of total claims during the Study period, the analysis compared the aggregate appeals data to the aggregate claims data submitted for the MAC pricing analysis portion of this Study. Only aggregate numbers were compared; actual claims were not linked to individual appeals for this analysis. Because different data sets were used, the following adjustments were applied:

- **Time period:** As requested, the PBMs submitted appeals data for calendar years 2014 and 2015; however, claims data request was for only calendar year 2015. For purposes of determining the rate of appeals as a percent of total claims, only 2015 appeals data was utilized.
- **Funding type/Line of business:** The appeals data request was limited to fully-insured, commercial-based claims appeals. PBM 1 was unable to separate the appeals by funding type and line of business, so its data reflects other appeals that might not be subject to OIC's appeals process and may result in an overstated appeals incidence rate for this PBM.

The claims data also presented some analytical challenges, as PBM 3 and PBM 6 were unable to delineate the fully-insured, commercial claims. As a result, their appeal incidence rates may be under-stated.

All data are shown in the aggregate, and split between the LARGE pharmacy and SMALL pharmacy categories (Exhibit 64).

Exhibit 64. Claims and Appeals total for Study Set, partitioned by SMALL / LARGE pharmacies

	PBM1	PBM2	PBM3	PBM4	PBM5	PBM6	TOTAL
Time Period of Claims	1/1/15 - 12/31/15	1/1/15 - 12/31/15	1/1/15 - 12/31/15	1/1/15 - 12/31/15	1/1/15 - 12/31/15	1/1/15 - 12/31/15	
Claims Type	FI Only	FI Only	FI + Other	FI Only	FI only	FI + Other	
TOTAL Rx's to Study Set (FI Comm)	250,801	444,285	10,042,278	2,283,121	7,990,629	12,263,692	33,274,806
Rx for LARGE pharmacies	191,263	398,565	7,444,500	1,896,528	6,491,283	9,193,392	25,615,531
Rx for SMALL pharmacies	59,538	45,720	2,597,778	386,593	1,499,346	3,070,300	7,659,275
percent Small Pharmacies	24%	10%	26%	17%	19%	25%	23%
Time Period of Appeals	6/12/14 - 12/31/15	1/1/14 - 12/31/15	1/1/14 - 12/31/15	1/1/14 - 12/31/15	1/1/14 - 12/31/15	7/1/14 - 12/31/15	
TOTAL Appeals to Study Set (FI Comm)	2,669	9,984	9,486	72,835	779	8,944	104,697
2014 Appeals	959	4,139	2,039	11,881	376	3,450	22,844
2015 Appeals	1,710	5,845	7,447	60,954	403	5,494	81,853
2015 Appeals	1,710	5,845	7,447	60,954	403	5,494	81,853
Large Pharmacies	425	5,344	6,050	52,276	124	2,910	67,129
Small Pharmacies	1,285	501	1,397	8,678	279	2,584	14,724
SMALL as a percent	75%	9%	19%	14%	69%	47%	18%
Appeals as percent of claims for:							
TOTAL Study Set (FI Comm)	0.68%	1.32%	0.07%	2.67%	0.01%	0.04%	0.25%
SMALL pharmacies	2.16%	1.10%	0.05%	2.24%	0.02%	0.08%	0.19%

Observations

- Given the volume of prescriptions in the state of Washington, different PBMs generated different level of appeals in calendar year 2015. Across the six PBMs, between 0.01% – 2.67% of all claims produced appeals at an average rate of 0.25%. The rate was lower when viewing only the SMALL pharmacies, which produced a rate of 0.02% – 2.24% of claims generated appeals and an overall average rate of 0.19%.
- Appeals generated by PBMs had varying levels of exposure to SMALL pharmacies, which could reflect MAC management practices. For example, PBM 1 had 75% of appeals coming from SMALL pharmacies while PBM 2 had only 9% coming from SMALL pharmacies.

Given the above observations, the Study concludes that OIC is likely to receive more appeals for some PBMs than others. If so, OIC may wish to reaching out individually to PBMs with higher appeal incidence rates to identify root-causes for the purpose of reducing the number of future appeals.

PBM Denial Rates

To calculate appeal denial rates, the self-reported PBM appeals data for the two-year Study period was reviewed and partitioned into two study sets: one for LARGE pharmacies and another for SMALL pharmacies. The appeal denial rates were calculated as the ratio of the denied appeals to total appeals (Exhibit 65).

Exhibit 65. PBM Appeal Denial Rates, CYs 2014 and 2015

Time Period of Appeals	PBM1* 6/12/14 - 12/31/15	PBM2 1/1/14 - 12/31/15	PBM3 1/1/14 - 12/31/15	PBM4 1/1/14 - 12/31/15	PBM5 1/1/14 - 12/31/15	PBM6 7/1/14 - 12/31/15	TOTAL
TOTAL Appeals for Study Set (FI Comm)	2,669	9,984	9,486	72,835	779	8,944	104,697
Appeals for LARGE Pharmacies	846	9,517	7,563	62,176	151	2,975	83,228
Appeals for SMALL Pharmacies	1,823	1,010	1,923	10,659	628	5,969	22,012
Chain	66	181	213	1,988	22	114	2,584
PSAO	22	15	13	6	-	529	585
Independent	1,699	811	1,697	8,665	606	5,326	18,804
Unknown	36	3	-	-	-	-	39
Appeals Denied							
TOTAL Study Set (FI Comm)	2,016	8,957	8,598	67,420	688	7,942	95,621
LARGE Pharmacies (15+ Pharmacies)	610	8,103	6,788	57,768	142	2,966	76,377
SMALL Pharmacies (<15 Pharmacies)	1,406	854	1,810	9,652	546	4,976	19,244
Chain	37	161	197	1,738	16	110	2,259
PSAO	13	14	9	6	-	313	355
Independent	1,333	676	1,604	7,908	530	4,553	16,604
Unknown	23	3	-	-	-	-	26
Denial Rates							
TOTAL Study Set (FI Comm)	76%	90%	91%	93%	88%	89%	91%
LARGE Pharmacies (15+ pharmacies)	72%	85%	90%	93%	94%	100%	92%
SMALL Pharmacies (<15 pharmacies)	77%	85%	94%	91%	87%	83%	87%

*PBM 1 could not provide the breakout between FI Commercial appeals and other (Medicare/Medicaid), so might be overstated.

Observations:

- While appeal denial rates varied by PBM, most were 85% or higher with the exception of PBM 1 which had a notably lower aggregate denial rate of 76%.
- The majority of SMALL pharmacy appeals came from independent pharmacies.
- No clear pattern emerged regarding the difference in denial rates between SMALL and LARGE pharmacies. Two of the six PBMs, however, had higher denial rates for SMALL pharmacies than for LARGE pharmacies.

Appeals Over Time

Exhibit 66 shows the appeal volume over time for all six PBMs during the two-year Study period. Two PBMs, however, did not submit appeal data for the entire Study period:

- PBM 1 did not report appeals data for the January 1, 2014 – July 1, 2014 time period.
- PBM 3 did not report appeals data for the January 1, 2014 – June 12, 2014 time period.

Exhibit 66: Number of SMALL Pharmacy Appeals By Month, CYs 2014 and 2015

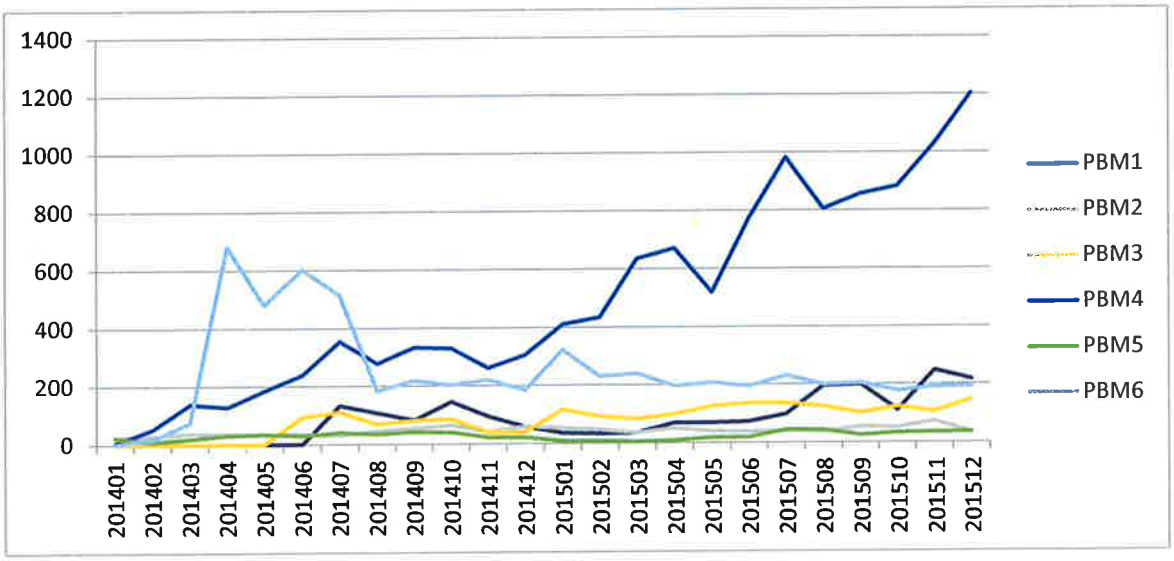
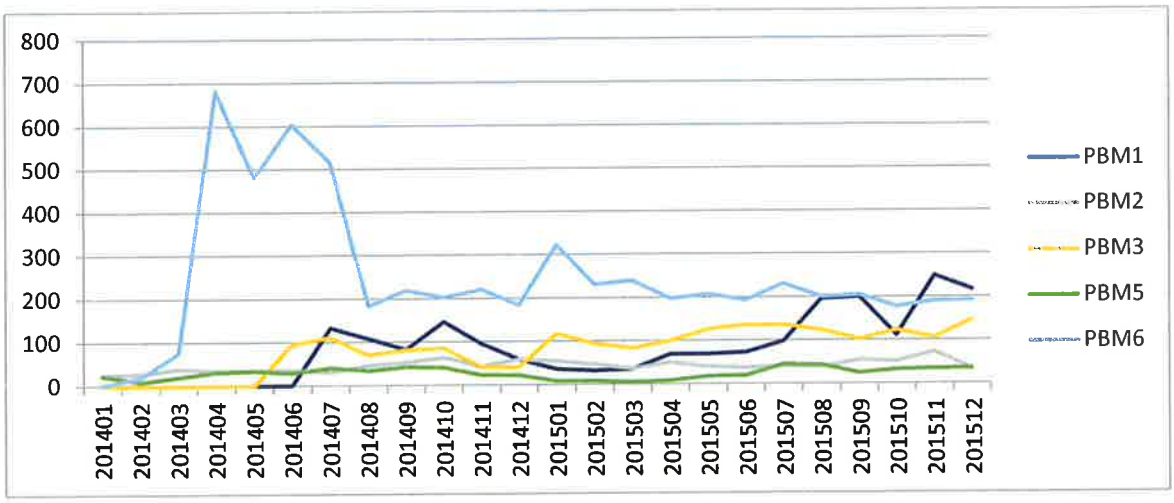


