PPTA
Plasma Protein Therapeutics Association

Issue Brief

Impact of Medicaid Reimbursement on Access to Therapies
October 2007

Summary

The burden of financing Medicaid faced by governors and state legislators across the country is a heavy one. Medicaid is the fastest growing component for many state budgets.[1] The funds are needed to provide low-income enrollees with access to vital health care services. Basic economic theory shows that access to this care depends upon adequate reimbursement. The federal Medicaid statute codifies this principle by requiring states to have reimbursement mechanisms "sufficient to enlist enough providers so that care and services are available."[2] This creates a difficult balancing act for decision-makers who must control costs while ensuring enrollees access to health care.

Prescription drug costs are a major driver of the growing Medicaid costs and as a result they are often the target of state cost control strategies. A common cost control strategy employed by most states in recent years is to reduce reimbursement levels for pharmacy services. This creates access problems for Medicaid enrollees when the reimbursement becomes so low that providers are unable to provide the therapies. This situation often arises when acquisition costs are greater than reimbursement, commonly referred to as being "under water."

Background

The Plasma Protein Therapeutics Association (PPTA) is the primary advocate for the world's leading producers of plasma therapies. Plasma therapies treat unique, life-threatening diseases and disorders. Life-saving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, intravenous immunoglobulins (IVIG) to treat complex diseases in persons with immune deficiencies and neurological disorders, and therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as chronic obstructive pulmonary disease and substantially limits life expectancy. PPTA's member companies produce 80 percent of the plasma therapies used in the United States. These therapies differ significantly from commonly advertised, chemical-based pharmaceutical products.

Prescription Drug Reimbursement

State Medicaid programs pay for outpatient prescription drugs dispensed by a licensed pharmacy, or an enrolled physician filling his own prescriptions, according to their filed

[1] *THE FISCAL SURVEY OF STATES: JUNE 2007*, the National Governors Association and the National Association of State Budget Officers.
[2] 42 U.S.C.A.§1396a(a)(30)(A)

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state Medicaid plans. Federal law gives the states broad authority to develop their own payment formulas as long as they comply with the provisions of 42 C.F.R. 447.331 – 334. The basic formula for reimbursement is ingredient cost plus dispensing fee. Some states include an enrollee copayment.

States set ingredient cost reimbursement based on some combination of the four pricing methods below. Pursuant to federal law, they will pay the lesser of the pricing method or the provider's usual and customary charge to the general public.

Average Wholesale Price (AWP) is the average price that wholesalers charge retailers for their products as listed in annually published compendia.

Wholesale Acquisition Cost (WAC) is the average net cost the wholesaler pays the manufacturer for the product.

Federal Upper Limit (FUL) is the maximum amount to be paid for a drug as established by the federal government.

State Maximum Allowable Charge (SMAC) is the maximum amount a particular state establishes for payment of selected multi-source generic drugs; these can be lower than FUL prices.

The chart below shows the ingredient cost for each state.

Ingredient Costs		
State	**Ingredient Cost**	**SMAC**
Alabama	WAC +9.2% then AWP-10%	Yes
Alaska	AWP-5%	No
Arizona	AWP-15%	No
Arkansas	AWP-20% (generic); AWP-14% (brand)	Yes
California	AWP-17%	Yes
Colorado	AWP-35% (generic); AWP-13.5% (brand)	Yes
Connecticut	AWP-40% (generic); AWP-14% (brand)	Yes
Delaware	AWP-14% (traditional -retail independent & retail chain pharmacies); AWP-16% (non-traditional long term care & specialty pharmacies)	Yes
DC	AWP-10%	No
Florida	Lower of AWP-15.45%; WAC+5.75%; FUL or SMAC	Yes
Georgia	AWP-11%	Yes
Hawaii	AWP-10.5%	Yes
Idaho	AWP-12%	Yes
Illinois	AWP-25% (generic); AWP-12% (brand)	Yes
Indiana	AWP-20% (generic); AWP-16% (brand)	Yes
Iowa	AWP-12%	Yes
Kansas	AWP-27% (generic); AWP-13% (single source); AWP-13% (brand)	Yes
Kentucky	AWP-12%	Yes
Louisiana	AWP-13.5% (AWP-15% for chains)	Yes

