Issues in Missouri Health Care 2009

Medication Marketplace: Getting the Best Price on Prescription Drugs for Missourians

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.

Issue Statement

Prescription drug costs for years have been among the leading cost drivers in health care in general and in Medicaid in particular. For the fiscal years 2006 through 2009, anywhere from 29 to 33 states have implemented cost containment strategies around the Medicaid drug benefit. At the same time, drug therapies are playing an increasing role in the plans of care for people who are elderly or who have disabilities or chronic conditions. How states address these twin pressures of price and demand can have a significant impact on the efficacy of the medical treatment provided to MO HealthNet recipients.

Background

Missouri's Medicaid program, known as MO HealthNet, is administered by the MO HealthNet Division within the Department of Social Services. Pharmacy benefits are available under risk-based, capitated managed care and under traditional fee-for-service. Fee-for-service pharmacy spending in state fiscal year 2007 was $543.3 million for 9.6 million prescriptions.[1] The state currently receives federal matching funds on its Medicaid spending at a Federal Medical Assistance Percentage (FMAP) of 63.19 percent. To qualify for this funding, MO HealthNet must operate under the constraints of federal laws and regulations. This issue brief describes MO HealthNet fee-for-service prescription drug pricing, key federal requirements, and policy implications.

State-Phased Down Contribution for Dual Eligibles

The Medicare Modernization Act (MMA) added Medicare Part D prescription drug coverage through private prescription drug plans in 2006. The law also required that beginning January 1, 2006 individuals dually enrolled in Medicare and Medicaid (known as "dual eligibles") transition from Medicaid to Medicare Part D prescription coverage. However, states continue to help finance the prescription costs of the dual eligibles through a phased down contribution, commonly called the "clawback." The clawback is calculated based on a state's 2003 per capita pharmacy spending for the dual eligibles and trended forward each year for inflation. Starting in 2006, the calculated amount of the clawback for each state was discounted 10 percent. Over a ten year period the discount gradually increases to 25 percent and thereafter will remain constant. Each state must pay

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[1] MO HealthNet *Division Appropriation Summaries.* January 28, 2008. Available at http://www.dss.mo.gov/mis/apprpsum/hlthcare09/dms1pgap.pdf

the adjusted per capita amount monthly for its dual eligibles enrolled in Part D. The clawback does not phase out entirely.[2]

As the dual eligibles transitioned to Medicare Part D, the number of MO HealthNet prescriptions dropped about 50 percent, from 19.1 million (2005) to 9.6 million (2007). Even though prescription volume decreased, the state still incurs continued clawback liabilities that amounted to over $175.5 million during state fiscal year 2007 for the approximately 128,000 dual eligibles.[3]

Pharmaceutical Manufacturer Rebates

Under federal law, each state qualifies for manufacturer drug rebates on Medicaid fee-for-service prescriptions. Manufacturers desiring Medicaid coverage for their products must sign rebate agreements with the federal government. Once signed, the Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services calculates and sends states unit rebate amounts for the manufacturer's drugs. A state then invoices manufacturers quarterly for rebates based on its paid prescription utilization. Each drug's unit rebate amount is confidential under federal law and is not publically available outside the rebate billing process.

MO HealthNet also has chosen to negotiate additional state supplemental rebates with manufacturers leveraged on a preferred drug list. This approach identifies preferred products in high cost drug classes that are based on clinical and cost effectiveness. A drug not identified as preferred typically 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. Unlike federal rebates, supplemental rebate levels vary from state-to-state and are dependent on a state's prescription drug volume and negotiations with manufacturers.

Resulting revenue from federal and state supplemental rebates is shared between the state and federal governments based on a state's FMAP. Since Missouri's FMAP is now 63.19 percent, the federal government would receive $0.6319 on every rebate dollar collected.

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[2] 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.
[3] MO HealthNet *Division Appropriation Summaries.* January 28, 2008. Available at http://www.dss.mo.gov/mis/apprpsum/hlthcare09/dms1pgap.pdf

Pharmacy Reimbursement

MO HealthNet prescription drug reimbursement is based on a formula that includes payment for procuring drug products and for dispensing a prescription. Medication therapy management (MTM) is paid separately on a different fee schedule than the prescription.

Product Cost Payment – Sole-Source and Multiple-Sole Drugs

State Medicaid programs use different payment mechanisms for sole-source and multiple source drugs. The following sections include definitions and pricing explanations related to the different payment mechanisms.

Sole-Source Drugs – "On-Patent Brands"

Referring to a drug as "sole-source" means only one product is approved on the market for a particular active ingredient, strength, and dosage form (e.g., tablet, capsule, vial, etc.). These drugs often are called on-patent brands, because a manufacturer still holds the drug's patent and no generics are available. Federal requirements allow states broad flexibility to set payment rates for sole-source drugs. Chosen methodologies historically have included the pricing indices: Average Wholesale Price (AWP) or Wholesaler Acquisition Cost (WAC). States obtain AWP and WAC data from national pricing compendia services, such as First DataBank and Medispan. Neither AWP nor WAC is defined in federal law or regulation.

