Safe and Effective Approaches to Lowering State Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs (9/9/04)

As a result of increasing prescription drug costs, State Medicaid programs have implemented a variety of cost-containment mechanisms in their drug programs over the past few years. These mechanisms have allowed states to reduce their pharmacy expenditures and maintain beneficiary access to a vital part of their overall healthcare. This paper describes some of these cost-containment mechanisms and highlights several states that have achieved reduced costs with each technique. In general, states have not yet taken advantage of all of these approaches. CMS can provide consultation and support to assist states in using these and other methods to lower their drug costs without compromising quality of care.

Aggressive Generic Substitution Policies

Generic drug products that have been approved by the FDA must meet the same rigorous standards for safety and effectiveness as brand-name drugs. In addition to being safe and effective, the generic product must have the same active ingredient or ingredients, be the same strength, and have the same labeling for the approved uses as the reference brand product. The generic product must also be available in the same dosage form, and have the same route of administration as the brand name product. Thus, generic products will perform the same as their respective reference brand products. Similarly, generic manufacturing and packaging sites must pass all of the same quality standards as those of brand name drugs and the generic products must meet the same specifications as any approved new drug product (source: http://www.fda.gov/cder/ogd/welcome_to_ogd.htm). Today, in part as a result of regulatory reforms at the FDA and provisions in the Medicare Modernization Act to promote generic drug entry, generic drugs are more widely available than ever in the United States, and, as a result of competition, usually at prices that are lower than in other developed countries. Generic drugs account for over half of all prescriptions in the United States, and many private health plans have generic drug penetration rates of over 90 percent in cases where they are available (that is, the drugs are used in more than 90 percent of cases when there is a generic version of the brand-name drug). However, generics are not as widely used in some Medicaid programs.

The low prices of generic drugs in the United States means that they are an important potential source of savings for states. According the Generic Pharmaceutical Association, the average price of a generic prescription drug is $22.79 compared to $76.29 for the average brand name prescription drug (source: www.gphaonline.com). The potential cost-savings that can be achieved by the use of generic drugs has prompted thirty-nine states to require that the generic version of a drug be dispensed to Medicaid beneficiaries when one is available. Under these mandatory generic substitution policies, the brand

name drug remains available to beneficiaries through prior authorization. Examples of "best practices" involving generic drugs include:

Minnesota – Minnesota has had a mandatory generic substitution policy in place for nearly a decade. Under this policy, generic drugs must be dispensed to beneficiaries if:

- The generically equivalent drug is approved and is determined as therapeutically equivalent by the FDA (as is required by the Food, Drug, and Cosmetic Act);
- In the pharmacists or dispensing physician's professional judgement, the generically equivalent drug is safely interchangeable with the prescribed drug; and
- The charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed.

Because approved generic drugs are functionally equivalent to the brand-name version, beginning January 2004, even if the practitioner has written "Dispense as Written – Brand Necessary" or "DAW – Brand Necessary" on the prescription, physicians are required to obtain authorization from the state Medicaid agency before a brand name drug is dispensed. Previously, the generic substitution mandate could be overridden if the practitioner specified on the prescription that the brand name drug was medically necessary. Minnesota estimates that this 2004 change to the mandatory generic substitution policy increased their current generic utilization rate from 55 percent to 57 percent. This change is expected to save $10 million annually.

Idaho – Idaho's mandatory generic substitution policy has been in place since 2000. The policy requires prior authorization for brand name drugs under Medicaid when an acceptable generic form is available. Specifically, the state requires a patient to fail on two generic products and also requires a completed MedWatch form before consideration is given to most brand name products. This policy has served as a deterrent to unnecessary brand name requests and has resulted in an increase in generic utilization from 46.7 percent in fiscal year 2002 to 53 percent in fiscal year 2003. Pharmacy groups in the state have been very supportive of the state's generic substitution policy. This mandate for generic substitution has saved $11.7 million in State and Federal funds.

Supplemental Rebate Agreements

States that wish to pursue Medicaid supplemental rebates in addition to rebates already received under the national drug rebate agreement have the option to negotiate such rebates with drug manufacturers as specified in Federal law. States generally do this by contracting with a private pharmacy benefit manager to negotiate lower process on their behalf. States also have the option to negotiate either state-specific supplemental rebates for their Medicaid population or participate in a multi-state pooling supplemental rebate agreement. Under a multi-state pooling supplemental rebate agreement, participating states pool together the number of Medicaid beneficiaries in an effort to increase purchasing power to generate larger rebates and discounts from manufacturers. While

many states have shown interest in participating in the multi-state pooling agreements, we do not expect all 50 states to participate in the same pool. While multi-state pooling may be particularly beneficial to small states, larger states may find it more in their interest to negotiate rebates separately in order to better meet the needs of their Medicaid population. States are also encouraged to continue negotiating individual state-specific supplemental rebates, either in addition to, or in lieu of a multi-sate pooling agreement. Currently, 33 states are receiving Medicaid supplemental rebates in addition to those received under the National Rebate Agreement.

