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Medicaid Payment for Generic Drugs:
Achieving Savings and Access

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OVERVIEW — *Medicaid payment for generic prescription drugs has been a point of contention for the pharmacy industry over the past few years because of reimbursement formula changes contained in the Deficit Reduction Act (DRA) of 2005. The Patient Protection and Affordable Care Act (PPACA) includes provisions to resolve some of these issues. The DRA reduced the maximum amount the federal government would pay state Medicaid programs for generic drugs, and the Centers for Medicare & Medicaid services (CMS) final regulation, to implement the DRA provisions was met with a lawsuit from the pharmacy industry. An injunction by the federal district court, followed by a congressional moratorium, kept CMS from implementing the regulation and kept the pre-DRA formula for the generic drug payment limit in place. PPACA provisions increase maximum federal reimbursement levels for Medicaid generic drugs, but the impact on the pharmacy industry depends on CMS implementation and state policies. This paper examines Medicaid payment for generic drugs, the DRA and PPACA changes to generic drug reimbursement, the concerns of the pharmacy industry, and the potential impact on access.*

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Payment for prescription drugs under Medicaid has long been a significant issue for states and the federal government. An optional benefit offered by all states, Medicaid prescription drug benefits are one of the greatest costs to states and one of the most challenging to control. From 2000 to 2004, states experienced double-digit growth rates in drug expenditures, and from 2000 to 2002 the rate of increase in state spending on prescription drugs (19 percent) was greater than that of total Medicaid spending (12 percent).[1] A shift of prescription drug costs from Medicaid to Medicare Part D for those dually eligible for Medicare and Medicaid reduced Medicaid direct expenditures on drugs by over a third in 2006; nonetheless, drug expenditures still account for 13 percent of total Medicaid spending, making outpatient prescription drugs the second-largest spending category for Medicaid nationally, after long-term care.[2] Prescription drug expenditures by Medicaid in 2010 are projected to be $23.9 billion, over 9 percent of the projected U.S. total spending on prescription drugs.[3] Rising drug prices, increased drug utilization, and increases in the Medicaid population all contribute to the growth of Medicaid outpatient prescription drug expenditures.

Most prescription drugs reimbursed by Medicaid are dispensed by retail pharmacies. Pharmacies participating in Medicaid purchase prescription drugs through the regular drug distribution chain (that is, manufacturers and wholesalers). In general, payment to pharmacies for prescription drugs, both brand and generic, includes payment for the ingredient cost, which is usually based on published prices (for example, the average wholesale price [AWP] and the wholesale acquisition cost [WAC]), and a dispensing fee, which covers pharmacy overhead expenses, such as salaries, rent, utilities, labels, and bottles.

Under Medicaid, states have discretion to set both prescription drug ingredient payment rates and dispensing fees. States generally do not have access to pharmacies' acquisition costs and therefore establish

a best estimate of the price paid by pharmacies, using published prices from drug compendia, such as Red Book, First Data Bank, and Medi-Span, for the drug to determine the state's reimbursement to pharmacies. States predominantly use AWP or WAC to estimate pharmacy acquisition costs. Generally, states reimburse pharmacies for brand name drugs at the lower of the estimated pharmacy acquisition cost (plus a dispensing fee) or the pharmacy's usual and customary charge to the general public. The Office of the Inspector General (OIG) at the Department of Health and Human Services has found that published prices (that is, AWP and WAC) are higher than prices paid in actual sales transactions.[4] (See text box on the difficulties of setting appropriate drug reimbursements.)

Lack of Transparency: The Challenge of Setting Appropriate Drug Reimbursements

The large number of actors in the chain of prescription drug distribution and financing, the various discounts and rebates that drug prices are subject to, and the confidentiality of negotiated sales prices make it extremely difficult to determine the actual drug acquisition costs of providers. Furthermore, there are no drug pricing indices that provide accurate, aggregate market price information. List price data (for example, AWP) provided by manufacturers and published in drug pricing compendia such as Red Book and the Pharmaceutical BlueBook are the most accessible data, but they are not based on actual market transactions. Payers, including states, must rely on the published list prices because there are no alternatives, but at the same time, these prices are not real; payers cannot verify the accuracy of the manufacturer list prices. Pharmacy point-of-sale data can be purchased from firms such as IMS Health; however, these data do not capture the numerous time-delayed rebates that reduce the ultimate net price paid for a given prescription drug.

