

*Issues in Missouri Health Care 2011*

Basic Pharmacy Reimbursement Principles in MO HealthNet

## **Acknowledgement**

This is one in a series of issue papers on critical health care issues facing Missouri and the nation prepared by Health Management Associates, Inc., a national health care policy research and consulting firm, and made possible by funding from the Missouri Foundation for Health and the Healthcare Foundation of Greater Kansas City. The papers are intended to provide nonpartisan expert analysis in an accessible format that will contribute to the public dialogue on the state of health care in Missouri. Questions should be directed to Thomas McAuliffe, Policy Analyst, Missouri Foundation for Health, 314.345.5574, [tmcauliffe@mffh.org](mailto:tmcauliffe@mffh.org).

## Issue Statement

Medicaid pharmacy spending across the United States was \$25.2 billion in fiscal year 2009. This spending level was offset 38 percent by manufacturer drug rebates, resulting in net expenditures of \$15.5 billion.<sup>1</sup> To address continued budget constraints, 33 states implemented pharmacy controls during fiscal year 2010.<sup>2</sup> At the same time, states remain aware that drug therapies play an essential role in care plans for their beneficiaries, especially for those who are elderly or have disabilities or chronic conditions. How states address the pressure of continued drug cost increases and the demand for the latest product innovations has a significant impact on the efficacy of medical treatment.

This issue brief is written for individuals who are unfamiliar with the basics of Medicaid prescription drug pricing, and provides a basis for reviewing future policy implications facing state Medicaid programs, including MO HealthNet (Missouri's Medicaid program).

## Background

This section describes key programs and recent changes impacting a state's prescription drug pricing and expenditures.

### Medicare Part D and the Phased-Down State Contribution for Dual Eligibles

The Medicare Modernization Act (MMA) added Medicare Part D prescription drug coverage and required that individuals enrolled in both Medicare and Medicaid ("dual eligibles") transition from Medicaid pharmacy coverage to Part D starting in January 2006. States, however, still help finance the prescription costs of the dual eligibles through a phased-down state contribution, commonly called the clawback. The clawback is calculated based on a state's 2003 per capita pharmacy spending for its dual eligibles, and is trended forward each year for inflation. The resulting amount was discounted 10 percent in 2006; the discount gradually increases to 25 percent by 2015 and remains constant thereafter.<sup>3</sup> Monthly, each state pays the adjusted per capita amount for its dual eligibles based on its current share of the federal medical assistance percentage (FMAP). As MO HealthNet dual eligibles transitioned to Part D, the state's fee-for-service prescriptions dropped about 50 percent, from 19.1 million (2005) to 9.6 million (2007).<sup>4</sup> This change was counterbalanced by general revenue liabilities for the clawback, which in state fiscal year 2008 accounted for \$169 million for about 129,000 dual eligibles.<sup>5</sup>

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1 Financial Management Reports, FY 2007 through FY 2009 (federal fiscal year October 1 through September 30), obtained from CMS upon HMA request

2 Medicaid Cost Containment Actions Taken by States, FY 2010 (federal fiscal year), available at [statehealthfacts.org](http://statehealthfacts.org)

3 Smith, Gifford, and Kramer. *Observations on the Initial Implementation of the Medicare Prescription Drug Program: Perspectives of State Medicaid Directors through a Focus Group Discussion*. Kaiser Commission on Medicaid and the Uninsured. May 2006.

4 *Pharmacy*, MO HealthNet Division Appropriation Summaries, Missouri Department of Social Services, August 15, 2008, available at <http://www.dss.mo.gov/mis/apprpsum/hlthcare09/dms1pgap.pdf>

5 *Pharmacy-Medicare Part D Clawback*, MO HealthNet Division Appropriation Summaries, August 15, 2008, available at <http://www.dss.mo.gov/mis/apprpsum/hlthcare09/dms1pgap.pdf>

## Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (SSA) requires a manufacturer to sign a rebate agreement with the federal government or forego coverage of its drugs by state Medicaid programs.<sup>6</sup> Forty-seven states, including Missouri, also bill manufacturers for supplemental rebates either individually or as part of multi-state groups.<sup>7</sup> Unlike federal rebates, supplemental rebate levels vary from state to state and are dependent on prescription drug volume and negotiations with manufacturers.