Exhibit 66 shows that PBM 4 had a large increase in the number of appeals per month starting in June 2015 – the same time ESSB 5857 was adopted – and continuing through the end of 2015.

Exhibit 67 presents the same data as Exhibit 66 but excludes the data for PBM 4 to better show the variation across the other PBMSs that is less visible in Exhibit 66 due to the scale of the PBM 4 results.

Exhibit 67: Number of SMALL Pharmacy Appeals By Month (Excluding PBM 4), CYs 2014 and 2015

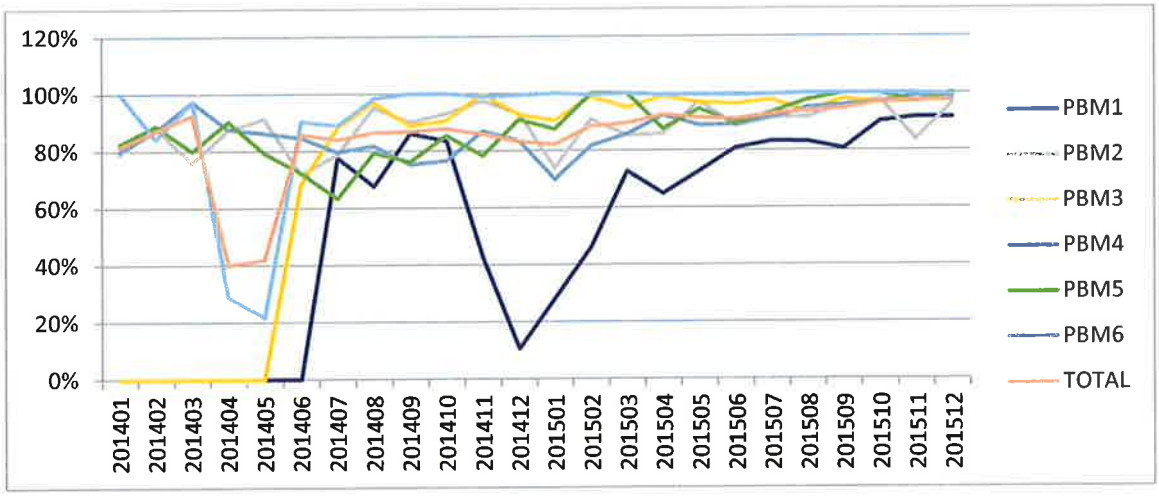


Observations

- Appeal volumes for PBM 1 were initially higher than 100 per month, then fell below 100 for a 9-month period. During the second half of 2015, PBM 1 had notably higher appeals volume compared to its appeals volume in 2014 and the first half of 2015.
- Compared to the other PBMs, PBM 2 and PBM 5 maintained low appeal volume throughout the Study period.
- PBM 3 saw slow growth through 2015 in the volume of appeals.
- Appeal volumes for PBM 6 quickly grew to a high level by April 2014. Shortly after implementation of SB 6137 in June 2014, appeals volume for PBM6 subsided to a level that it sustained for the remainder of the study period.

The analysis calculated and reviewed the monthly appeal denial rates for each PBM to determine if there were any seasonal patterns. Exhibit 68 shows the monthly denial rates for SMALL pharmacies only over the Study period.

Exhibit 68: SMALL Pharmacy Denial Rates, CYs 2014 and 2015



Observations:

- Denial rates for PBM 1, PBM 2 and PBM 4 each fell around January 2015 and increased thereafter.
- While PBM 2 and PBM 4 returned to their normal denial-rates rather quickly, PBM 1 took longer to do so.

There was no seasonal pattern found for appeal denial rates. While experience of HMA and its subcontractor tells them that a PBM's management of its MAC list and/or quarterly changes in manufacturer pricing may impact the number of appeals submitted, this is not clearly apparent in the data nor chart above.

Appeal Concentration

The analysis also reviewed the appeals generated by different pharmacies in Washington state to determine whether appeals were spread evenly across all pharmacies or whether a subset of

pharmacies generated a larger number of appeals. Exhibit 69 shows the number and percentage of LARGE and SMALL pharmacies in Washington that submitted appeals.

Exhibit 69: Number of SMALL and LARGE Pharmacies in Washington

	Pharmacies Submitting No Appeals	Pharmacies with Appeals Submitted	TOTAL	Percent Submitting Appeal
LARGE	480	291	771	38%
SMALL	291	254	545	47%
TOTAL	**771**	**545**	**1,316**	**41%**

For SMALL pharmacies, the appeals were summarized at a pharmacy level, and that data set was organized in a descending order. Manipulating the data in this way allowed for a review of the concentration of appeals by SMALL pharmacies.

With roughly 79% of the total appeal volume coming from LARGE pharmacies, further analysis was conducted to determine whether appeals from SMALL pharmacies were concentrated in several pharmacies or dispersed among the group (Exhibit 70). 80% of the appeals submitted by SMALL pharmacies came from only 44 (17%) of the SMALL pharmacies.

Exhibit 70: SMALL Pharmacy Appeal Concentration, CYs 2014 and 2015

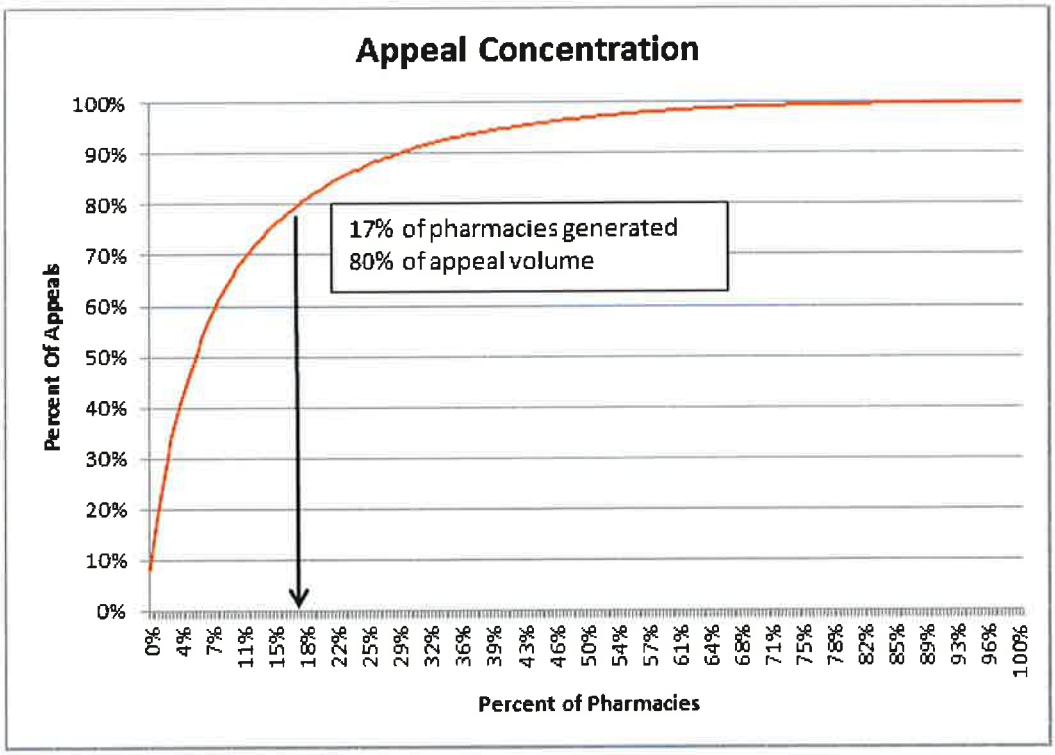


Exhibit 71 shows the distribution of appeals for the top 44 appealing SMALL pharmacies across the six PBMs.