Ingredient Costs		
State	**Ingredient Cost**	**SMAC**
Maine	AWP-15%; direct supply drug list-usual & customary charge or AWP-17% plus $3.35 professional fee or FUL or MAC plus $3.35 professional fee (Mail order lowest of usual & customary charge, AWP-20% plus $1.00 professional fee-for exceptions see State plan, FUL or MAC plus $1.00 professional fee)	Yes
Maryland	Lower of AWP-12% or WAC+8%, direct price +8%, or distributor price when available	Yes
Massachusetts	WAC+5%	Yes
Michigan	AWP-13.5% (independent pharmacies [1-4 stores[]; AWP15.1% (chain [5+ stores[])	Yes
Minnesota	AWP-11.5%	Yes
Mississippi	Lower of brand: FUL, AWP-12%, WAC+9%; generic: FUL, AWP-25%	Yes
Missouri	Lower of AWP-10.43% or WAC+10%	Yes
Montana	AWP-15%	No
Nebraska	AWP-11%	Yes
Nevada	AWP-15%	No
New Hampshire	AWP-16%	Yes
New Jersey	Lower of AWP-12.5%	Yes
New Mexico	AWP-14%	Yes
New York	AWP-13.25% (brand); AWP-20% (generic) or the State Maximum Acquisition cost if lower; AWP-12% (specialized HIV pharmacies)	No
North Carolina	AWP-10%, ASP+6%	Yes
North Dakota	Lower of AWP-10%, WAC+12.5%	Yes
Ohio	WAC+7% or its equivalent, AWP -14.4%	Yes
Oklahoma	AWP-12%	Yes
Oregon	AWP-11% (institution), AWP-15% (non-institution)	Yes
Pennsylvania	Lower of WAC +6%, AWP -15%	Yes
Rhode Island	WAC	No
South Carolina	AWP-10%	Yes
South Dakota	AWP-10.5%	Yes
Tennessee	AWP-13%	Yes
Texas	Lower of AWP-15% or WAC+12%	Yes
Utah	AWP-15%	Yes
Vermont	AWP-11.9%	Yes
Virginia	AWP-10.25%	Yes
Washington	AWP-14% (single source & multiple source [w/2-4 manufacturers]), AWP-50% (multiple source from 5+ manufacturers), AWP-19% (brand-mail order), AWP15% (generic-mail order)	Yes
West Virginia	AWP-15% (brand), AWP-30% (generic)	No
Wisconsin	AWP-11.25%	Yes
Wyoming	AWP-11%	Yes
Source: CMS Approved State Plans (REVISED 06/29/2007) http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/RxReimbursementRateJune2007Qtr.pdf		

Dispensing fees are established by states to reimburse pharmacies for the cost of dispensing the product. There is no set amount that states must pay as dispensing fees. States may pay different fees based on where the product is dispensed, and what

type of product is dispensed. For example, some states pay a higher dispensing fee for generics.

Some states require certain enrollees to pay copayments for their prescriptions. Pregnant women, children and long-term care enrollees are exempt from copayments.

The chart below shows the Medicaid dispensing fees and copayments for prescription drugs.

Medicaid Dispensing Fees and Copayments		
State	**Dispensing Fee**	**Co-Pay**
Alabama	$5.40	$.50-$3.00*
Alaska	$3.45-$11.46 (based on pharmacy/ Medicaid volume)	$2.00
Arizona	$2.00 (FFS only)	none
Arkansas	$5.51	$.50-$3.00*
California	$7.25; $8.00 (legend -skilled nursing & intermediate care facilities)	$1.00
Colorado	$4.00 (retail pharmacy); $1.89 (institutional pharmacy)	$.75 (generic); $3.00 (brand)
Connecticut	$3.60	$1.00
Delaware	$3.65	none
DC	$4.50	$1.00
Florida	$4.23 (regular pharmacies); $7.50 (qualified 340B entities/ingredient cost)	2.5% of payment up to $300
Georgia	$4.63 (brand for profit pharm); $4.33 (brand not for profit); $5.13 (generic for profit pharm); $4.63 (generic not for profit)	$.50 (generic); $.50-$3.00*(brand); $.50 (preferred brand)
Hawaii	$4.67	none
Idaho	$4.94 ($5.54 for unit dose)	none
Illinois	$4.60 (generic); $3.40 (brand)	$0.00 (generic); $3.00 (brand)
Indiana	$4.90	$3.00
Iowa	$4.26	$1.00 (non-preferred brand) (no more than $25.00), $2.00 (non-preferred brand) (between $25.01 and $50.00), $3.00 (nonpreferred brand) ($50.01 or more)
Kansas	$3.40	$3.00
Kentucky	$4.51	$1.00
Louisiana	$5.77	$.50-$3.00*
Maine	$3.35; $4.35 & $5.35 (compounding); $12.50 (insulin syringe)	$2.50 (generic & brand) (not to exceed $25 per mo.) (Mail order not subject to co-pay) $3 per day RHC (max of $30 per mo., per individual)
Maryland	$3.69 (generic); $2.69 (brand); $4.69 (generic-NH); $3.69 (brand-NH); $7.25 (home IV therapy)	$1.00 (generic); $1.00 (brand, PDL); $3.00 (brand name non-PDL)
Massachusetts	$3.50 (single source), $5 (multiple source); $10 (340B drugs)	$1.00 (multi-source & non-legend OTC); $3.00 (non-exempt)
Michigan	$2.50; $2.75 (long term care)	$1.00 (generic); $3.00 (brand)
Minnesota	$3.65 (+$.50 for legend unit dose drugs)	$1.00 (generic); $3.00 (brand)