Average Wholesale Price (AWP) is the list price from a drug wholesaler to a pharmacy and is not the actual price paid, since pharmacies negotiate discounts.[4] To estimate acquisition costs, payers have reimbursed pharmacies at AWP minus a discount. The discount levels used by states vary from 5 percent in Alaska to 17 percent in California (Table 1).

Table 1: Sample State Medicaid AWP Discounts, June 2008

States	AWP Discount
Alaska	5%
Alabama, District of Columbia, Georgia, Hawaii, Missouri, Nebraska, North Carolina, North Dakota, South Carolina, South Dakota, Virginia, and Wyoming	10 - 11%
Arizona, Florida, Indiana, Montana, Nevada, New Hampshire, Pennsylvania, Oregon, Texas, Utah, and West Virginia	15 - 16%

[4] *2007 State Perspectives Medicaid Pharmacy Policies and Practices*, National Association of State Medicaid Directors and Health Management Associates, November 2007. www.nasmd.org

California	17%

Source: Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2008. Centers for Medicare and Medicaid Services. Available at www.cms.gov

Wholesaler Acquisition Cost (WAC) is the list price from a manufacturer to a drug wholesaler or other direct purchaser. To estimate pharmacy costs available from wholesalers, payers typically mark-up WAC. Eleven states use WAC-based rates that range from no markup in Rhode Island to a 12.5 percent markup in North Dakota. Most states use WAC in combination with discounted AWP payments. For example, Missouri reimburses sole-source drugs based on the lower of AWP less 10.43 percent or WAC plus 10 percent.

Multiple-Source Drugs – "Generics" and "Off-Patent Brands"

Referring to a drug as "multiple-source" means there are multiple manufacturers for the drug that are pharmaceutical equivalents having the same active ingredient(s), strength, and the same dosage form. These drugs include non-innovator products (often called generics) and the innovator drug (off-patent brand).

For decades, CMS has issued prices on multiple-source drugs called Federal Upper Limits (FULs). 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. The Deficit Reduction Act of 2005 (DRA) mandated changes to the FUL calculation based on Average Manufacturers Prices (AMPs) and made the previously confidential AMPs used in the federal drug rebate program publically available. Pharmacies are skeptical the new FULs will recognize reimbursement for their actual acquisition costs. Several national pharmacy associations sued CMS and petitioned Congress for relief. In July 2008, the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275, was enacted and prohibited implementation of the AMP-based FULs prior to October 1, 2009.[5] In the interim, FUL rate setting reverted back to the pre-DRA provisions (Table 2).

Table 2: DRA Changes to FULs

Changes	Pre-Deficit Reduction Act	Post-Deficit Reduction Act
FUL Calculation	AWP + 150% of least costly therapeutic equivalent	AMP + 250% of least costly, widely available therapeutic equivalent
FUL Drugs	3 or more sources available *(Innovator Brand + 2 Generics)*	2 or more sources available *(Innovator Brand + 1 Generic)*
FUL Updates	Quarterly (but usually less frequent)	Monthly

[5] Federal Upper Limits, www.cms.hhs.gov, accessed September 17, 2008

MO HealthNet pays multiple-source drugs at the lower of a state MAC rate or the FUL. This logic applies both to the non-innovator generic drugs and to off-patent innovator brands (unless an exception is granted through prior authorization). Approved exceptions and multiple-source drugs without MACs or FULs are paid the same as sole-source drugs.

Dispensing Fee Payment

In addition to product cost payment, MO HealthNet pays pharmacies a $4.84 standard dispensing fee for services related to filling a prescription. MTM, described in detail in a following section, is not included in this reimbursement. An enhanced fee of $4.82 is added to the $4.84 standard dispensing fee resulting in a total $9.66 fee. This level is one of the highest in the nation according to federal documentation of Medicaid prescription reimbursement dated June 2008.[6]

The enhanced fee is funded in part from pharmacy provider taxes, which are used to leverage additional federal matching funds. To illustrate this joint funding, the $4.82 enhanced fee is supported by provider tax revenue ($1.77) while the federal government pays the remaining $3.05 (or 63.19 percent, which is the state's current FMAP). Federal requirements for provider healthcare taxes are complex and generally stipulate the taxes must:

- Be broad-based applying to all pharmacies.
- Be uniform.
- Avoid hold harmless arrangements.

MO HealthNet temporarily suspended the enhanced fee and pharmacy provider tax in July 2008. State staff explained the variable tax was transitioning to a flat tax of approximately 1 percent. When the tax is re-implemented, MO HealthNet plans a mass adjustment to previously paid pharmacy claims to recognize the enhanced fee. The Missouri Pharmacy Association supports the provider tax and has created the Pharmacy Agency Corporation to perform administrative activities related to the tax on behalf of pharmacies.[7]

Overall Prescription Drug Reimbursement Logic

The MO HealthNet fee-for-service prescription drug reimbursement is summarized in Table 3. The summary lists a pricing basis termed usual and customary charge that has

[6] *Medicaid Prescription Reimbursement Information by State – Quarter Ending June 2008*. Centers for Medicare and Medicaid Services. Available at www.cms.gov
[7] *Pharmacy Provider Tax and Enhanced Fee*, MO HealthNet News, July 1, 2008.

not been previously discussed. Under federal requirements, pharmacies are prohibited from billing Medicaid more than their usual and customary charge to the general public. This applies across all drugs, both source-sole and multiple-source.