Exhibit 71: PBM Distribution of Appeals From Top 44 Appealing SMALL pharmacies, CYs 2014 and 2015

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6	TOTAL
Top 44 Pharmacies	1,141	560	1,367	8,473	436	5,604	17,581
Distribution	6%	3%	8%	48%	2%	32%	100%

Exhibit 72 compares the magnitude of reimbursement variances between the top 44 appealing SMALL pharmacies and all pharmacies in Washington. The percentages represent the variance in the paid ingredient cost to the pharmacy and the benchmark price relative to the paid ingredient cost.

Exhibit 72: Ingredient Cost Reimbursement by PBM Paid to the Top 44 Appealing SMALL Pharmacies Compared to All Pharmacies, CYs 2014 and 2015

Comparison of the Top Appeals SMALL Pharmacies to All Pharmacies						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Top Appeals SMALL Pharmacy Group Variance to NADAC % of Paid Ingredient Cost (PIC)	0.4%	0.2%	0.2%	0.1%	0.5%	0.6%
All Pharmacies Variance to NADAC % of PIC	13.4%	-5.4%	5.0%	3.9%	9.9%	3.9%
Top Appeals SMALL Pharmacy Group to Benchmark MAC 1 % of PIC	0.6%	-0.3%	-0.2%	-0.3%	0.0%	0.1%
All Pharmacies Variance to Benchmark MAC 1 % of PIC	20.5%	-25.8%	-6.8%	-7.7%	-0.2%	-10.3
Top Appeals SMALL Pharmacy Group to Benchmark MAC 2 % of PIC	0.8%	-0.3%	-0.1%	-0.3%	0.2%	0.1%
All Pharmacies Variance to Benchmark MAC 2 % of PIC	24.2%	-31.4%	-2.7%	-8.9%	4.4%	-8.9%

Due to data limitations, that analysis was unable to match appeal claims to the NADAC price list for further analysis.

Observations:

- Of all the SMALL pharmacies that submitted appeals to the PBMs, 17% (or 44 pharmacies) generated roughly 80% of all the appeals volume. If the appeals volume had been evenly distributed across all pharmacies submitting appeals, Exhibit 69 would have presented a 45-degree line.
- The top 44 appealing SMALL pharmacies were primarily appealing reimbursements from PBM 4 and PBM 6 (with 48% and 32% of the volume respectively).
- For drugs subject to NADAC pricing, all of the top 44 appealing SMALL pharmacies were paid, in aggregate, at higher rates than NADAC, but at a lower rate than the average for all Washington pharmacies.

- For drugs included on the benchmark MAC List 1, all but one PBM paid the top 44 appealing SMALL pharmacies' ingredient costs at a higher rate than the average for all pharmacies statewide.
- For drugs included on the benchmark MAC List 2, four of the six PMBs paid the top 44 appealing SMALL pharmacies' ingredient costs at a higher rate than the average statewide pharmacies.
- Of the top 44 appealing SMALL pharmacies, 35 were independents, eight were considered chains and one was considered a PSAO.
- Of the top 44 appealing SMALL pharmacies, nine were in urban locations, five were in suburban locations, and 30 were in rural locations. By geography, 12 were in eastern Washington (east of the Cascades), 10 were in the central I-5 corridor (defined as King, Pierce, Snohomish, and Thurston Counties), and 22 were in the rest of western Washington.
- Of SMALL pharmacies submitting appeals, 37% (108) submitted fewer than 10 appeals over the Study period.

OIC should consider individualized outreach to the relatively small number of pharmacies that appear to be submitting the majority of appeals to identify root causes and solutions that might reduce the number of future appeals from these pharmacies.

Price Review of Appeals

Using the claims data provided for the MAC pricing analysis when available, the analysis matched appeals to the claims payment data set and reviewed the reimbursement paid to the pharmacies on those claims. The mapping of the appeals and claims data presented the following challenges:

- Claims data could not be matched to appeals data for PBM 3 and PBM 6 due to the limitations of the data fields that were provided in the appeals data set.
- Approximately 5,170 appeal records from 2015 could not be tied to the claim files. Data such as date-of-service, National Drug Code (NDC), and National Counsel for Prescription Drug Programs (NCPDP) number was used to match claims, but there were inconsistencies in these two data sets that did not allow all claims to be matched.
- Because the claims file only contained claims with dates of service from 2015, only the appeals with 2015 dates of service were reviewed.

Exhibit 73 summarizes the distribution of appeals by the ingredient cost amount paid to the pharmacy.

Exhibit 73: Distribution of Appeals Based on Pharmacy Reimbursement (All Pharmacies), CY 2015

Paid Ingredient Amount to Pharmacy	Total Appeals	Appeal Distribution	Appeal Distribution (Cumulative)	Total Denied Appeals	Denied Appeal Distribution	Denied Appeal Distribution (Cumulative)	Denial Rate
$0-$4	8,988	14.1%	14.1%	8,050	13.5%	13.5%	90%
$4-$8	7,085	11.1%	25.2%	6,314	10.6%	24.1%	89%
$8-$12	18,145	28.4%	53.6%	17,500	29.3%	53.4%	96%
$12-$16	8,342	13.1%	66.7%	7,912	13.3%	66.7%	95%
$16-$20	4,121	6.5%	73.2%	3,844	6.4%	73.2%	93%
$20-$30	5,187	8.2%	81.3%	4,843	8.1%	81.3%	93%
$30-$40	3,374	5.3%	86.6%	3,213	5.4%	86.7%	95%

Paid Ingredient Amount to Pharmacy	Total Appeals	Appeal Distribution	Appeal Distribution (Cumulative)	Total Denied Appeals	Denied Appeal Distribution	Denied Appeal Distribution (Cumulative)	Denial Rate
$40-$50	1,584	2.5%	89.1%	1,490	2.5%	89.2%	94%
$50-$60	1,242	1.9%	91.1%	1,186	2.0%	91.2%	95%
$60-$70	874	1.4%	92.4%	810	1.4%	92.5%	93%
$70-$80	908	1.4%	93.9%	850	1.4%	93.9%	94%
$80-$90	338	0.5%	94.4%	295	0.5%	94.4%	86%
$90-$100	450	0.7%	95.1%	405	0.7%	95.1%	89%
$100-$125	642	1.0%	96.1%	609	1.0%	96.1%	94%
$125-$150	570	0.9%	97.0%	526	0.9%	97.0%	92%
$150-$175	275	0.4%	97.5%	238	0.4%	97.4%	86%
$175-$200	353	0.6%	98.0%	326	0.5%	98.0%	91%
$200-$225	408	0.6%	98.7%	396	0.7%	98.6%	97%
$225-$250	114	0.2%	98.8%	112	0.2%	98.8%	98%
$250-$275	79	0.1%	99.0%	71	0.1%	98.9%	90%
$275-$300	113	0.2%	99.1%	105	0.2%	99.1%	93%
$300-$325	40	0.1%	99.2%	36	0.1%	99.2%	90%
$325-$350	35	0.1%	99.3%	33	0.1%	99.2%	94%
$350-$375	101	0.2%	99.4%	100	0.2%	99.4%	98%
$375-$400	43	0.1%	99.5%	41	0.1%	99.5%	95%
$400-$425	18	0.0%	99.5%	18	0.0%	99.5%	100%
$425-$450	46	0.1%	99.6%	46	0.1%	99.6%	100%
$450-$475	27	0.0%	99.6%	26	0.0%	99.6%	96%
$475-$500	17	0.0%	99.7%	16	0.0%	99.6%	94%
$500 +	223	0.3%	100.0%	215	0.4%	100.0%	96%
TOTAL	**63,742**	**100.0%**		**59,626**	**100.0%**		**93%**

Observations:

- The majority of appeals were on lower cost drugs: 89% of the appeals came from claims where the pharmacy was reimbursed less than $50.00 for the ingredient cost of the drug. It is important to note that this cost distribution represented the PBM reimbursement paid to the pharmacy – not necessarily the cost that the pharmacy requested for reimbursement.
- The appeal denial distribution followed the appeal distribution closely, generally within one percentage point at every band of drug cost.
- There was no discernable pattern of differing denial rates at different price levels. The denial rates were almost always above 90%.

Estimate of the Number of appeals OIC will receive

The Study estimates that OIC is likely to receive 13,500 – 15,500 appeals on average annually. This estimate is based on the following assumptions:

- All denied appeals will come to OIC and all pharmacies will use the second-level appeals process. While some pharmacies might reconsider their appeal based on information provided by the PBM, the Study conservatively assumed the OIC appeal process would be used for all denied appeals. Although PBMs provide an alternate NDC roughly 90% of the time when denying an appeal, the pharmacy could disagree and utilize the OIC process. No reduction in potential appeals due to pharmacies feeling satisfied with PBM responses was assumed.
- PBMs will maintain the business practices that generated the appeals during the Study period.
- The total number of denied appeals reported for calendar years 2014 and 2015 for SMALL pharmacies was 19,244 with a majority of these coming from Independent pharmacies. Although this study period spans 24 months, the Study only analyzed the ending 18-months of data. This was because two PBMs did not submit appeals data for first six months of 2014, which was prior to implementation of SB 6137. This yielded an average of 1,069 denied appeals per month, or roughly 12,828 annually. Although PBM 1 was unable to separate fully-insured commercial appeals from non-fully insured appeals, they only made up 7% of the total appeals over the Study period.
- The fully-insured population will remain relatively stable from 2015 to 2017. Large swings in the insured population, including growth in individual health care plans, can affect the estimate. If there is large growth in these areas, the appeal growth would be in-line with growth of membership in these plans.
- There will be modest growth in the number of drugs that are subject to the MAC appeals process. Industry utilization trends for generic drugs are in the low single digits. Increases in generic dispensing rates have stabilized due to fewer blockbuster patent expirations. the Study estimates that these two factors combined produce an estimated increase of 5%–10% of generic drug utilization for 2017.
- The high rate of appeals for PBM 4, compared to the other PBMs, will continue. The Study does not assume that PBM 4 will adjust its business practices to change the rate of appeals from rate observed during the Study period. If PBM 4 changes business practices, this could substantially decrease the number of appeals that the OIC receives.
- A 10% margin was added to the upper end of the estimate to account for appeal volatility. Also, because the study set of appeals came only from six PBMs (which cover 98% of the fully-insured commercial business in Washington state), the Study's margin assumption of 10% should provide additional coverage for the remaining portion of fully-insured commercial business not analyzed in this Study.