Florida State-Specific Supplemental Rebate Agreement – Florida began collecting state-only supplemental rebates in 2001 in conjunction with the establishment of its Preferred Drug List (PDL). Currently, the state receives supplemental rebates on brand name drugs, but not on generics. The state's Pharmacy and Therapeutics (P & T) Committee determines which classes of drugs will be included on the PDL and takes into account clinical factors and therapeutic evaluations when making those determinations. Once the class of drugs has been narrowed to include only those that are therapeutically equivalent, the state's contractor then opens the drug class to supplemental rebate negotiations with the manufacturers of the products within that class. A manufacturer must offer a minimum supplemental rebate of 25.1 percent of Average Manufacturer Price (AMP) in order to get on the PDL; if not, the drug will most likely be subject to prior authorization under Medicaid. Beginning July 1, 2004, the minimum supplemental rebate amount accepted by the state will increase to 29.1 percent of AMP. The state anticipates a savings of $24 million with this increase and does not expect to lose participation from any of the approximately 80 manufacturers that currently pay supplemental rebates.

Multi-State Pooling Supplemental Rebate Agreement- Five states, Michigan, Vermont, Alaska, Nevada, and New Hampshire, received authorization on April 22, 2004 to participate in a multi-state pooling supplemental rebate agreement. Two additional states, Minnesota and Hawaii, were authorized to join this agreement on September 9, 2004. Individual savings for states range from $1 million to $8 million in 2004. Collectively, these seven states anticipate Federal savings of $19.5 million for Federal Fiscal Year 2004. Altogether, the pooled purchasing program will cover approximately 1.1 million beneficiaries.

Successful Disease Management Programs in Medicaid

Disease management programs are an emerging strategy for states to improve care and are designed to reduce overall expenditures, including drug expenditures, through more appropriate medication use for Medicaid beneficiaries with chronic illnesses. These programs usually include adherence to evidence-based medical practice guidelines, provide support services to assist physicians in monitoring their patients, more closely manage patient care including the proper use of drugs, and promote patient adherence to an individual treatment plan, which includes improved medication compliance. While pharmacy costs may increase, overall expenditures usually decrease as a result of disease

management programs by reducing the number of emergency room visits and hospitalizations.

Washington - Beginning in April 2000, Washington began a disease management program for categorically needy Medicaid beneficiaries not in managed care who have asthma, congestive heart failure, diabetes, and End Stage Renal Disease or chronic kidney disease. The state recently extended the program to include Chronic Obstructive Pulmonary Disease (COPD). The state is paying a competitively selected Disease Management Organization on a capitated basis to provide the services. The program currently serves about 175,000 beneficiaries. Through preventive care and patient education, the project hopes to help participants effectively manage their disease conditions and reduce unnecessary hospitalizations and emergency room use. Nurses manage a caseload of participants. The majority of participants are served through telephone contacts, while participants with more complex conditions also receive face-to-face services. The state anticipates savings of 5 percent of the overall medical costs for program participants.

North Carolina - North Carolina's Community Care program uses networks of physicians to focus on improved quality, utilization, and cost effectiveness. Thirteen networks with more than 2,000 physicians work with local health departments, hospitals, and social service agencies to better manage the care of 513,000 Medicaid beneficiaries. This program began in January 2000 to provide disease management services to children with asthma. In March 2001, the program expanded to provide disease management services to diabetic children. The program focuses on following evidenced-based clinical care practices and by tracking participants to ensure that the proper care is being delivered. Results have been positive. Participants in the asthma disease management program show a 46 percent increase in appropriate use of inhaled corticosteroids, 35 percent lower hospitalizations, and 34 percent lower emergency department visits. Under the Diabetes Disease Management program, eye referrals have increased by 22 percent and flu vaccinations by 12 percent. Community Care also has a program to reduce emergency department use through care management follow-up with frequent users that has reduced use by 13 percent and costs by 30 percent. Its Pharmacy Management Initiative has lowered drug costs of participants by 22 percent through use of a preferred drug list and is expected to save $9 million in 2004 through its pharmacy program that reviews the drug regime of nursing home residents and recommends changes consistent with appropriate prescribing practices. The Community Care Networks are funded by a $2.50 per member per month payment from the state.

Electronic Transmission of Prescriptions (E-Prescribing)

Florida - In 2001, Florida initiated a pilot project in 2001 to provide hand-held devices to physicians that displayed the Medicaid preferred drug list in order to make it easier for the physician to prescribe a medication on that is on the preferred list. In 2002, the device was expanded to provide clinical information about prescription drugs and to allow for the inclusion of patient medical histories. This additional information alerts physicians to adverse drug interactions and to patient drug allergies. Currently, approximately 1000 prescribers use the device, with 500 on a waiting list. Florida intends to expand the

number of prescribers to 3000. This will allow for 80 percent of drugs to be e-proscribed in Florida. It will improve medical care, reduce cost, and prevent fraud and abuse. This has resulted in less inappropriate or duplicative prescribing (polypharmacy), a reduction in severe drug interactions, and fraud reduction from individuals seeking narcotics prescriptions from multiple physicians.

Summary

Although some states have already implemented the cost-savings mechanisms described in this paper, many others have not yet benefited from the expenditure reductions that these techniques can provide. Few states have yet adopted all of these proven approaches to lowering drug costs without compromising quality, and (in the case of disease management and e-prescribing) states have actually improved quality.

CMS will continue to assist all states in adopting safe, proven approaches to lowering drug costs. CMS has issued specific guidance on multi-state pooling via a State Medicaid Director's (SMD) letter. CMS will also provide a description of these cost-savings mechanisms on the CMS Drug Rebate Program web page, to give all states a centralized resource for cost-savings information. We will continue to add other examples of state best practices, to help make sure that all states are taking advantage of all of the tools available to lower their drug costs and other medical expenses safely in Medicaid.