The Patient Protection and Affordable Care Act (ACA) not only enacted health care reform and a 2014 Medicaid expansion but included many detailed changes affecting the Medicaid drug rebate program, as outlined below (Table 1).<sup>8,9</sup>

**Table 1. Changes to the Federal Medicaid Rebate Program, effective January 1, 2010**

Changes to the Federal Medicaid Rebate Formula	Amended Section of Social Security Act
Increases the base unit rebate amount from 15.1 to 23.1 percent of Average Manufacturers Price (AMP) on most brands – except limits (a) clotting factors and (b) drugs used exclusively for pediatric indications to 17.1 percent of AMP instead of 23.1 percent.	1927(c)(3)
Increases the base unit rebate amount from 11 percent to 13 percent of AMP on generics.	1927(c)(3)
Applies an additional rebate for line extensions of existing oral solid brands, e.g., adding a slow release form or new strength of a drug already being sold.	1927(c)(2)
Limits the total unit rebate amount to no more than 100 percent of AMP.	1927(c)(2)
Authorizes a Federal Rebate Recapture of savings from manufacturer rebate revenue collected by states from #1 through 3 above.	1927(b)(1)

## New Federal “Recapture” of Medicaid Drug Rebate Savings

The ACA requires savings from the new rebate changes (Table 1) to be “recaptured” 100 percent by the federal government—instead of the current practice of sharing revenue based on a state’s FMAP. States with supplemental rebate programs have explained that the federal “recapture” results in a net loss to them. Their supplemental rebates have increased total rebates (i.e., federal

6 The Omnibus Budget Reconciliation Act of 1990 added Section 1927 and authorized the Medicaid drug rebate program starting in 1991.

7 States with Supplemental Rebate Agreements, March 2010, available at [www.cms.hhs.gov/Reimbursement/22\\_SupplementalDrugRebateAgreements.asp](http://www.cms.hhs.gov/Reimbursement/22_SupplementalDrugRebateAgreements.asp)

8 The Patient Protection and Affordable Care Act (P.L. 111-148) and a reconciliation act (P.L. 111-152) are collectively known as the Affordable Care Act.

9 The Medicaid expansion is expected to add nearly 16 million new enrollees. The federal government will be financing about 95.4 percent of the Medicaid expansion between 2014 and 2019 and the states the remainder.

and state combined) for many drugs above 15.1 percent of Medicaid average manufacturer price (AMP or the old base rebate); and now, under the ACA, the previously shared rebate revenue between 15.1 and 23.1 percent of AMP, the new base rebate, will be recaptured 100 percent by the federal government.

### **Drug Rebate Equalization between Medicaid Fee-For-Service and Managed Care Settings:**

Before enactment of ACA, manufacturer rebates were not available for drugs paid under “capitation” arrangements with Medicaid managed care organizations (MCOs).<sup>10</sup> Fourteen of the 38 states with risk-based MCOs, including Missouri, excluded or carved out drugs from their contracts and paid pharmacy benefits for MCO enrollees under their fee-for-service program to obtain rebate revenue.<sup>11</sup> The cost effectiveness of pharmacy carve-outs has been a long-standing debate among state Medicaid officials, federal policymakers, and providers. Those who argue that carve-outs undermine MCO care management, resulting in increased utilization and spending,<sup>12</sup> advocated that Medicaid rebates be applied to capitated Medicaid drug payments. The ACA authorized such “drug rebate equalization” and stipulated that states must administer the rebates for both fee-for-service and MCO drug claims. Centers for Medicare and Medicaid Services (CMS) indicated this change was effective March 23, 2010. Further instructions are anticipated shortly to address how implementation will be handled retroactively, and what prescription data exchanges will be required between MCOs and states.