Recommendations on the most useful documents for OIC to require from parties to an appeal

The Study reviewed the types of data that each PBM reported that it requests from a pharmacy to support the appeals process as well as what the PBM reports back to the pharmacy following a determination. Exhibits 74 and 75 illustrate each of the data types reported.

Exhibit 74: PBM Required Data from Pharmacies to Support PBM Appeal Process

Data Element	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Pharmacy Name, Chain/Affiliation Code	X		X	X		

Data Element	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Pharmacy Contact Information	X		X	X		
NPI/NCPDP	X	X	X	X		X
Prescription Number	X	X	X	X		X
Date of Service	X	X	X	X		X
Drug Identification (i.e., NDC, GPI, Name, Strength) - *Not all items required by all PBMs*	X	X		X	X	
BIN/PCN		X		X		
Patient Information			X			
Pharmacy Comments			X	X		
Pharmacy Drug Acquisition Cost (may also require invoice copy)	X	X		X		X

Exhibit 75: PBM Data Returned to the Pharmacy Following Appeal Determination

Data Returned to Pharmacy	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Appeal Date	X	X	X	X	X	X
Appeal Determination Date	X	X	X	X	X	X
Appeal Determination	X	X	X	X	X	X
Appeal Comments	X	X	X	X	X	X
Alternate NDC	X	X	X	X		X
Effective Date of New MAC Price	X	X	X	X		X

Based on a review of the materials provided and taking into consideration what OIC will need to make a reasonable determination on an appeal, we have included as Appendix III to this report a sample OIC Appeals Form that specifies the data and documentation submissions that we believe OIC should require from the parties to an appeal.

PBM MAC-Related Appeals Processing

Overview

The Study includes a review of the PBM MAC appeals processes to provide the OIC with baseline information. Areas reviewed include:

- Timeframe for appeals resolution by the PBM (in accordance with RCW 19.340.100(3));
- Provision of an alternative National Drug Code (NDC) for denied appeals (in accordance with RCW 19.340.100(4)(b));
- Updates of the MAC pricing within one day (in accordance with RCW 19.340.100(5)(a));
- PBM telephone contacts for submitting MAC appeals (in accordance with RCW 19.340.100(4)(a)); and
- General PBM MAC appeals policy review.

The analysis in this section is intended to be informational only and in no way should be considered a compliance audit. In some cases, the PBM did not provide sufficient data or information to allow the reviewers to gain a full understand of the PBM's processes. Absence of data does not imply that a PBM is not in compliance with the terms of the regulation, but instead is a limitation of the dataset or PBM reporting capabilities. Further, the observations in this report are not intended to be used for enforcement purposes, but merely to show our conclusions based on the information reported.

Further, the appeal data set contains appeal records prior to the enactment of so data may not reflect compliance practices of the PBMs.

Key Findings

- PBMs reported faster resolution of denied appeals than upheld appeals: 84% of denied appeals were processed in 10 days and 4% were not completed within 30 days; 58% of upheld appeals were processed in 10 days and 10% were not completed within 30 days.
- For SMALL pharmacies, the timeframes were longer with 55% processed within 10 days and 85% processed within 30 days.
- Three of the six PBMs provided the alternate NDC greater than 90% of the time.
- Only three PBMs provided information relating to the requirement to update their MAC list pricing within one day of a pricing change. Of those three, MAC lists updates within the one-day timeframe were made between 87% and 100% from the determination date.
- Each PBM in the Study had a telephone contact number for pharmacies to use to speak with PBM personnel, although direct contact with a live PBM representative was not always available on the first call. The majority of the call center hours of operation observed in the Study were 24 hours a day, seven days per week.
- Each PBM provided policies and procedures or a summary of processes that indicated that the PBM had an appeals resolution timeframe within the requirement of the regulation (30 days).
- The PBMs' response times for appeals ranged from three to 30 days
- The window of time a pharmacy had to submit an eligible MAC appeal varied by PBM.
- The Study found that PBMs have sufficient policies and procedures or processes to fulfill the telephonic contact center requirements of RCW 19.340.100.

- All but one PBM in the Study had specific policies and procedures for handling MAC pricing inquiries and appeals, and response times within the parameters required by regulation. Depending on day of the week and time that a placed a call, live assistance was not always available but callers had the option of leaving a voice message. At the time this report was prepared, not all calls were returned.
- In some cases, the administrative intermediaries working on behalf of pharmacies, or, Pharmacy Services Administrative Organizations (PSAOs), aggregated MAC inquiries for submission to PBMs. The "batching" of these requests potentially extended the overall wait time for a pharmacy to receive a response to its MAC appeal.

Method

Data Request

After relevant appeals from "SMALL" pharmacies (defined as pharmacies with fewer than 15 chain store locations) were identified, a subset of MAC appeals data was studied to determine the following:

- Whether the PBM sent an alternative NDC for denied appeals; and
- The timing of MAC list pricing updates based upon approved appeals.

Exhibit 76 lists the subset of MAC appeals data and PBM submission of that data.

Exhibit 76: PBM Data Request and Received

Appeals Data Type	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
i. Appeal determination	Yes	Yes	Yes	Yes	Yes	Yes
ii. Appeal comments	Yes	Yes	Yes	Yes	Yes	Yes
iii. Appeal date	Yes	Yes	Yes	Yes	Yes	Yes
iv. Determination date	Yes	Yes	Yes	Yes	Yes	No[1]
v. Determination letter/notification	Yes	Yes	Yes	Yes	Yes	Yes
vi. If determination was denied, include the reason for the denial and the NDC of the drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the MAC (RCW 19.340.100[4][c])	Yes	Yes	Yes	Yes	Yes	Yes
vii. If the appeal was upheld, include verification that an adjustment was made no later than one day after the date of determination and that all similarly situated pharmacies in the state were updated as well (RCW 19.340.100 [4][c])	No[1]	Yes	Yes	Yes	Yes	Yes

Notes:

[1] Exhibits and analysis were adjusted to account for these discrepancies and noted.

PBMs were asked to submit all policies and procedures related to the MAC appeals process. All but one PBM (PBM 4) submitted specific internal policies and/or procedures addressing appeals, investigations, and disputes over MAC pricing. PBM 4 instead provided a written summary describing its current appeals process. Further, two PBMs submitted excerpts from provider manuals on MAC appeals which serve as general instructions to pharmacies. Every PBM provided telephonic hours of operation and three provided website and email addresses for the submission of appeals. Five PBMs provided data on call center metrics, but they were not specific to MAC appeals. Two PBMs provided call logs, but only one was specific to MAC appeals.

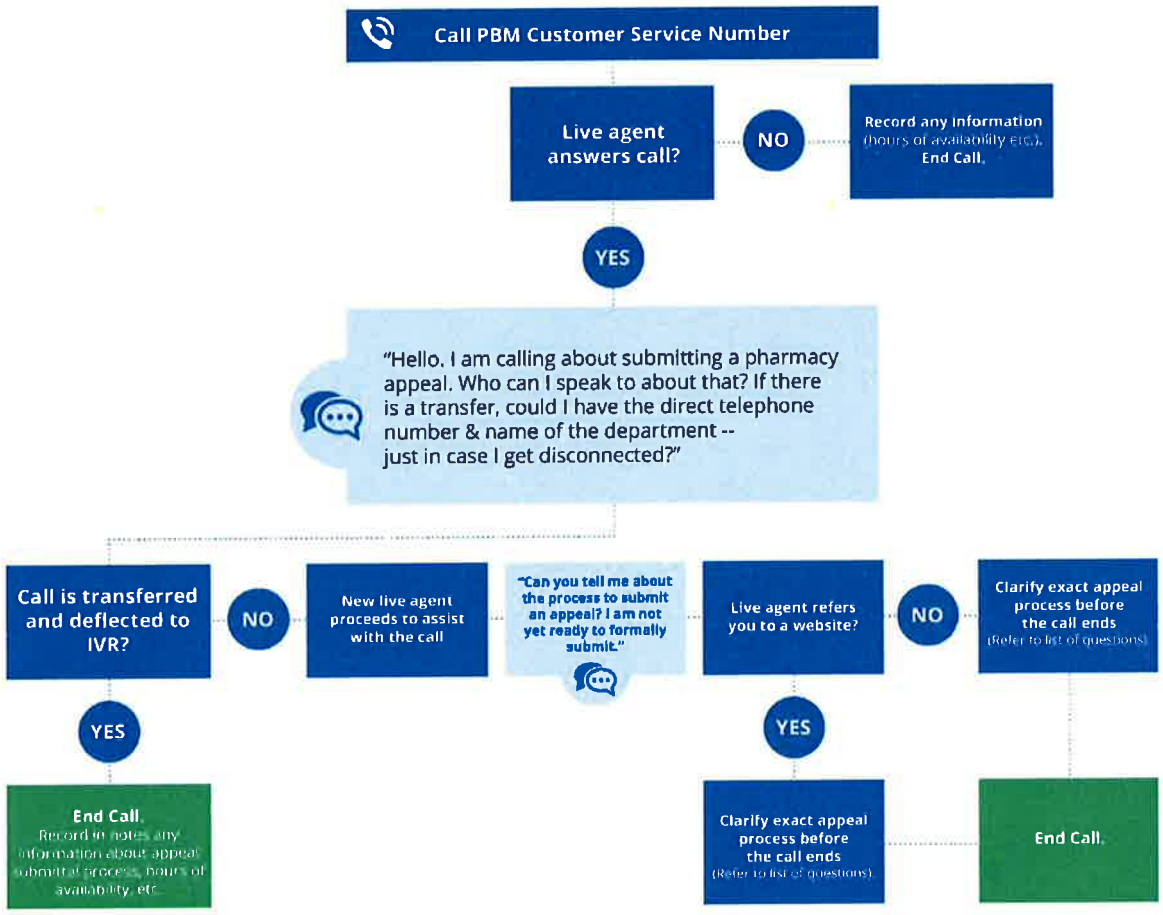
Exhibit 77 summarizes the data request and information from the selected PBMs.