CONTROLLING COSTS

Both the federal government and states use various techniques to control costs. Many of these are unique to the Medicaid program.

State Efforts

State techniques for controlling Medicaid drug spending and utilization differ from those used by the private sector. The Medicaid statute precludes states from using many private-sector tools, such as drug formularies and mail-order–only requirements, for prescription drug cost containment. States, however, have discretion to use other techniques, such as prior authorization, preferred drug lists, nominal copays (ranging from $0.50 to $3.00), drug utilization review, disease management, and supply limits, such as monthly/annual prescription limits, day supply limits, and step-therapy requirements, to help contain costs. These techniques allow states to achieve some of the benefits of private tools, such as a formulary.

In addition, states can negotiate supplemental rebates from drug manufacturers in exchange for providing drugs more favorable status in terms of utilization management policies like prior authorization or step therapy.[5]

One of the most successful drug cost-containment approaches that states employ is aggressive generic substitution policies. Currently, 39 states require generic versions of drugs to be dispensed to Medicaid beneficiaries when available. Under these programs, brand name drugs are generally available only through prior authorization. Generic drug utilization has proven to be an effective source for savings: Minnesota, for example, estimates it saves $10 million annually through its generic substitution program. These programs drive overall usage of generic drugs in Medicaid. According to CMS, generic drugs account for 55 percent of total Medicaid prescriptions and as much as 67 percent in some states.[6]

Besides increasing the use of generics, states have succeeded in limiting spending through maximum allowable cost (MAC) programs. MAC programs limit state Medicaid reimbursement for certain drugs. According to CMS, 45 states and the District of Columbia have MAC programs.[7] States with MAC programs publish lists of selected generic and multisource brand drugs along with the maximum price the state Medicaid program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing Medicaid for drugs on a state's MAC list.[8] State methods for setting MAC prices include setting prices at the lowest published price for a generic version of the drug, setting prices based upon surveys of pharmacies to determine acquisition costs, and using the federal upper limit (FUL) price (see below) as the MAC price. States with established MAC programs have reported annual pharmacy budget savings of up to 4 percent.[9]

Since Medicaid is financed jointly by the federal government and the states, the federal government also has a financial stake in what Medicaid pays for prescription drugs. Additional federal measures, namely the Medicaid Drug Rebate Program and the FUL ceiling help ensure that the federal government is a prudent buyer of drugs. The Medicaid Drug Rebate Program provides state Medicaid programs a rebate from manufacturers for brand name and generic drugs, based on the discounted prices offered by manufacturers to other large purchasers. The quarterly rebates paid by manufacturers are shared

between the states and the federal government. In 2005, manufacturers paid Medicaid about $6.5 billion in drug rebates.[10]

Federal Upper Limit (FUL)

The Medicaid FUL for drugs, established in 1987, caps the level at which the federal Medicaid program will reimburse states for certain prescription drugs that have generic alternatives. According to CMS, as of September 2009, more than 700 multiple-source or generic drugs were on the Medicaid FUL price list. By limiting how much the federal government will pay states for prescription drugs that have generic alternatives, the federal government creates an incentive for states to direct Medicaid beneficiaries to use generic drugs instead of costlier brand name drugs and to limit the price the program pays pharmacies for those drugs. FUL prices for brand name drugs with generic alternatives are set by CMS. States can pay above or below the FUL amount for individual prescription drugs, as long as the aggregate expenditures for drugs with FULs do not exceed the amounts that would be spent by applying the FUL limit, plus a reasonable dispensing fee. According to CMS, the FUL "is intended to balance the interests of both pharmacists and the government in achieving efficiency, economy, and quality of care."[11]

Before enactment of the Deficit Reduction Act (DRA) of 2005, the FUL for drugs with generic alternatives was set at 150 percent of the lowest price published in national drug pricing compendia. Prices published in the national compendia are reported by drug manufacturers and are generally based on the AWP. Viewed as the "sticker price" for a drug and not an actual paid price, the AWP is always higher than the price paid by distributors (for example, pharmacies), once discounts and rebates for various transactions in the distribution chain are taken into account.[12]

Paying Too Much?

CMS has long criticized the use of published prices from drug pricing compendia for setting state Medicaid reimbursement levels, claiming that the practice leads to artificially inflated payments, since rebates and discounts paid throughout the drug distribution chain are not accounted for in the AWP. Using published prices, Medicaid reimbursements for prescription drugs often exceed actual pharmacy drug acquisition costs, particularly for generic drugs. A 2004 OIG review of 25

What Is the AMP?