Medicaid Dispensing Fees and Copayments		
State	**Dispensing Fee**	**Co-Pay**
Mississippi	$3.91 (brand); $4.91 (generic); $3.91 (long term care)	$3.00
Missouri	$4.09	$.50-$2.00*
Montana	$4.70	$1.00
Nebraska	$3.27-$5.00 (based on service delivery, unit dosage or 3rd party payors)	$2.00
Nevada	$4.76; $22.40 daily (home IV therapy); $16.80 daily (NF home IV therapy)	$1.00 (generic); $2.00 (brand)
New Hampshire	$1.75	$1.00 (generic); $2.00 (brand & compound)
New Jersey	$3.73; $4.07 (addt'l services)	none
New Mexico	$3.65	none
New York	$4.50 (generic); $3.50 (brand)	$1.00 (generic); $3.00 (brand); $.50 (OTC)
North Carolina	$5.60 (generic); $4.00 (brand)	$1.00 (generic); $3.00 (brand)
North Dakota	$5.60 (generic); $4.60 (brand)	$3.00 (brand)
Ohio	$3.70	$3.00 (if not on PDL); $2.00 (preferred brand drugs)
Oklahoma	$4.15	$1.00-$2.00*
Oregon	$3.50 (retail); $3.91 (institutional)	$2.00 (generic); $3.00 (brand)
Pennsylvania	$4.00	$1.00
Rhode Island	$3.40 (outpatient), $2.85 (long term care)	none
South Carolina	$4.05 (independ pharm); $3.15 (institutional)	$3.00
South Dakota	$4.75 ($5.55 for unit dose)	$2.00
Tennessee	$2.50 (long term care dual eligib); $5.00 (NH only -if 28 days+)	N/A
Texas	$5.14	None
Utah	$3.90 (urban); $4.40 (rural)	$3.00
Vermont	In-State -$4.75 Out-of-State-$3.65	$1.00-$3.00*
Virginia	$4.00 (brand); $4.00 (generic); $5.00 (unit dose drugs)	$1.00
Washington	$4.20-$5.20 (based on 3-tiered pharmacy volume); $3.25 (mail order)	none
West Virginia	$2.50 (brand); $5.30 (generic); $8.25 (340B drugs)	$.50-$3.00*
Wisconsin	$4.88	$.50 (over-the-counter); $3.00 (brand); $1.00 (generic)
Wyoming	$5.00	$2.00
Source: CMS Approved State Plans (REVISED 06/29/2007) http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/RxReimbursementRateJune2007Qtr.pdf		

Cost Containment Measures

Medicaid costs are likely to increase every year because of price-level and caseload increases. These increases place pressure on legislators to reduce spending elsewhere in the Medicaid program. To reduce costs, the legislators could reduce services, reimbursement or eligibility. Legislators are apprehensive about cutting services or eligibility, so reimbursement is often the first area considered. Cutting reimbursement for pharmaceuticals involves changing the variables in the

reimbursement formula. Ingredient costs and dispensing fees could be lowered, and copays could be increased.

The Deficit Reduction Act of 2005 (DRA) aids states in their pursuit to contain Medicaid costs. The DRA requires the Secretary of Health and Human Services to provide states with the Average Manufacturer Prices ("AMP") on a monthly basis. The AMP is perceived to be more accurate than the AWP because it is a regulatory filing, and as a result, it is anticipated that some states will use the data to change their ingredient cost reimbursement from AWP-based to AMP-based to save money.