Exhibit 77: Data Request and Information Received

PBM Data Request	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
MAC Appeals P&Ps	Yes	Yes	Yes	No, informal summary	Yes	Yes
Telephonic Contact Info and Availability	Daytime hours/7 days a week	24 hours/ 7 days a week	24 hours/ 7 days a week	24 hours/ 7 days a week	24 hours/ 7 days a week	24 hours/ 7 days a week
Call Center Standards and Metrics for Appeals Process	P&Ps submitted, not actual performance data	No, general Pharmacy Help Desk standards,	No	No, customer Service metrics but not specific to appeals.	No, aggregate book of business for 2014 and 2015	Yes
Call Logs	Yes	No	No	No	Yes	Yes

In addition to reviewing the policies and procedures, a total of 18 secret shopper calls were made (three calls per PBM). Each PBM received calls during regular business hours, after hours, and on the weekend. A process diagram for the secret shopper calls is provided as Exhibit 76 below. The secret shopper presented himself as an assistant calling on behalf of a pharmacist preparing for a MAC appeal. The secret shopper called into the phone number provided by the PBM and verified the hours of operation. Where possible, the secret shopper outlined a process in order to compare to the standards described in that particular PBM's policies and procedures. The secret shopper was not provided with a pharmacy NCPDP/NPI number, specific RX number for a prescription, or patient number and thus was unable to pursue the call as a complete MAC pricing appeal.

Exhibit 78: Flowchart for Secret Shopper Call



Data Analysis

Timeframes for adjudicating MAC appeals

The Study reviewed the number of days that elapsed between the date of appeal and the determination date and sorted the results into four 10-day increment categories summarized in Exhibit 79. (Note: For 8,945 claims, incomplete data prevented us from measuring the time between submission and resolution.)

Exhibit 79: Distribution of Appeals Based on Determination Timing (All Pharmacies), CYs 2014 and 2015

TOTAL Pharmacies	Successful Appeals	Distribution	Unsuccessful Appeals	Distribution	TOTAL	Distribution
0 – 10 days	4,679	58%	73,245	84%	77,924	81%
10 – 20 days	1,867	23%	7,583	9%	9,450	10%
20 – 30 days	736	9%	3,278	4%	4,014	4%
30 or more days	792	10%	3,572	4%	4,364	5%

TOTAL Pharmacies	Successful Appeals	Distribution	Unsuccessful Appeals	Distribution	TOTAL	Distribution
TOTAL	8,074	100%	87,678	100%	95,752	100%

Exhibit 80 summarizes these results for the SMALL pharmacies only.

Exhibit 80. Distribution of Appeals Based on Determination Timing (SMALL Pharmacies), CYs 2014 and 2015

SMALL Pharmacies	Successful Appeals	Distribution	Unsuccessful Appeals	Distribution	TOTAL	Distribution
0 – 10 days	956	55%	11,987	84%	12,943	81%
10 – 20 days	386	22%	1,268	9%	1,654	10%
20 – 30 days	152	9%	457	3%	609	4%
30 or more days	256	15%	565	4%	821	5%
TOTAL	1,750	100%	14,277	100%	16,027	100%

Observations

- From a distribution perspective, PBMs appeared to respond more rapidly to unsuccessful appeals, with a determination in about 84% of unsuccessful appeals occurring in the first 10 days after an appeal was initiated.
- SMALL pharmacies tended to follow the same patterns as all pharmacies.
- Approximately 10% of all successful appeals were determined after the 30-day mark. Under the provisions of ESSB 5857, all of these determinations would be appealable and could add to the numbers of second level appeals to OIC.

Review of providing NDCs for denied appeals and updating MAC lists within one day for upheld appeals

Exhibit 81 summaries PBM results with respect to the following components of ESSB 5857:

- Update the MAC price when the appeal was approved, within one day
- Provide the NDC of an alternate drug that the pharmacy can purchase, when the appeal is denied.

Note: PBM 1, PBM 5, and PBM 6 did not provide enough data to determine if they were adjusting MAC prices within one day.

Exhibit 81: Adherence to Other Requirements, CYs 2014 and 2015

	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Providing alternative NDC for Denied appeal	50%	93%	97%	93%	77%	59%
Adjusting MAC price within 1 day	n/a	100%	87%	100%	n/a	n/a

Observations:

- PBM 1 and PBM 6 had a low rate of compliance with respect to providing a similar NDC that could be purchased by a pharmacy at or below a MAC price. PBMs 2, 3, and 4 appeared to have high rates of compliance.
- When the data was provided, PBMs 2, 3, and 4 had a reasonably high rate of adjusting the MAC prices within one day.

Call Center Operations

The scope of the Study called for a review of Contact Center/Pharmacy Help Desk availability. The analysis included a review of MAC policies and procedures for submitting appeals, response time standards, and telephonic availability of each PBM in the Study. All but one PBM submitted formal policies and procedures pertaining to Maximum Allowable Cost (MAC) pricing appeals.

Key findings:

- Each PBM in the Study had a telephone contact number for pharmacies to speak with PBM personnel, although direct contact with a live PBM representative was not always available on the first call. The majority of the call center hours of operation observed in the Study were 24 hours a day, seven days per week.
- Each PBM's policy and procedure or summary of processes indicated it had an appeals resolution timeframe within the requirement of the regulation (30 days).
- The PBMs' response times ranged from three to 30 days.
- The window of time a pharmacy had to submit an eligible MAC appeal varied by PBM.

In some cases, the administrative intermediaries working on behalf of pharmacies, or, Pharmacy Services Administrative Organizations (PSAOs), aggregated MAC inquiries for submission to PBMs. The "batching" of these requests potentially extended the overall wait time for a pharmacy to receive a response to its MAC appeal.

Secret shopper calls confirmed each call center's available hours. Qualitative observation revealed that wait times varied widely after calls were answered. Although telephone contacts were available, PBMs activated a "leave message" function, requiring a pharmacy to request a call-back on a specific inquiry. Of the three PBMs where a voicemail was left, only one returned the call at the time this report was prepared.

Telephonic Contacts

Of the PBMs that provided specific information on their MAC appeals processes, the majority described a telephonic pharmacy inquiry process involving pharmacy help desk staff as the first line of contact. PBM help desk staff were not typically responsible for handling or resolving the appeals. Instead, they would triage a call by identifying the issue as specific to MAC pricing and then forward the call to a MAC team within the PBM for resolution.

Although telephonic contacts were available for all PBMs in the Study, many encouraged or required other modes for contacting the PBM for submission of MAC pricing appeals. One PBM directed the secret shopper to an online portal for submission of appeals. Other PBMs provided a fax number or email address as alternatives to a telephonic appeal submission. Pharmacies were required to fill out a PBM-specific MAC pricing inquiry form with specific information to facilitate the investigation process.

Time Limit for Submission of Appeals, Timeframe for Resolution, and MAC Effective Date

Each PBM required a specific timeframe for pharmacies to submit appeals on MAC pricing, although the timeframes varied widely from ten to 60 business days. The initiation of the timeframe was defined as the claims fill-date or date of service.

PBM appeals resolution times as indicated in policies and procedures ranged from seven to 30 business days. Each PBM outlined a formal response process (once an appeal determination is made) in their policies or summary. Two PBMs indicated that the response to an appeal is provided to the submitting party in electronic format; four PBMs did not specify the method of how a response is delivered.

In addition to PBM response time, the policies and procedures or summary of processes for the effective date of MAC change after an appeals determination is formalized were analyzed. Four PBMs had the practice of adjusting the MAC pricing one calendar day after the date of determination; two provided no commentary or information on this request.

Call Center Availability

Five of the PBMs provided access to pharmacies 24 hours a day, seven days a week and one (identified in this report as PBM 1) only offered daytime operating hours, seven days a week. When a live person was not available and given the option to leave a voicemail, the secret shopper left a message articulating a general question about the process for filing MAC pricing appeals and left a call back number. Of the four voicemails left with three PBMs, only one call was returned (within 20 hours). The other three calls had not been returned at the time this report was prepared.