Table 3: MO HealthNet Fee-For-Service Prescription Drug Reimbursement
Generally, MO HealthNet prescription drug reimbursement is the lowest of: • AWP less 10.43 percent plus a dispensing fee • WAC plus 10 percent plus a dispensing fee • FUL plus a dispensing fee • State MAC rate plus a dispensing fee • Usual and customary charge

For managed care, some plans choose to *carve-out* pharmacy from their capitation rates, in which case enrollee prescriptions are paid under the above fee-for-service methodology. Other plans, which do not carve out these services, are allowed to set their own pharmacy rates with the exception of HIV/AIDS protease inhibitor drugs. This drug class is carved-out for all plans and is reimbursed under fee-for-service for all managed care enrollees. Under federal law, prescriptions paid under capitated managed care do not qualify for federal or state supplemental manufacturer rebates, but fee-for-service carve-outs do.

Medication Therapy Management (MTM)

MO HealthNet recently recognized additional reimbursement for MTM. Implementation began in phases, with the first starting in January 2008 focusing on diabetes and asthma education. Subsequent phases will integrate chronic obstructive pulmonary disease, cardio-vascular disease, depression, gastro-intestinal disease, migraine, osteoporosis, and various other conditions.

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." Pharmacist-provided services include, but are not limited to:

- Performing assessments of a patient's health status.
- Developing a medication treatment plan.
- Monitoring a patient's response to therapy.
- Communicating essential information to other primary care provider.
- Providing training on the appropriate use of medications.
- Coordinating MTM services within the healthcare delivery system.[8]

[8] The Pharmacist's Role in Medicare Medication Therapy Management Services, Alliance for Pharmaceutical Care,

To obtain payment, pharmacists providing services must use an automated, web-based computer system called DirectCare Pro. This system allows a pharmacist to reserve intervention opportunities for specific patients, document completed activities, and generate a bill for payment. Table 4 lists the MO HealthNet reimbursement for MTM services. This reimbursement is available in addition to the fee paid when a prescription is dispensed.

Table 4: MO HealthNet Reimbursement for MTM

Reimbursement	Description of Pharmacist Service
$50	MTM service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient (State 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, establish patient. (State Limit: 1-time per calendar month per participant per intervention)
$5	For each additional 15 minutes

Implications

Even though the Medicaid prescription volume dropped by about 50 percent with the dual eligibles' transition to Medicare Part D prescription drug coverage; administrative challenges related to the pharmacy benefit were not lessened. Key issues include:

- *Product Cost Reimbursement*: Historically-used pricing indices, particularly AWP, are under close scrutiny. State Attorney Generals across the nation and the U.S. Department of Justice have shown that manufacturers have falsely inflated AWPs to create a higher "spread" between the actual acquisition cost and the published AWP and that the manufacturers then use this AWP spread to market their products. The State of Missouri has successfully sued various manufacturers engaging in these pricing schemes. National pricing compendia – First DataBank and Medispan – are also under litigation that alleges AWP misrepresentation. Settlement terms are likely to prohibit their publishing of AWPs and development of replacements are underway. Some states have indicated interest in using AMP to replace AWP reimbursement.[9] Such efforts are likely to meet pharmacy resistance, as recently evidenced by objections to AMP-based FULs that were recently delayed by federal law.
- *Overall Prescription Drug Reimbursement*: MO HealthNet provides relatively generous pharmacy reimbursement in comparison to other states. Hopefully, this

[9] *2007 State Perspectives Medicaid Pharmacy Policies and Practices*, National Association of State Medicaid Directors and Health Management Associates, November 2007. www.nasmd.org

encourages pharmacist counseling and therapy management that will ultimately lead to more appropriate medication use and better health outcomes. Ongoing studies may be warranted to substantiate this premise.

- *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 as well as recognize reimbursement for a MTM. Depending on CMS support for its continuance, this could be a "best practice" for other states to draw down federal funds and improve patient care.
- *Managed Care Organizations:* MO HealthNet policies allow optional pharmacy carve-outs from the managed care capitation rates, in which case enrollees receive fee-for-service coverage. This approach is unique and its cost-effectiveness and patient care impacts should be reviewed. One issue already being addressed by MO HealthNet relates to mental health medications. Enrollees are being encouraged to report problems obtaining mental health medications to the state for resolution. Managed care plans also were advised that preferred drug lists different than fee-for-service may be implemented, but "medically necessary" non-preferred products must be covered through prior authorization to ensure consistent coverage with fee-for-service.[10]

Missouri, like other states, must be poised to face these and other challenging policy issues that have resulted from changes in federal requirements and available funding. At the same time states must balance provider expectations for continued levels of pharmacy reimbursement.

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[10] *Access to Mental Health Medications…*, MO HealthNet News, September 22, 2008.