### **Centers for Medicare and Medicaid Services’ Survey of Prescription Prices**

Section 1927(f) of the SSA allows Centers for Medicare and Medicaid Services (CMS) to survey and compile pharmacy retail prices representative of a nationwide average of consumer purchase prices. A request for proposals (RFP) recently issued by CMS indicated the awarded vendor’s database will provide “state Medicaid agencies a valid array of covered outpatient drug prices from ingredient costs paid by retail community pharmacies to those prices available to the consumer.” States believe this new resource will be a “comparative” benchmark and not mandatory for state payments to pharmacies.

### **Pharmacy Reimbursement Principles**

Reimbursement recognizes a pharmacy’s costs for procuring drug products and for dispensing prescriptions.<sup>13</sup> Each state is required to comprehensively describe its pharmacy payment

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10 Section 1927(j) of the SSA

11 CBO Budget Options, Volume 1 Health Care, Dec 2008, available at [www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf](http://www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf); HMA added three states Indiana, Missouri, and Ohio with carve-outs implemented in 2009 and 2010. States with full pharmacy carve-outs include CT, DE, DC, IL, IN, IA, MO (starting October 2009), NE, NY, OH, TN, TX, WI, and WV. Other states may have partial pharmacy carve-outs for select drugs, e.g., psychotropics, HIV/AIDS drugs, and antihemophilia drugs.

12 President Obama’s Budget Would Extend Drug Rebates to Medicaid Health Plans, Mar 19, 2009, available at [www.aishealth.com/ManagedCare/Medicaid/MAN\\_Obama\\_Budget\\_Medicaid.html](http://www.aishealth.com/ManagedCare/Medicaid/MAN_Obama_Budget_Medicaid.html)

13 Readers should refer to Appendix A for definitions relating to drug descriptors and pricing terms.

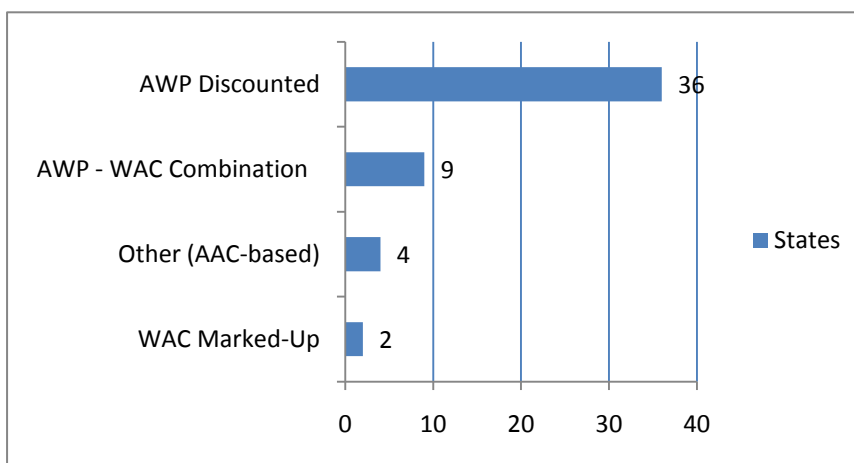
methodology in its State Plan, and to pay no more for a prescription than a pharmacy's usual and customary charge to the general public.

### Payment for Procuring Drug Products

A state has considerable flexibility within federal requirements to set its product cost payment methodology.<sup>14</sup> Unique federal requirements apply to single source and multiple source drugs, as explained below.

- *Single Source Drugs:* Single source drugs are often called patented brands, because the manufacturer still holds the patent and no generics are available on the market. Federal regulations stipulate payment must be at Estimated Acquisition Cost (EAC). EAC is the state's best estimate of the price generally and currently paid by providers. Most states use a derivative of Average Wholesale Price (AWP) or Wholesaler Acquisition Cost (WAC) to reimburse these drugs.<sup>15</sup> Basically, AWP is the wholesaler list price to a pharmacy and WAC is the manufacturer list price to wholesalers or direct purchasers. Purchasers do not pay drug acquisition costs at either AWP or WAC, as discounts and rebates apply. For single source drugs, 36 states pay based on AWP minus a discount ranging from 5 percent to 17 percent. Eleven states use WAC-based rates that range from no markup (i.e., Rhode Island) to a 12.5 percent markup (i.e., North Dakota). Many states with WAC-based reimbursement use it combined with discounted AWP payments (Figure 1). For example, Missouri pays single source drugs based on the lower of AWP less 10.43 percent or WAC plus 10 percent.