Call Center Performance

Actual call center statistics were submitted by four of the six PBMs. One PBM submitted target statistics but not actual performance data. Another PBM did not submit either target or performance measures. None of the PBMs were able to separate call statistics specific to the appeals process. Additionally, data revealed that calls are not identifiable by call type or client. The statistics submitted on average speed to answer, call abandonment rates, and service levels showed performance close or better than industry standards (benchmark for average speed to answer is 28 to 30 seconds; abandonment rates of 5% and service level 80% of calls answered under 20 seconds[75]). However, caution should be used when interpreting and comparing these results to other data sets since the data provided for this Study were gathered from different time periods. The data also represented a broad array of call requests and used inconsistent definitions of specific metrics. The secret shopper calls revealed anecdotal experience that is inconsistent with the metrics described in the following section (see "Secret Shopper Calls" below). To draw more definitive conclusions, further review and analysis of call center activity and performance metrics is recommended.

Secret Shopper Calls

Every PBM in the Study received secret shopper calls. When a PBM was contacted, a staff member requested specific information on the member (e.g., member name, ID number, date of birth, etc.) and provider (e.g., NCPDP/NPI number, Rx number, member information, etc.) to properly process the appeal. All of the calls were initiated with pharmacy help desks or customer service call centers and

[75] Call Center Performance Benchmarks, Feb 27, 2015. Accessed at: https://www.talkdesk.com/blog/call-center-performance-benchmarks/

subsequently directed to a department that could manage the appeal over the phone. When a live representative was not available to manage the appeal, the caller was directed to a voicemail queue or suggested email or web submission of the appeal.

Every PBM call center was available for live assistance. Some offered the caller an option to leave voicemail messages during the hours specified in the data request. Some of the PBMs required specific data input (e.g., the member of provider data described above) before the calls are further directed. The secret shopper let four voicemails with three PBMs. These voicemails included a message with a general MAC pricing inquiry and a call back number. Qualitatively, there was wide variability in call quality. After the calls were answered, the wait times ranged from 0 to approximately 12 minutes. Caution should be used when attempting to general conclusions from these calls as they are a small subset of the large volume of calls that PBMs typically receive. Further reviews such as sampling calls already made on specific MAC inquiries across a number of independent pharmacies may be a better way to assess experience specific to the MAC pricing appeals processes. Making these calls would require collaboration and permission from pharmacies and was not within the scope of this Study. Exhibit 82 summarizes this section's findings.

Exhibit 82: Summary of PBM Operational Policies for Submitting and Responding to Pharmacy Appeals

Areas Assessed	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
Dedicated MAC Appeals Staff	Yes	Yes	Yes	Yes	Yes	Yes
Modes of submitting an appeal other than by phone	Email Fax Website	None provided	Web	None provided	Email	Email Website
Time frame for submitting a MAC appeal	60 days from date of service	30 days from date of service	30 days from date of service	30 days from date of service	60 days from date of service	30 calendar days
PBM Appeals Resolution time	7 days	Range from 3 to 30 days depending on stage	7 business days	30 days	Earlier of seven business days or ten calendar days of receipt	7 business days
PBM response mechanism	Not specified	Not specified	Not specified	Not specified	Email	Email

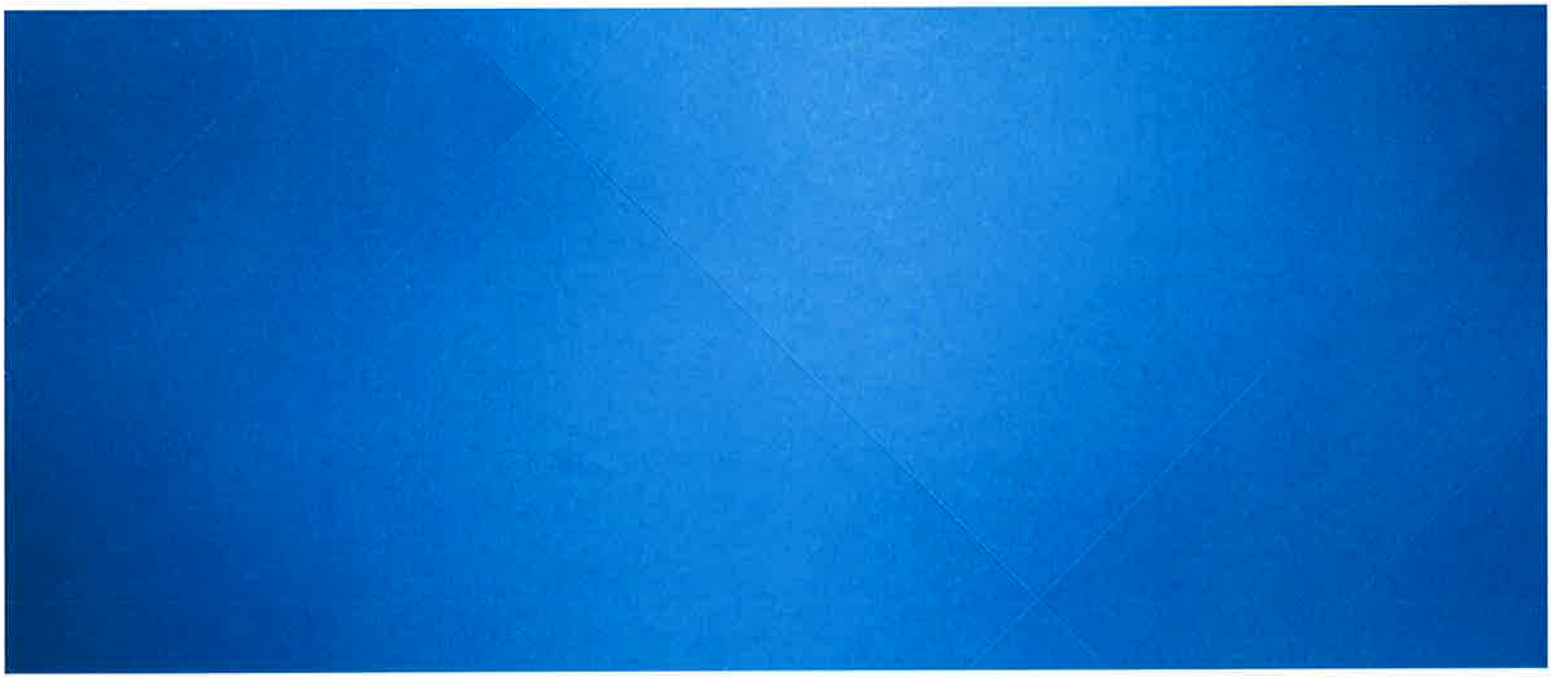
Pharmacy Services Administrative Organizations

One notable Study finding is the impact of Pharmacy Services Administrative Organizations, or PSAOs, on PBM MAC appeal response times. PSAOs are organizations that provide a broad range of services on behalf of independent or chain pharmacies. In 2013, U.S. Government Accountability Office (GAO) conducted a study on the number, role and ownership of PSAOs.[76] The study found that PSAOs generally provide PBM and supplier contract negotiation, as well as help-desk services. PSAOs negotiate and enter into agreements with third party payers on behalf of member pharmacies, including PBMs. Among the PBM related services, PSAOs often aggregate appeals and inquiries on behalf of pharmacies. For pharmacies affiliated with PSAOs, the inquiries may be sent to a centralized area. These are then triaged and reviewed prior to submission to the PBMs.

Through interviews with PBM officials and a review of PBM documents the analysis confirmed that PBMs permit the submission of appeals from independent pharmacies through PSAO representatives. All organizations surveyed indicated that they would allow independent pharmacies to submit appeals either directly or through their PSAOs. In the latter scenario, the PBMs would not have the opportunity to address the appeal until the PSAO submitted the appeal. Thus, the submitting pharmacy experienced a longer turnaround time by submitting through an intermediary. This delay in response potentially affected PBM turnaround times for processing MAC appeals.

[76] United States Government Accountability Office. Report to the Ranking Member, Committee on Energy and Commerce, House of Representatives. Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations. January 2013.

APPENDIX



I. PBM Data Request Form

STATE OF WASHINGTON OFFICE OF INSURANCE COMMISSIONER: STUDY OF PHARMACY CHAIN OF SUPPLY

Data Request

HOW TO SUBMIT YOUR DATA

Please send the email address of the submitter of the data to:

awinter@healthmanagement.com

Anne Winter will send you a link to join the secure share website. Once you receive the link, you will be able to log in to submit your data files. Please contact Anne Winter at 480-229-0418 if you have questions.

PLEASE NOTE: The following data request pertains to insured pharmacy claims transactions within the State of Washington and for State of Washington pharmacies only. It's also important to have the files denote if the claims were paid for fully insured individuals, Medicaid individuals, and Medicare individuals.

1. **Claims Data:** Please provide a claims file extract – via secure FTP with all claims transactions incurred during the period of January 1, 2015 through December 31, 2015 using a National Council for Prescription Drug Programs (NCPDP) version 5.1 or later compliant layout. Table A below includes the required fields we need to conduct the review. If the file includes reversal records, please indicate the method for adjusting claims with reversals. Please include:

   A. Record layout and detailed data dictionary

   B. Claims control report, including: record counts, total submitted expenses, total allowed expense, and total paid expenses.

   C. Clarification as to what types of records the data set include. (check all that apply)

      ☐ Paid claims only, already adjusted
      ☐ Paid claims, adjustments not yet applied
      ☐ Reversal records
      ☐ Denied claims
      ☐ Other (please specify):

   D. Please confirm if the claims file contains records based on the audit period invoice date or date of service.

   E. If the file includes adjustment records, please explain how the adjustment records should be processed to result in accurate paid claims? What fields are required to uniquely identify a claim and match it to relevant reversals?