The average manufacturer's price (AMP) is the average price wholesalers and other large purchasers pay manufacturers for prescription drugs that are sold to retail pharmacies. The AMP was created in the Omnibus Budget Reconciliation Act (OBRA) of 1990 for the Medicaid Drug Rebate Program to serve as a benchmark to determine rebate amounts manufacturers pay states for Medicaid drug purchases. The intent was to ensure that rebates were based on actual manufacturer prices paid, not on reported retail prices. The Medicaid rebate for brand name drugs is 23.1 percent of the AMP or the difference between the AMP and the "best price" (BP) per unit (AMP-BP), whichever is greater. The generic drug rebate is 13 percent of the AMP.

The AMP is calculated using sales transaction data, and it reflects cash discounts, volume discounts, and other reductions in the actual price paid. Manufacturers' sales to wholesalers for retail pharmacies for a particular drug are divided by the number of units sold.

Drug manufacturers are required to report AMP data for all Medicaid-covered drugs to CMS quarterly. States do not have access to AMP data, which are proprietary. Before the enactment of the DRA and PPACA, the AMP had been used only for the purpose of determining rebates and not as a basis for reimbursement.

*Best price *is the lowest manufacturer price paid for a drug by any purchaser (defined by the Medicaid statute as "any wholesaler, retailer, provider, health maintenance organization, or nonprofit or government entity," with some exceptions). A drug's reported best price is required to reflect all discounts, rebates, and other pricing adjustments.*

drugs found, for example, that the FULs for 23 of the drugs (150 percent of the lowest compendia drug price method) were more than double the average acquisition costs for their generic equivalents. For 13 drugs, the FUL amounts were at least 5 times higher than the average pharmacy acquisition costs.[13]

THE DEFICIT REDUCTION ACT

Changing Medicaid reimbursement could have a significant impact on total Medicaid drug expenditures. With the DRA, Congress sought to link the FUL for generic drugs to actual sales pricing data, which better reflect provider acquisition costs. Congress chose to use the average manufacturer's price (AMP), which is based on pricing data from sales transactions between manufacturers and wholesalers, as the basis for reimbursement. The DRA statutorily changed the FUL formula from 150 percent of the lowest published compendia price to 250 percent of the lowest reported AMP. Drug manufacturers have been reporting drug AMPs to CMS for the Medicaid Drug Rebate Program since the program's creation in 1990 (see text box).

The AMP is substantially lower than the AWP, particularly for generic drugs. Comparing the AMP to published prices for 24,000 national drug codes, the OIG found that the AMP is lower than the AWP for generic drugs by 70 percent at the median. For brand name drugs, the AMP is 23 percent lower than the AWP for single-source brand name drugs and 28 percent lower for multisource brand name drugs.[14]

The DRA also expanded the number of drugs subject to a FUL price: A FUL price will be set when at least two suppliers provide the drug (that is, list the drug in national pricing compendia). Previously, three

suppliers of a drug had to be available before a FUL price would be set by CMS. Finally, the DRA requires that AMP data be reported monthly and that CMS publish the data on its Web site for access by states and consumers to make pricing and reimbursement more transparent. CBO has estimated that, over five years, the DRA changes to pharmacy reimbursement will generate Medicaid savings of $3.6 billion on drugs with FULs.[15]

CMS Regulation

In addition to making the AMP the new base price for determining FULs, the DRA directed CMS to provide formal guidance for the determination of the AMP. Statutory provisions for the Medicaid Rebate Program have never been finalized in regulation; consequently, definitions of statutory terms have not been codified. As a result, the methods for calculating AMP have been found to be unclear and incomplete, with manufacturers including different market prices in their AMP determinations. The inclusion or exclusion of certain sales transactions can affect a drug's AMP, which in turn affects how much a manufacturer has to pay in rebates for that specific drug.

Which sales prices are included in a drug's AMP hinges upon what is considered to be the "retail class of trade" for the drug. Neither the Medicaid rebate agreement signed by manufacturers to participate in Medicaid nor CMS guidance defines the term "retail pharmacy class of trade," although they do specify some of the kinds of sales that manufacturers should include and exclude from the AMP. Manufacturers have been inconsistent in defining retail class of trade for drugs when compiling AMP calculations.[16] Critics point to the lack of a formal CMS definition for the term as a loophole that permits inconsistent price reporting by drug manufacturers and manipulation of the rebate formula to reduce rebate liability.