**Figure 1. Number of States Using Various Medicaid Product Cost Reimbursement Methodologies**



Sources: Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2010, available at [www.cms.gov](http://www.cms.gov) and state websites for Alaska and Oregon

14 42 CFR §447.502, §447.512, and §447.518

15 States obtain AWP and WAC data from national pricing compendia services, e.g., First DataBank and Medi-Span.

- CMS has recently approved a new Alabama “Average Acquisition Cost” (AAC) methodology that bases reimbursement for acquiring drugs on actual invoices paid by pharmacies.<sup>16</sup> Under the Alabama plan, an independent contractor will perform a random sample of all enrolled pharmacies twice each year. Each pharmacy will participate once every two years by submitting a month’s invoices. The contractor will then calculate the average cost per drug. If an AAC price is not established, payment will be based on WAC plus 9.2 percent. Tied to this change, the state is increasing its dispensing fee from \$5.40 to \$10.64, as supported by an independent, confidential survey of pharmacies.<sup>17</sup> Oregon is also proposing a switch to AAC, which would go into effect January 1, 2011.<sup>18</sup> Its approach is similar to Alabama’s, but Oregon plans to use WAC plus 6.25 percent when an AAC cannot be determined, and its pharmacy dispensing fee will vary depending on a pharmacy’s annual prescription volume, with a \$14.01 fee for fewer than 50,000 prescriptions, \$10.14 for fewer than 70,000 prescriptions, and \$9.68 for more than 70,000 prescriptions. New Mexico and Texas, while not adopting AAC, will modify their AWP discounts or WAC markup rates based on pricing data obtained from manufacturer and pharmacy invoices.
- *Multiple Source Drugs, with Federal Upper Limits or State Maximum Allowable Cost Rates:* Multiple source drugs include noninnovator (i.e., generics) and innovator drugs (brands with no patent protection). For decades, CMS has issued Federal Upper Limits (FULs) on these drugs. States may opt to use the FULs or their own state Maximum Allowable Cost (MAC) rates—as long as payments do not exceed, in aggregate, the amount that would have been paid if the FULs were used. Payment exceptions above the FULs or state MAC rates are allowed when a brand is medically necessary for a beneficiary, confirmed usually through prior authorization.
- *Multiple Source Drugs, with no FUL or State MAC:* When a multiple source drug does not have a FUL or MAC rate, most states use pricing the same as a single source drug. However, ten states (Arkansas, Colorado, Connecticut, Illinois, Indiana, Kansas, Kentucky, Mississippi, New York, and Virginia) have implemented Average Wholesale Price (AWP) discounts for noninnovator generic drugs falling into this category. These generic AWP discounts are commonly between 20 to 30 percent, but one state, Colorado, uses AWP minus 45 percent.

### **Payment for Dispensing Prescriptions**

Federal regulations define a dispensing fee as the fee a state Medicaid agency pays a pharmacy to dispense a prescription. Included are pharmacy costs to transfer a prescription to a Medicaid

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16 CMS Approves AAC Drug Pricing, Dispensing Fee Increase, September 17, 2010, available at [http://www.medicaid.alabama.gov/documents/Resources/4-G\\_Publications/MM\\_September\\_2010\\_Final\\_9-17-10.pdf](http://www.medicaid.alabama.gov/documents/Resources/4-G_Publications/MM_September_2010_Final_9-17-10.pdf)

17 Steckel, FY 2011 Budget Request Presentation, December 14, 2009, available at [http://www.medicaid.alabama.gov/documents/News/Special\\_Presentations/FY11\\_Budget\\_Presentation/CHS\\_FY11\\_Budget\\_Presentation\\_12-14-09\\_FINALa.pdf](http://www.medicaid.alabama.gov/documents/News/Special_Presentations/FY11_Budget_Presentation/CHS_FY11_Budget_Presentation_12-14-09_FINALa.pdf)