Table A: Claims Data Elements Required (ALL fields requested below should be based on pharmacy NOT carrier/client reimbursement)

+ **Adjudicated date**	+ **Formulary indicator**
+ **Amount pharmacy billed**	+ **GCN or GPI**
+ **Amount pharmacy paid**	+ **Media (POS/mail/paper)**
+ **AWP unit cost**	+ **Metric decimal quantity**
+ **Basis of cost paid (i.e. AWP, MAC, U&C etc.)**	+ **NDC**
+ **Carrier number or other number to indicate Fully insured, Medicaid, and Medicare client**	+ **PBM reimbursement unit cost (i.e., MAC unit cost, AWP unit cost, other)**
+ **Compound code**	+ **Pharmacy chain status (independent, chain)**
+ **Copay**	+ **Pharmacy class (pharmacy, mail-order, nursing home)**
+ **Date of service**	+ **Pharmacy demographic (rural, urban, suburban)**
+ **DAW (dispense as written)**	+ **Pharmacy ID # (NCPDP, NPI)**
+ **Days supply**	+ **Pharmacy paid ingredient cost**
+ **Deductible (if applicable)**	+ **Sales tax (if applicable)**
+ **Dispensing fee**	+ **Transaction status**
+ **Drug indicator (generic, single-source, multi-source)**	+ **Usual & customary charge**
+ **Drug name**	

2. **Maximum Allowable Cost (MAC) List:** A MAC list with GPIs/GCNs/NDCs, including effective and termination dates. Please ensure that the MAC list has been reviewed to ensure it is de-duplicated and accurate for the January 1, 2015 through December 31, 2015 period. Provide all policies relating to the construction of your MAC list(s) during the same period. Include frequency of review and update, number of off cycle updates during the period, triggers for an off cycle update.

3. **Pharmacy Appeals Listing**

   A. A full listing of pharmacy pricing appeals for the January 1, 2014 through December 31, 2015 period. The list should include, but is not limited to:

   + Explanation of all form fields
   + Data required from the pharmacy by the PBM
   + Type of appeal
   + Appeal determination
   + Appeal comments
   + Appeal date
   + Determination data
   + Determination letter/notification
   + Pharmacy type

- If determination is denial, include the reason for the denial and the NDC of the drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the MAC (RCW 19.340.100[4][c])
- If the appeal is upheld, include verification that an adjustment was made no later than one day after the date of determination and that all similarly situated pharmacies in the state were updated as well (RCW 19.340.100[4][c])

B. Provide a copy of your appeals policy, including the process for appeals, the internal timing requirements and the teams that manage the process.

Due to HIPAA requirements, claim history data that includes confidential information should only be sent to Mercer via e-mail if the data is encrypted (e.g., encrypt feature of WinZip 9.0 or more recent version). Alternatively, a CD or DVD containing the data can be sent to Mercer via overnight delivery. Or, the data file can be placed on a secure FTP site, which requires prior arrangement between Mercer and the claims administrator.

Note: If password protected files are provided, passwords should be provided separately by telephone.

4. Pharmacy Call Center Information

A. PBM Call Center Data: (Need data by caller type, i.e., pharmacy vs. provider. If possible provide subcategory of caller types, i.e., specialist vs Primary Care Physicians)
- Documented P&Ps related to call center standards and metrics on appeals process
- PBM call center metrics related to inquiries and appeals required by the contract and service level agreement (e.g., average handling time, service level, customer satisfaction, etc.)
- Call logs
- First response and final response time to an appeal
- Availability for telephone inquiry and appeals
- Number of inquiries by provider and pharmacy
- Number of calls to resolution
- Description of the inquiry categories
- Number of inquiries that lead to appeals
- Time from inquiry to appeals resolution

II. Detail Level Tables for Pharmacy Class MAC Reimbursement Analysis

The information contained in this Appendix are detail level tables for the MAC reimbursement analysis for Pharmacy Class. As mentioned, it's not useful to make comparisons of pricing for these breakouts because reimbursement for the non-community/retail pharmacies may be effectuated differently, including 340B pricing.

PBM MAC Reimbursement Dollar Variance to NADAC Pricing – Pharmacy Class

PBM MAC Reimbursement Dollar Variance to NADAC Pricing - Pharmacy Class						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
COMMUNITY/RETAIL PHARMACY	$ 5,209,254	$ (565,719)	$ 6,026,711	$ 438,793	$ 9,568,495	$ 7,112,285
LONG TERM CARE PHARMACY	$ 345,019	$ 37,395	$ 504,061	$ -	$ 300,400	$ 594,393
CLINIC PHARMACY	$ 455,592	$ 7,439	$ 62,517	$ -	$ 266,546	$ 536,577
INSTITUTIONAL PHARMACY	$ 76,419	$ 2,094	$ 18,832	$ -	$ 35,985	$ (245,186)
Total	**$ 6,100,260**	**$ (518,866)**	**$ 6,667,203**	**$ 438,791**	**$ 10,599,017**	**$ 8,100,105**

Variance to NADAC % of Paid Ingredient Cost – Pharmacy Class

Variance to NADAC % of Paid Ingredient Cost - Pharmacy Class						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
COMMUNITY/RETAIL PHARMACY	13.5%	-6.6%	4.9%	3.9%	9.9%	3.7%
LONG TERM CARE PHARMACY	12.8%	5.8%	9.4%	0.0%	9.6%	11.9%
CLINIC PHARMACY	13.8%	5.0%	3.6%	0.0%	13.1%	10.0%
INSTITUTIONAL PHARMACY	12.5%	2.2%	2.4%	0.0%	8.1%	-13.6%
Total	**13.4%**	**-5.4%**	**5.0%**	**3.9%**	**9.9%**	**3.9%**

PBM MAC Reimbursement Dollar Variance to Benchmark MAC 1 Pricing – Pharmacy Class

PBM MAC Reimbursement Dollar Variance to Benchmark MAC 1 Pricing - Pharmacy Class						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
COMMUNITY/RETAIL PHARMACY	$ 8,037,298	$ (2,401,978)	$ (8,582,163)	$ (866,294)	$ (216,697)	$ (20,703,897)
LONG TERM CARE PHARMACY	$ 484,764	$ (23,598)	$ 136,307	$ -	$ 27,031	$ (129,751)
CLINIC PHARMACY	$ 703,720	$ (19,022)	$ (219,415)	$ -	$ 139,844	$ (177,482)
INSTITUTIONAL PHARMACY	$ 65,374	$ (17,063)	$ (186,447)	$ -	$ (45,130)	$ (190,671)
Total	**$ 9,310,374**	**$ (2,465,778)**	**$ (8,969,654)**	**$ (866,349)**	**$ (192,308)**	**$ (21,336,531)**

Variance to Benchmark MAC 1 % of Paid Ingredient Cost – Pharmacy Class

Variance to Benchmark MAC 1 % of Paid Ingredient Cost - Pharmacy Class						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
COMMUNITY/RETAIL PHARMACY	20.8%	-27.8%	-7.0%	-7.7%	-0.2%	-10.7%
LONG TERM CARE PHARMACY	17.9%	-3.7%	2.5%	0.0%	0.9%	-2.6%
CLINIC PHARMACY	21.3%	-12.7%	-12.6%	0.0%	6.9%	-3.3%
INSTITUTIONAL PHARMACY	10.7%	-18.2%	-23.8%	0.0%	-10.1%	-10.5%
Total	**20.5%**	**-25.8%**	**-6.8%**	**-7.7%**	**-0.2%**	**-10.3%**

PBM MAC Reimbursement Dollar Variance to Benchmark MAC 2 Pricing – Pharmacy Class

PBM MAC Reimbursement Dollar Variance to Benchmark MAC 2 Pricing - Pharmacy Class						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
COMMUNITY/RETAIL PHARMACY	$ 9,484,914	$ (2,837,083)	$ (3,323,055)	$ (998,159)	$ 4,222,100	$ (17,980,653)
LONG TERM CARE PHARMACY	$ 444,533	$ (114,564)	$ 119,355	$ -	$ 105,878	$ (294,563)
CLINIC PHARMACY	$ 913,203	$ (17,946)	$ (144,946)	$ -	$ 233,132	$ 25,481
INSTITUTIONAL PHARMACY	$ 99,958	$ (18,843)	$ (175,339)	$ -	$ (15,327)	$ (165,643)
Total	**$ 10,966,744**	**$ (2,993,369)**	**$ (3,596,743)**	**$ (998,197)**	**$ 4,757,374**	**$ (18,546,424)**

Variance to Benchmark MAC 2 % of Paid Ingredient Cost – Pharmacy Class

Variance to Benchmark MAC 2 % of Paid Ingredient Cost - Pharmacy Class						
	PBM 1	PBM 2	PBM 3	PBM 4	PBM 5	PBM 6
COMMUNITY/RETAIL PHARMACY	24.5%	-32.9%	-2.7%	-8.9%	4.4%	-9.3%
LONG TERM CARE PHARMACY	16.4%	-17.9%	2.2%	0.0%	3.4%	-5.9%
CLINIC PHARMACY	27.7%	-12.0%	-8.3%	0.0%	11.5%	0.5%
INSTITUTIONAL PHARMACY	16.4%	-20.1%	-22.3%	0.0%	-3.4%	-9.2%
Total	**24.2%**	**-31.4%**	**-2.7%**	**-8.9%**	**4.4%**	**-8.9%**