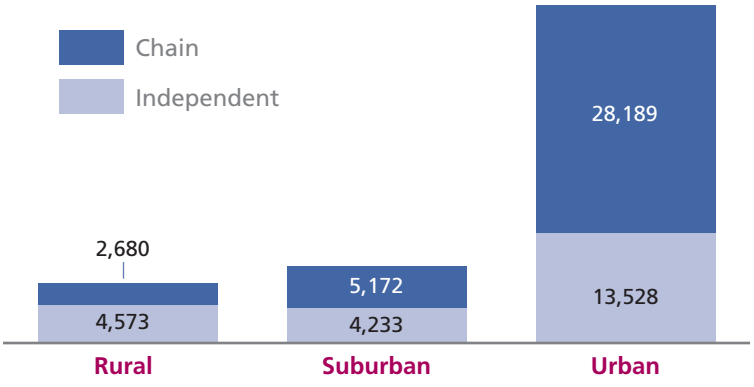
The CMS final regulation implementing the DRA provision defined the AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." Retail pharmacy class of trade was defined as "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public." This definition included sales transactions through mail-order pharmacies.

Pharmacy Concerns

The retail pharmacy industry alleged that the new FUL formula of 250 percent of the AMP would not cover their generic prescription drug acquisition costs. The industry argued that the DRA's AMP definition was overly broad and did not appropriately reflect the price in the retail class of trade because it included mail-order prices and some specialty-pharmacy prices that are not available to retail pharmacies. As a result, they argued, the AMP would be artificially low, reimbursement for generic drugs would be inadequate, and pharmacies might not be able to afford to stock these generics.

The pharmacy industry claimed that the decreased reimbursement rates would particularly affect independently owned pharmacies. According to the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), community or independently owned retail pharmacies are often the only providers in rural areas. The associations were concerned that the change in the FUL would result in "a loss of local pharmacy services and access for low-income patients in many rural and inner-city areas as pharmacists either drop out of the Medicaid program or close their doors after operating at a loss."[17] (See Figure 1 for distribution of independent and chain pharmacies by geographic location and Table 1, next page, for number of retail and independent pharmacies by state.) The industry expected the new FUL formula to have a greater impact on independent pharmacies than on chain-store pharmacies, since independents rely on pharmacy sales for more of their total revenue than chains. Chain drug stores have greater nonpharmacy sales, such as gift cards, food, and sunglasses. Furthermore, it was believed that, because independents must buy generic prescription drugs through wholesalers while large chains and mail-order programs can purchase generics directly from manufacturers, their acquisition costs can differ and

FIGURE 1
Number of Independent and Chain Pharmacies, by Geographic Location



Source: SK&A Healthcare Information Solutions "Consumer Access to Pharmacies in the United States, 2007," prepared for the Pharmaceutical Care Management Association, May 2007; available at http://pcmanet.org/assets/2008-03-25_Research_SKA%20Research%20Consumer%20Access%20to%20Pharmacies%202007%205_1_07.pdf.

independents would be at greater risk of financial losses due to the new DRA payment formula.

TABLE 1 | Number of Retail and Independent Pharmacies, by State, March 2007

	No. of Retail Pharmacies	No. of Independent Pharmacies
United States	58,355	22,334
Alabama	1,229	583
Alaska	93	48
Arizona	1,001	404
Arkansas	724	168
California	5,350	2,243
Colorado	828	264
Connecticut	622	160
Delaware	162	20
District of Columbia	110	41
Florida	4,267	1,537
Georgia	1,938	721
Hawaii	171	96
Idaho	272	120
Illinois	2,201	716
Indiana	1,146	251
Iowa	716	350
Kansas	589	306
Kentucky	1,002	493
Louisiana	1,013	512
Maine	252	55
Maryland	1,036	293
Massachusetts	1,077	230
Michigan	2,120	722
Minnesota	985	349
Mississippi	767	423
Missouri	1,157	512
Montana	229	136
Nebraska	429	237
Nevada	438	72
New Hampshire	243	51
New Jersey	1,810	684
New Mexico	292	120
New York	4,131	1,978
North Carolina	1,781	720
North Dakota	170	140
Ohio	2,237	615
Oklahoma	850	481
Oregon	657	215
Pennsylvania	2,774	1,012
Rhode Island	188	37
South Carolina	957	365
South Dakota	184	104
Tennessee	1,425	530
Texas	4,056	1,544
Utah	422	171
Vermont	130	45
Virginia	1,385	432
Washington	1,173	408
West Virginia	466	187
Wisconsin	150	371
Wyoming	120	62