18 Proposed changes in pharmacy reimbursement methodologies, September 2010, available at <https://apps.state.or.us/cf1/OHP/OHPadmin/files/10-950%20rx%20reimbursement%20methodologies.pdf>

beneficiary, e.g., performing drug utilization review, measuring or mixing a drug, filling a container, counseling a beneficiary or providing the completed prescription. State Medicaid dispensing fees for brand drugs vary from a low of \$1.75 (New Hampshire) to a high of \$11.46 (Alaska).<sup>19</sup> Most states have dispensing fees between \$3 and \$6. Pharmacy representatives indicate dispensing fees used by state Medicaid programs and other insurers are often below their actual dispensing costs, but this deficit is cross-subsidized by product cost payment over a pharmacy's actual acquisition costs.<sup>20</sup>

### MO HealthNet Pharmacy Reimbursement

MO HealthNet pharmacy reimbursement is based on a combination of AWP discounted, WAC markups, FULs, and state MAC prices, as listed in Table 1. The next sections describe key MO HealthNet payment approaches and strategies.

**Table 2. MO HealthNet Pharmacy Reimbursement Methodology**

1. Fee-for-service (FFS) pharmacy reimbursement is the lowest of:
2. Average Wholesale Price (AWP) less 10.43% plus a dispensing fee,
3. Wholesale Acquisition Cost (WAC) plus 10% plus a dispensing fee,
4. Federal Upper Limit (FUL) plus a dispensing fee,
5. State Maximum Allowable Cost (MAC) rate plus a dispensing fee, or
6. Usual and customary charge.

### MO HealthNet Dispensing Fees

In addition to product cost payment, MO HealthNet pays pharmacies a standard and an enhanced dispensing fee. Combined, these fees currently total \$9.66; for generics, an additional preferred incentive fee is applied. (Table 2).

**Table 3. MO HealthNet Dispensing Fee Rates**

Fee	Rate	Comments
Standard Fee	\$4.84	Base fee paid to pharmacies.
Enhanced Fee	\$4.82	Fee funded from revenue collected from pharmacy provider taxes, which are used to leverage additional federal matching funds.
Generic Product Preferred Incentive	\$4.00	This fee started January 1, 2010, and is paid in addition to other existing dispensing fees.

<sup>19</sup> 42 CFR 447.502

<sup>20</sup> Expert Report of Zachary Dyckman, Ph.D. for the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) Regarding Cross-Subsidization of Pharmacy Reimbursement Rates in the State of California, October 19, 2009

These fees are supported by a pharmacy “provider tax” that is used to leverage additional federal matching funds. Related federal requirements are complex and generally stipulate the taxes must be broad-based, applying to all pharmacies uniformly, and must avoid hold harmless arrangements. The Missouri Pharmacy Association supports the state’s provider tax, and created the Pharmacy Agency Corporation to perform administrative activities related to the tax on behalf of pharmacies.<sup>21</sup>

### Preferred Drug List and Supplemental Manufacturer Drug Rebates

MO HealthNet negotiates state supplemental manufacturer rebates leveraged on a preferred drug list. This approach identifies preferred products in high-cost drug classes that are based on clinical effectiveness and cost effectiveness. A drug not identified as preferred is reimbursed only with prior authorization and documentation of medical need. During the preferred drug process, MO HealthNet offers manufacturers an opportunity to provide supplemental rebates in addition to federal rebates. The supplemental rebates, if given, may allow a manufacturer’s products to become competitively priced and avoid prior authorization requirements. Resulting revenue from federal and state supplemental rebates (Table 3) is shared between the state and federal governments based on the state’s FMAP. An exception is the new federal “recapture,” previously described.

**Table 4. MO HealthNet Drug Rebate Revenue**

<b>Fiscal Year</b>	<b>Initial Rx Spend</b>	<b>Federal Rebates</b>	<b>Supplemental Rebates</b>	<b>Net Cost Pharmacy Spend</b>	<b>Rebate % of Initial Spending</b>
2007	\$610,742,500	\$177,455,500	\$16,576,800	\$416,710,200	31.8%
2008	\$671,510,600	\$205,934,100	\$20,758,400	\$444,818,100	33.8%
2009*	\$732,077,400	\$236,960,600	\$22,630,700	\$472,486,100	35.5%

Source: MO Health Net Medicaid Pharmacy Report, the Lewin Group, November 16, 2009, \* 2009 data is annualized.