III. Sample Recommend OIC Appeals Form

Sections 1 – 3 to be completed by the submitting pharmacy		
Section 1: Pharmacy Information		
Pharmacy Name:	National Provider Identifier (NPI):	
Street Address:	City:	Zip:
Contact Name:	Contact Email:	
Contact Phone:	Chain Affiliation:	
Section 2: Appeal Information		
Pharmacy Benefit Manager (PBM):	PBM Appeal Date: Click here to enter a date.	
PBM Contact Name:	PBM Contact Email:	PBM Contact Phone:
PBM Appeal Determination Date: Click here to enter a date.	PBM Provided Alternate National Drug Code (NDC):	
PBM Reason for Denial *(please include a copy of PBM notification)*:		
Section 3: Drug Information		
Drug Name:	Drug Strength:	
Date of Service: Click here to enter a date.	Prescription Number:	
Invoice Unit Acquisition Cost *(please include a copy of the invoice for this drug)*:		
Invoice Date: Click here to enter a date.	Units Dispensed:	
PBM Maximum Allowable Cost (MAC) unit rate allowed:		
Reason Unable to Purchase PBM Alternate NDC At PBM Reimbursement Rate:		
Additional Comments:		
Sections 4 – 6 to be completed by OIC		
Section 4: Intake		
Date Received: Click here to enter a date.	Method of Appeal:	
Section 5: OIC Determination		
Determination:	Reason:	
Unit Cost Approved:	Date Pharmacy Notified of Determination: Click here to enter a date.	
Date Unit Cost Effective: Click here to enter a date.	Date PBM Notified of Determination: Click here to enter a date.	
Section 6: PBM Change Verification		
Date PBM Confirmed Unit Cost Updated: Click here to enter a date.		
PBM Confirmed Pharmacy Was Notified to Resubmit Claim(s):		
Date Closed: Click here to enter a date.		

IV. Appeals Processes in Other States

Overview

In the past few years, states have increasingly passed legislation design to improve transparency with MAC pricing. PBM MAC pricing appeals laws are one of the actions that states have taken to provide increased transparency. The appeals process helps ensure that pharmacies are reimbursed fairly. MAC pricing transparency and appeals regulations in other states were reviewed and compared with Washington's for the OIC's review.

Key Findings

- OIC's 30-day submission window is an average length of submission time and OIC's 30-day response time is generous compared to like states.
- The outcome of approved and denied appeals was very similar across comparable states and Washington.
- OIC has three significant standards that go above and beyond the standards set by comparable states.

Method

A scan of MAC pricing transparency regulations was performed to compare other states' regulations to Washington's. 29 states have MAC transparency laws in some phase of development. Fourteen states have passed PBM MAC appeals process laws. Key requirements were summarized and can be found in Exhibit 84. Four states that are similar to Washington in size and population were chosen and additional analysis was conducted. Those states include:

- Colorado
- Minnesota
- Oregon
- Utah

Data Analysis

Exhibit 83 lists key MAC pricing appeals process requirements in Washington and the four selected states. The components include:

- Submission of appeal timeline
- PBM response timelines
- PBM response requirements

Exhibit 83: Select States' MAC Appeals Requirements

Washington State Compared to Other States					
Criteria	**WA**	**CO**	**MN**	**OR**	**UT**
Appeal Window	Not Addressed	21 days following initial claim	15 business days following initial claim	30 days after the claim is submitted	21 days following initial claim adjudication
Submitted To	PBM	PBM	PBM	PBM	PBM
Threshold	Pharmacy paid amount that is greater than the reimbursement rate	Not Addressed	Not Addressed	Pharmacy paid amount that is greater than the reimbursement rate	Not Addressed
Appeal Decision Made	Within 30 days of submission	Within 21 days after appeal	Within 7 business days after appeal is received	7 business days	Within 14 business days
If Appeal Approved	PBM makes reasonable adjustment the day after the appeal is approved	PBM makes adjustment to a date not later than one day after the date of determination	PBM makes adjustment to a date not later than one day after the date of determination; adjusts price to similarly situated pharmacies as defined by the plan sponsor	PBM makes an adjustment for the pharmacy that filed the appeal from date of original claim adjudication forward	Not Addressed
If Appeal Disapproved	PBM must provide reason for denial and NDC of drug within MAC rate	PBM must provide reason for denial and NDC of drug at or below benchmark price	PBM must provide reason for denial and NDC of drug within MAC rate	PBM must provide reason for denial and NDC of drug within MAC rate	PBM must provide reason for denial and NDC of drug within MAC rate

Observations

- Washington's requirement's for approved and denied MAC appeals is similar to the four states selected.
- Generally, when appeals are approved, states require the PBM to reimburse the pharmacy within a short time frame.

OIC had three standards that are not required in the comparison group states:

- The requirement to have a second level appeals process at OIC for denied appeals
- The automatic denial of an appeal if the PBM does not respond to an appeal within 30 days
- A limitation on who can file a second level appeal to pharmacies with fewer than 15 stores

Exhibit 84 provides a summary of the fourteen state MAC appeals laws. The exhibit provides the following:

- Legislation citation
- Effective date
- Summary of the legislation
- Website to locate the legislation

Exhibit 84: Summary of 14 States' MAC Appeals Laws

States with MAC Rate Appeal Laws				
State	Law	Date	Excerpt	Site
CO	HB 14-1213 Colorado Revised Statute 25-37-102(13)	6/6/2014	Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing.	http://www.leg.state.co.us/clics/clics2014a/csl.nsf/fsbillcont2/563FCE3875CA50E087257C3000067611/$FILE/1213_enr.pdf
GA	HB 470 Georgia Annotated Codes; Title 26 Chapter 4 Article 6 and Title 33 Chapter 64	7/1/2015	All contracts between a pharmacy benefits manager and a contracted pharmacy are between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, shall include a process to internally appeal, investigate, and resolve disputes regarding multi-source generic drug pricing.	http://www.legis.ga.gov/Legislation/en-US/display/20152016/HB/470
KY	KY SB117 KRS 304.17A-162	4/9/2016	Establish a process for contracted pharmacies, pharmacy services administration organizations, or group purchasing organizations, to appeal, investigate, and resolve disputes regarding the maximum allowable cost pricing.	https://legiscan.com/KY/bill/SB117/2016
LA	SB 410 Subpart C-1 of Part II of Chapter 6 of Title 22 of the Louisiana Revised Statutes	8/1/2014	The pharmacy benefits manager shall provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs for a specific NDC or NDCs as not meeting the requirements of this Subpart or being below the cost at which the pharmacy may obtain the NDC.	https://legiscan.com/LA/text/SB410/2014
MI	SB 0656 (2013) 1939 PA 280	7/12/2014 Effective 91 days after session adjourns	The department of community health and contracted health plans shall utilize a process for maximum allowable cost pricing reconsiderations that must be	http://www.legislature.mi.gov/documents/2013-2014/publicact/pdf/2014-PA-0167.pdf

States with MAC Rate Appeal Laws				
State	Law	Date	Excerpt	Site
			available and provided to providers and pharmacists.	
MN	2016 Minnesota Statutes 151.71	2014	Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing.	https://www.revisor.mn.gov/statutes/?id=151.71
MT	Montana Code Annotated 2015 33-22-173	2015	In contracting with a pharmacy, a plan sponsor or pharmacy benefit manager shall provide a procedure by which a pharmacy may appeal the price of a drug or drugs on the maximum allowable cost list.	http://leg.mt.gov/bills/mca/33/22/33-22-173.htm
ND	HB 1363 chapter 19-02.1 of the North Dakota Century Code	4/12/2013	Provide a reasonable administrative appeals procedure to allow a dispensing pharmacy provider to contest a listed maximum allowable price rate.	https://legiscan.com/ND/text/1363/id/697653
NY	Senate Bill 3346-B § 280-a to the Public Health Law	12/11/2015	A pharmacy benefit manager shall, with respect to contracts between a pharmacy benefit manager and a pharmacy or, alternatively, a pharmacy benefit manager and a pharmacy's contracting agent, such as a pharmacy services administrative organization, include a reasonable process to appeal, investigate and resolve disputes regarding multi-source generic drug pricing.	https://www.nysenate.gov/legislation/bills/2015/S3346/amendment/B
OR	ORS 735.534	2016	A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing.	http://www.oregonlaws.org/ors/735.534
TN	SB 1789 Amends TCA Title 56, Chapter 7, Part 31	3/31/2016, signed 3/23/2016	If a pharmacy chooses to contest the listed maximum allowable cost for a particular drug or medical product or device, the pharmacy shall have the right to designate a pharmacy services administrative organization or other agent to file and handle its appeal of the maximum allowable cost of the drug or medical product or device.	https://legiscan.com/TN/bill/SB1789/2015

States with MAC Rate Appeal Laws				
State	Law	Date	Excerpt	Site
UT	H.B. 113 Amends 31A-22-640	3/31/2014	Provide a process for the contracted pharmacy to appeal the maximum allowable cost.	http://le.utah.gov/~2014/bills/static/hb0113.html
VA	HB 2031 Adds Virginia Code 38.2-3407.15:2	3/23/2015	Any contract between a carrier and its intermediary, pursuant to which the intermediary has the right or obligation to establish a maximum allowable cost, and any provider contract between a carrier and a participating pharmacy provider or its contracting agent, pursuant to which the carrier has the right or obligation to establish a maximum allowable cost, shall contain specific provisions that require the intermediary or carrier to provide a process for an appeal, investigation, and resolution of disputes regarding maximum allowable cost drug pricing.	https://legiscan.com/VA/text/HB2031/2015
WI	SB 21 2015 Wisconsin Act 55	7/12/2015	A pharmacy benefit manger shall include in each contract with a pharmacy a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing.	http://docs.legis.wisconsin.gov/2015/related/acts/55.pdf

V. Exhibits in this Study