Source: SK&A Healthcare Information Solutions, "Consumer Access to Pharmacies in the United States, 2007," May 2007; available at http://pcmanet.org/assets/2008-03-25_Research_SKA%20Research%20Consumer%20Access%20to%20Pharmacies%202007%205_1_07.pdf.

Note: SK&A's database of U.S. pharmacies and pharmacists is gathered from public sources, such as state pharmacy licensures and corporate registrations.

CMS concluded that the July 2007 rule would likely have a "significant impact" on some pharmacies and expressed its concern about the impact on small pharmacies, particularly those in low-income areas where there is a high concentration of Medicaid beneficiaries. According to NACDS, there are approximately 21,000 small pharmacies.

The pharmacy industry was also concerned that the impact of the AMP-based formula for FULs would be compounded by the publication of the AMPs, information previously considered proprietary. Once the AMPs are published on the CMS Web site, other third-party payers are likely to adopt Medicaid FULs and use them for their reimbursement caps within their own drug benefit programs. The AMP will become the new reference price for all payers.

Would AMP-Based FULs Pay Too Little?

Both the GAO and the OIG looked extensively at the impact the AMP rule would have on Medicaid generic drug reimbursement. The GAO compared the AMPs as they would be calculated under the new rules and the average retail acquisition costs of the drugs that were most frequently dispensed to Medicaid beneficiaries and of the most-costly Medicaid-reimbursable drugs; 77 drugs were examined. According to the GAO, the "estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs." For the drugs with the highest Medicaid expenditures, the difference was 65 percent.[18]

The OIG has stated that FUL reimbursement amounts under the new AMP-based formula would decrease for the vast majority of drugs and may not cover acquisition costs. The OIG used the AMP-based formula to determine the FULs for 521 drugs and found that 492 (94 percent) would be reduced under the DRA requirements, 334 (64 percent) by at least half. Examining pricing data for 25 selected high-expenditure drugs, the OIG found that average acquisition costs of 19 drugs would exceed the new FUL, meaning that pharmacies would have been able to purchase only 6 of the 25 drugs for less than the new FUL. Furthermore, 12 drugs had pharmacy acquisition costs that were more than double the new reimbursement limit.[19] Only 13 of the 25 selected drugs had at least one drug product available for a price at or below the new FUL.

The pharmacy industry filed a lawsuit against CMS, and an injunction from a federal district court delayed the implementation of the DRA's AMP and FUL requirements. The Medicare Improvement for Patients and Providers Act of 2008, passed in July 2008, further delayed implementation by imposing a congressional moratorium on when the CMS July 2007 final rule could go into effect. On September 3, 2010, CMS published a proposal to withdraw provisions of its 2007 regulation governing the determination of AMP and the setting of federal upper limits for generic drugs. Both of these DRA requirements have been superseded by the Patient Protection and Affordable Care Act (PPACA), which made changes to the definition of AMP and also redefined the methodology for calculating FULs (see below).

Do State MAC Lists Trump FUL Limits?

While the comparisons of FUL payments pre- and post-DRA are dramatic, comparisons of the AMP-based FUL to the 45 state MAC prices provides a clearer picture of the impact of a new FUL formula on pharmacy reimbursement within specific states. States have a lot of flexibility regarding which drugs are included in their MAC lists and what their prices are. In general, state MAC lists include more drugs and assign lower reimbursement prices than the FUL, although the size of MAC lists and their prices can vary from state to state. States relying on MAC lists for pharmacy reimbursement generally already pay less than the current FUL price. In those states where MAC prices are below FUL prices, switching to the AMP-based FUL will have no impact and will produce no decrease in pharmacy reimbursement. The degree to which pharmacies are affected by the AMP-based FUL depends on current reimbursement prices in the states, which cannot be assumed to be FUL prices. The GAO and the OIG have shown that reimbursement for pharmacies will decrease under the DRA AMP-based FUL formula if states are reimbursing at the current FUL prices. However, if current state reimbursement rates are less than the current FUL, then the pricing impact of the AMP-based FUL formula is diminished and possibly even nonexistent.