Missouri statutes<sup>22</sup> prohibit MO HealthNet from implementing preferred drug approaches for psychotropic medications for persons with mental illness diagnoses or other illnesses for which treatment with psychotropic medications is indicated. Select exceptions are allowed for dose optimization, new drug combinations consisting of one of more existing drug entities, or preference algorithms for serotonin-specific reuptake inhibitor (SSRI) antidepressants. No restrictions to access can be imposed that would preclude availability of any individual atypical

21 *Pharmacy Provider Tax and Enhanced Fee*, MO HealthNet News, July 1, 2008 and *Mass Adjustment of Pharmacy Claims*, MO HealthNet News, November 24, 2008.

22 Section 208.227 of the Missouri Revised Statutes

antipsychotic monotherapy for treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression.

### Medication Therapy Management

MO HealthNet recognizes additional reimbursement for Medication Therapy Management (MTM) services. Implementation began in 2008, focusing on diabetes and asthma education. Through MTM programs, pharmacists provide patient education and monitoring “to optimize the benefits of prescribed drugs, improve medication use, reduce the risk of adverse drug events and drug interactions, and increase patient adherence to prescribed regimens.”<sup>23</sup> MO HealthNet pharmacies providing MTM services must use a web-based computer system, DirectCare Pro. This system allows a pharmacist to reserve intervention opportunities for specific patients, document completed activities, and generate a bill to MO HealthNet. MTM reimbursement is available in addition to any fee paid when a prescription is dispensed (Table 5).

**Table 5. MO HealthNet Reimbursement for MTM**

Reimbursement	Description of Pharmacist Service
\$20	MTM service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient (Limit: 1-time per participant per lifetime intervention)
\$10	MTM service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient. (Limit: 1-time per calendar month per participant per intervention)
\$15	For each additional 15 minutes

### Managed Care Pharmacy Carve-Out

Starting October 1, 2009, MO HealthNet implemented a pharmacy carve-out and began processing drug claims for MCO enrollees under its fee-for-service preferred drug list criteria and reimbursement principles. This change affected medications dispensed in a pharmacy, physician office, clinic, and other outpatient facilities.

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23 The Pharmacist’s Role in Medicare Medication Therapy Management Services, Alliance for Pharmaceutical Care, available at <http://www.pswi.org/professional/patient/mtm.pdf>

## Implications

Following are key pharmacy issues that MO HealthNet will be facing during the next several years.

### Product Cost Reimbursement

A litigation settlement involving First DataBank and Medi-Span required that the vendors lower select AWP's on September 26, 2009. The reductions affected the "spread" between WAC and AWP, and reduced the 1.25 mark-up on WAC used to calculate AWP to a pre-2000 level of a 1.20 mark-up. First DataBank<sup>24</sup> also announced that it would cease publishing AWP's "no later than September 26, 2011." The American Medicaid Pharmacy Administrators Association (AMPAA) commissioned a 13-state working group to review AWP and product cost payment issues, supported with technical assistance from First DataBank staff. Later, representatives from the National Association of Medicaid Directors (NASMD) were added. In November 2009, the group provided reimbursement recommendations for replacing AWP. Noteworthy is a finding that WAC-based payments as used by MO HealthNet, in conjunction with a well designed MAC program, could serve as an interim pricing source for AWP on brand drugs until a better "average acquisition cost" benchmark is available. The report noted that implementing average acquisition cost payments would require considerable effort and staffing commitment, including the development of a precise definition for reporting data, the process for data acquisition, and identification of a reporting entity.

### Pharmacy Provider Tax

Missouri has implemented an innovative pharmacy provider tax to leverage additional federal matching funds. This tax provides needed revenue to help the state sustain current product cost and dispensing fee rates, and to recognize reimbursement for MTM services. Depending on whether CMS supports its continuance, this could be a "best practice" for other states to draw down federal funds and improve patient care. This additional revenue has allowed MO HealthNet to provide relatively generous pharmacy reimbursement in comparison to other states. For example, only one state, Alaska, has a higher dispensing fee than Missouri.