The DRA allows states to impose copayments on enrollees that exceed nominal amounts. These copayments may vary by eligibility group and service type. The federal law does place specific and aggregate limits on the states' ability to impose copayments on enrollees. For enrollees with incomes between 100% and 150% of the federal poverty level, the copayment may not exceed 10% of the cost. The copayment is capped at 20% of the cost for enrollees with incomes that exceed 150% of the poverty level. The aggregate copayment limit is 5% of the enrollee's family income. The DRA allows states to amend their state plan to give pharmacists the right to deny prescriptions to those enrollee's that do not pay the copayment. It should be noted that many observers have speculated that the increased administrative burdens associated with copayment enforcement and tracking would exceed any additional savings resulting from the copayments.

340B pricing expansion is a cost containment strategy that some states are considering. 340B drug pricing is an exception to the usual Medicaid reimbursement for prescription drugs. Named for section 340B of the Public Health Service Act, 340B pricing establishes price controls to limit the cost of drugs to federal purchasers and to certain grantees of federal agencies. The law requires manufacturers to enter into an agreement with the Secretary of the Department of Health and Human Services to provide discounted prices on its covered outpatient drugs to covered entities.[3] These prices are lower than Medicaid reimbursement. Covered entities include safety net health providers, disproportionate share hospitals, and community health centers and hemophilia treatment centers.[4] To receive 340B pricing a enrollee must receive health care services other than pharmacy from the 340B covered entity.

These cost saving strategies could negatively impact patient health if access to care and proper utilization are reduced as a result of the lower reimbursement.

Reduced reimbursement levels may result in providers deciding to no longer serve patients within the Medicaid program. A parallel can be drawn to the impact lower reimbursements for IVIG have had on the Medicare program.[5] The federal government reduced the reimbursement for IVIG to Medicare physicians beginning in January, 2005.

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[3] 42 U.S.C. § 256b(a)
[4] 42 U.S.C. § 256b
[5] *Assessing the Cost of IVIG Infusion Services in Physician Offices & Hospital Pharmacy Departments*, The Lewin Group (March 23, 2006).

The reimbursement did not equal the physician's cost for providing the IVIG to patients. As a result, many physicians stopped providing IVIG and their former patients received their IVIG treatment in hospital outpatient facilities. Physicians referring Medicare patients to hospitals have found that hospitals are sometimes unable to procure the same products, thus in some instances, requiring more time for clinical monitoring. Reductions in a state's Medicaid prescription drug budget could have the same potentially negative impact on patient access if reimbursement for plasma protein therapies is reduced to save costs.

Lower fees are not the only concern. Patient health would certainly suffer. It is a well established fact among the Medicaid population that copayments lead to lower utilization. And lower utilization, for enrollees with chronic conditions, often leads to pain and suffering. Take an enrollee with hemophilia for example. Failing to maintain their health with appropriate usage of plasma protein therapies will cause painful and crippling injury to an enrollee's joints and organs. The treatment for the inevitable complications will result in trips to the emergency room and possible admission to the hospital. Obviously this would cost the state Medicaid program more than any copayment would save.

Conclusion

PPTA is concerned that so much attention to the prescription drug line in a state's Medicaid budget could lead to unintended increases in the state's total Medicaid budget and poor health outcomes for its Medicaid enrollees that need plasma protein therapies. Reimbursement should be sufficient to ensure access to care for Medicaid enrollees that need plasma protein therapies, because access to care equals quality care.[6]

Enrollees, in close consultation with their physicians, make informed decisions regarding the particular therapy they will utilize. Plasma protein therapies are not interchangeable and open access to all products should remain unimpeded. Each therapy has been approved by the federal Food and Drug Administration for specific clinical indications. These are branded therapies, with no generic substitutes. Different therapies may require different dosages and regimens, and may be appropriate only for specific populations. Further, the effectiveness of particular therapies may vary with different populations or with specific individuals. Failure to maintain open access to this full range of licensed therapies could result in the adverse health outcomes.

For further information, please contact Bill Speir, Manager of PPTA State Affairs, at bspeir@pptaglobal.org.

[6] *See Aiming Higher: Results from a State Scorecard on Health System Performance,* The Commonwealth Fund (June 13, 2006).