ISSUES

As mentioned above, opponents to the change in the Medicaid reimbursement formula claim that independently owned pharmacies will

be most adversely affected by AMP-based reimbursement and will leave the Medicaid program, resulting in a limiting of Medicaid beneficiaries' access to pharmacies. However, the degree of competition in the pharmacy industry seems to have pharmacy access in general on a solid footing. There are over 59,000 retail pharmacies dispersed in urban, suburban, and rural areas throughout the country, including chain drug stores, independently owned drug stores, supermarket pharmacies, and pharmacies operated by mass merchandisers.[20] More than 21,000 are independently owned. Mail-order pharmacies also compete with these brick-and-mortar retail pharmacies.

A 2007 study conducted for the Pharmacy Care Management Association (PCMA), which represents pharmacy benefit managers, found that "on average, a consumer patronizing an independent pharmacy in the United States has access to 21 competing pharmacies located near their current pharmacy."[21] More specifically, the study found the following:

- In urban areas, where most independent pharmacies are located, consumers patronizing independents have access to 30 competing pharmacies within two miles of their current pharmacy.
- In suburban areas, independent pharmacy consumers have access to seven competing pharmacies located within five miles of their current pharmacy.
- In rural areas, independent pharmacy consumers typically have access to 14 competing pharmacies located within 15 miles of their current pharmacy.

Among the questions these findings raise are the following: What is an adequate number of pharmacies, independently owned or otherwise, for any given area? Do most areas have enough pharmacies? Too many pharmacies?

Although pharmacy capacity appears to be sufficient, at least on a national level, it is important to note that, with respect to Medicaid, high concentrations of low-income populations can be underserved by various providers, including pharmacies, and transportation can be a barrier to access. It is, therefore, conceivable that access could be limited in certain areas if pharmacies leave the Medicaid market.

Whether Medicaid access is affected by pricing changes depends on total pharmacy capacity and Medicaid pharmacy participation within a given area. Decisions to keep a pharmacy open or participating

in Medicaid are complicated and affected by a variety of factors, including but not limited to generic drug ingredient reimbursement. Also factored into pharmacy/drug store business decisions, including whether or not to participate in Medicaid, are pharmacy location, size, and type; generic and brand name dispensing fees; sales of nonpharmacy items; and size of pharmacy "books of business" (that is, Medicare, private-pay, and Medicaid).

Industry groups have argued that if the pharmacy margin on ingredient reimbursement is decreased, the dispensing fee must be increased by an equivalent amount to maintain the viability of the pharmacy. State Medicaid dispensing fees for generics and brand name drugs range from $2.00 to $12.50.[22] The average Medicaid dispensing fee is $4.25 per prescription, and some states pay higher dispensing fees for generics than brand name drugs.

While there may be state willingness to increase dispensing fees, it is important to remember that the federal government will share the costs of any dispensing fee increase, which would negate a portion of federal savings this reimbursement change is designed to achieve. CMS must approve Medicaid dispensing fee increases as part of a state plan amendment approval, although states could provide more without the federal Medicaid match.

PATIENT PROTECTION AND AFFORDABLE CARE ACT

PPACA changes the federal upper limit for generic drugs to no less than 175 percent of the weighted average AMP. The pharmacy industry believes the reimbursement levels under the new health law, which go into effect October 1, 2010, will be lower than current, pre-DRA levels but higher than the levels called for in the DRA. The fact that the FUL will be "no less than" 175 percent of the weighted average (based on utilization) of the AMP suggests that CMS could exercise its discretion to establish a higher FUL.

In addition, PPACA redefines AMP for use in the federal upper payment limits to apply to "retail community pharmacies" rather than the retail pharmacy class of trade. A retail community pharmacy is defined as "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices." The act also revises the list of entities whose

prices are statutorily excluded from AMP (that is, mail-order pharmacies, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies or pharmacy benefit managers. The new definition of AMP excludes some of the entities that can negotiate greater price concessions, so it will likely result in higher AMPs.

While the revised FUL formula and new definition for AMP may alleviate some concerns of the industry, once again the true impact of the revisions rests with the states. As explained above, states set reimbursement and often pay less than the federal upper limit, so the perceived reduction in reimbursement may have never truly existed.