### Managed Care Pharmacy Carve-Out

Now that states can collect drug rebates for both fee-for-service and capitated managed care prescriptions, carve-out decisions may need to be revisited. There are, however, many factors to consider when reviewing this issue, including:

- How will changes in provider tax and supplemental rebate revenue affect savings if drugs are carved back into managed care plans, or if managed care enrollment increases?
- Will carve-out and carve-in changes increase or decrease capitation rates paid?
- Will a state uniform preferred drug list maximize rebate income?

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24 Update Regarding AWP Litigation – Final Order and Judgment Entered, March 31, 2009, available at [www.firstdatabank.com/Support/awp-communications.aspx](http://www.firstdatabank.com/Support/awp-communications.aspx)

Medicaid drug reimbursement strategies are complex, involving not only payments to pharmacies, but also net effects of manufacturer rebates and coverages under preferred drug lists. Missouri, like other states, must be poised to face challenging policy issues resulting from changes in federal requirements and available funding. At the same time, the state must balance expectations for continued levels of pharmacy reimbursement, access to pharmacy services, and quality of care.

## Appendix A

### Definitions Relating to Pharmacy Reimbursement

Term	Meaning	Legal Reference
Single Source Drug	<p>Means a drug that is produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA), including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.</p> <p>One product is approved on the market for the active ingredient, strength, and dosage form (e.g., tablet, capsule, vial, etc.).</p>	Sec 1927(k) of the SSA and 42 CFR §447.502
Multiple Source Drug	<p>Means a drug multiple manufacturers distribute, each providing a pharmaceutical equivalent having the same active ingredient(s), strength, and dosage form.</p> <p>These drugs include noninnovator products, often called generics, and the innovator drug that was originally marketed under an original new drug application approved by the FDA.</p>	Sec 1927(k)(7) of the SSA provides requirements relating to multiple source drugs as used in the FUL process
Innovator Multiple Source Drug	<p>Means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the FDA.</p> <p>A Single Source Drug becomes an Innovator Multiple Source Drug as it loses its patent protection.</p>	42 CFR §447.502
Noninnovator Multiple Source Drug	<p>Means a multiple source drug that is not an innovator multiple source drug or a single source drug.</p> <p>Noninnovator Multiple Source Drugs are often referred to as generics.</p>	42 CFR §447.502
Brand Drug	Means a Single Source Drug or Innovator Multiple Source Drug.	42 CFR §447.502

Term	Meaning	Legal Reference
Dispensing Fee	<p>Means a fee for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed. It includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.</p>	42 CFR §447.502
Average Wholesale Price (AWP)	<p>Means the list price from a wholesaler to a pharmacy. AWP is not the price paid, as pharmacies negotiate discounts. Payers typically discount AWP to estimate a pharmacy's acquisition costs.</p>	Not defined in federal Medicaid law or regulation
Wholesale Acquisition Cost (WAC)	<p>Means the manufacturer's list price to wholesalers or direct purchasers. WAC is not the price paid, as manufacturers offer discounts. Payers typically mark up WAC to estimate a pharmacy's acquisition costs.</p>	Defined in Medicare law at Sec 1847A (c)(6)(B) of the SSA, but not Medicaid law
Average Manufacturer Price (AMP)	<p>Means the average price paid to the manufacturer for the drug in the United States by wholesalers, for drugs distributed to retail community pharmacies; and retail community pharmacies that purchase drugs direct from the manufacturer.</p>	Sec 1927(k) of the SSA

<b>Term</b>	<b>Meaning</b>	<b>Legal Reference</b>
Federal Upper Limit (FUL)	<p>Means a federal upper reimbursement limit set for a multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.</p> <p>FULs are set as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly Average Manufacturer Price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis.</p>	Sec 1927(e) of the SSA
Maximum Allowable Cost (MAC)	<p>Payment ceilings on multiple source drugs and select other drugs set by states and other payers.</p> <p>A state may implement its own MAC rates – as long as its payments do not exceed FULs in aggregate.</p>	Not defined in federal Medicaid law or regulation