CONCLUSION

It is clear that Congress is interested in aligning Medicaid drug reimbursement more closely with pharmacy acquisition costs by using prices based on actual sales rather than published prices. There are substantial disparities between AMP sales transaction data and published prices currently used for reimbursement, which could greatly affect federal and state Medicaid drug expenditures. The real impact of any new AMP-based FUL formula for generics, however, will vary across states and depend on current reimbursement prices. The MAC lists used in 45 states and the District of Columbia generally have lower reimbursement prices than the current FUL limits. A change in the FUL price only matters if the new AMP-based FUL is less than the existing MAC prices in those states. Regardless, like all Medicaid services, state Medicaid prescription drug payment rates must be sufficient to enlist enough pharmacies to ensure that covered services are available, at least to the extent that comparable care and services are available to the general population within a geographic area.

ENDNOTES

1. Centers for Medicare & Medicaid Services (CMS), "National Health Expenditures by Type of Service and source of funds, CY 1960-2008"; available at www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage.

2. Mandatory state "clawback" payments to the federal government for what state drug expenditures would have been for the dually eligible absent Medicare Part D are not considered drug expenditures.

3. CMS, "National Health Expenditure Projections 2009–2019"; available at www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2009.pdf.

4. Office of the Inspector General (OIG), "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program," U.S. Department of Health and Human Services, OEI-03-06-00400, June 2007; available at http://oig.hhs.gov/oei/reports/oei-03-06-00400.pdf.

5. Supplemental rebates are in addition to the statutorily required basic Medicaid rebate of 23.1 percent of the average manufacturer's price (AMP) for brand name drugs and 13 percent of the AMP for generic drugs.

6. Dennis Smith, CMS, "Medicaid Prescription Drug Reimbursement," testimony before the Subcommittee on Energy and Commerce, Committee on Energy and Commerce, U.S. House of Representatives, December 7, 2004; available at www.hhs.gov/asl/testify/t041207.html.

7. CMS, "Medicaid Prescription Reimbursement Information by State – Quarter Ending September 2009"; available at www.cms.hhs.gov/reimbursement/downloads/reimbursementchart3q2009.pdf.

8. If a federal upper limit (FUL) is applied to a drug, the payment, in the aggregate, may not exceed the FUL, even if the FUL is lower than the maximum allowable cost (MAC).

9. Richard G. Abramson *et al.*, "Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs," *Health Care Financing Review,* 25, no. 3 (Spring 2004): pp. 25–34.

10. For more information about the Medicaid Drug Rebate Program, see Christie Provost Peters, "The Medicaid Drug Rebate Program," National Health Policy Forum, The Basics, April 13, 2009; available at www.nhpf.org/library/the-basics/Basics_MedicaidDrugRebate_04-13-09.pdf.

11. Smith, testimony.

12. For more information on average wholesale prices, see Dawn M. Gencarelli, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?" National Health Policy Forum, Issue Brief 775, June 7, 2002; available at www.nhpf.org/library/issue-briefs/IB775_AWP_6-7-02.pdf.

13. OIG, "Deficit Reduction Act of 2005," p. iii.

14. OIG, "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices" OEI-05-05-00240, June 2005; available at http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf.

15. Congressional Budget Office, "Cost Estimate: S. 1932 Deficit Reduction Act of 2005," January 27, 2006; available at www.cbo.gov/ftpdocs/70xx/doc7028/s1932conf.pdf.

16. OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," A-06-06-00063, May 2006; available at http://oig.hhs.gov/oas/reports/region6/60600063.pdf.

17. "Industry looks to Congress, states for Medicaid relief," *Drug Store News,* August 31, 2007.

18. U.S. Government Accountability Office, "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs," GAO-07-239R, December 22, 2006; available at www.gao.gov/new.items/d07239r.pdf. In some cases the difference in prices is a few cents that, when based on the low price, represents a large percentage change.

19. OIG, "Deficit Reduction Act of 2005."

20. SK&A Healthcare Information Solutions "Consumer Access to Pharmacies in the United States, 2007" prepared for the Pharmaceutical Care Management Association, May 2007; available at http://pcmanet.org/assets/2008-03-25_Research_SKA%20Research%20Consumer%20Access%20to%20Pharmacies%202007%205_1_07.pdf.

21. SK&A, "Consumer Access to Pharmacies."

22. CMS, "Medicaid Prescription Reimbursement Information."