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Barr Laboratories, Inc.
440 North Capitol St, Washington, DC 20001

Options for Reducing Prescription Drug Expenditures through the Effective Implementation of Preferred Drug List (PDL) Programs Utilizing Pharmacy and Therapeutics (P&T) Committees

Barr Laboratories, Inc.

barr Laboratories, Inc.
440 North Capitol St, Washington, DC 20001

Rev: 4/1 pm

Options for Reducing Prescription Drug Expenditures through the Effective Implementation of Preferred Drug List (PDL) Programs Utilizing Pharmacy and Therapeutics (P&T) Committees

State governments are increasingly facing a grave fiscal crisis – providing affordable prescription drug coverage to consumers. According to the Albany Times Union, "A recent report by the National Governors Association made official what those of us who work with state governments already knew too well: The fiscal problems faced by the states this year are the worst since World War II. The problems are the results of a confluence of factors including the end of the stock market bubble, the sluggish national economy, the repercussions of 9/11 attacks and soaring health care expenses, which put stress on state Medicaid programs."

There are a number of practical solutions to lowering healthcare costs, while increasing access to affordable medicines. These include:

- Increasing the usage of generic pharmaceuticals;
- Educating consumers about their prescription drug choices;
- Modernizing prescribing regulations;
- Implementing Preferred Drug Lists; and
- Guarding against the erection of barriers to affordable prescription drugs.

All of these options emphasize the increased usage of more affordable generic products. Every year, generic pharmaceutical products are used to fill 47 percent of the prescriptions in the U.S. This equates to more than one billion prescriptions, saving consumers $8-10 billion on their prescription drug bill. The average price of a prescription filled with a generic drug in 2002 was $24.63. The average price of a prescription filled with a brand name drug in 2002 was $80.12. That's an average savings of 69 percent when the generic product is substituted for a brand product.

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Understanding PDLs

PDLs help states reduce program expenditures by creating a list of preferred drugs covered by state-funded programs. The lists are developed according to national medical best practice standards and based on an evaluation therapeutic indications, clinical effectiveness, cost and if a generic version exists. A Pharmacy and Theraputics Committee is formed to reviews all therapeutic action, safety, clinical outcome and cost data, several drugs from each class are termed "preferred drugs".

It is important to note that price alone does not preclude a drug from being included in a preferred drug list. If a less expensive version of a drug exists, but lacks "a significant, clinically meaningful therapeutic advantage" over other drugs, the less expensive drug is excluded. Similarly, if a medication is most often not best used as a first line therapy (either because of its cost or based upon the current medical standards for that therapy) a PDL may not include them. The preferred drug list thus becomes the physicians' guide to prescribing the best and most cost effective treatment for patients enrolled in state-funded programs. Physicians must prescribe from the preferred list unless they can provide medical justification for otherwise doing so.

This practice ensures that state-funded programs give patients the best treatment at the best price. Provider Synergies is the nation's leading provider of Medicaid preferred drug programs, providing services to Medicaid programs covering over 4 million recipients in the states of Florida, Illinois, Louisiana and West Virginia. These states will save over $200 million per year utilizing the innovative, market-based solutions from Provider Synergies. Clinically sound, cost-efficient preferred drug lists have been proven to efficiently reduce costs without sacrificing care for beneficiaries.

The use of preferred drug lists allows state agencies to preserve coverage of pharmaceuticals without drastic cuts in payments to physicians, pharmacies and other healthcare providers. Even more important, these programs have allowed the states to demonstrate progress in solving the prescription drug crisis for senior citizens and working poor.

In order to remain an effective cost-control measure, PDL's are typically reviewed every three or four months for inclusion of any new pharmaceuticals or any changes in medical best practice standards. As stated earlier, states may also initiate a supplemental rebate in conjunction with the PDL as a factor in determining a medication's actual cost for comparison to the cost of other therapies.

The Current State of PDLs

While not a new concept, PDLs are just recently finding their way into many state-funded

Medicaid and pharmaceutical assistance programs. A total of 22 states use a formulary, PDL or a type of prior authorization to contain costs. Some data suggest that states with PDLs save about 10 percent in their Medicaid budgets.

A good example is Illinois, which has maintained a list of preferred drugs that are available without prior authorization and operated a prior authorization process for non-preferred drugs since the early 1980's. Illinois attributes at least $100 million in reduced spending annually to their prior authorization and PDL program. Further, their current ratio (61% generic and 39% brand) is largely attributable to this approach.

Issues Related to Implementing PDLs

Two critical issues must be consider to effecively implement a PDL. These are:

- the establishment of robust Pharmacy and Therapeutics (P&T) Committees; and
- assuring that exception lists that accompany the implementation of a PDL are effectively structured to raise application of scientific and clinical analysis to a sufficient level to prevent misuse or abuse that would diminish savings.

P&T Committees

It is important to develop a strong, knowledgeable Pharmacy and Therapeutics Committee, free from the influence of any special interests, to provide sound clinical and pharmacological support for the selection of appropriate treatments for inclusion in the PDL. It is critical that the Committee relies on clinical data and scientific experience provided for them by an external, independent body that can access clinical expertise and information needed to reflect on local variances related to the practice of medicine. Most states that implement a PDL do so under contract with companies which have expertise in this area such as Provider Synergies, EDS or FirstHealth.

Equally as important is the composition of the Committee. It is important to have a balance Committee, with a ratio of at least one pharmacist to one physician. This takes into consideration the pharmacists' complete knowledge and experience with drugs and their interactions based on their education in pharmacology.

In addition, Committee members should also meet the following criteria:

a. Committee members should be licensed state medical professionals who are currently practicing in their field and involved in direct health care delivery and specific client health needs.

b. Committee members should be experts in evidence-based medical and scientific knowledge with consideration to ensure a balance between scientific knowledge and practical community experience.
c. Committee should include a medical director from either a health plan or a major state medical center.
d. Committee members should have current clinical experience or training in pharmacology, pharmacokinetics, adverse drug reactions, or pharmacogenetics.
e. Committee members should exclude current legislators, former legislators, lobbyists, pharmaceutical representatives or a patient advocate representative all of whom may be licensed as a pharmacist or physician but may not be truly independent of the influence of special commercial interests.

In forming and charging the Committee, the state must assure that the Committee members be required to annually complete and file a prepared disclosure form on any member's relationships with any and all pharmaceutical manufacturers including a financial disclosure of gifts and honoraria of any amount.

The Committee should meet at least four times a year and serve for staggered terms of two to three years. The Committee should also specifically be charged with fostering communications with all practicing health professionals in the state. Meeting notices and reports should be included on the state's Health Department website, and through other traditional methods of communicating with physicians, pharmacists and other healthcare providers.

Advice taken from other state medical directors suggests that the most important meeting of the Committee is the first one which should set the tone and establish the success for all other meetings and for the establishment of a successful PDL. That meeting should be well-structured leaving the Committee informed about their duties, the rules by which they will operate and on how they will make their decisions.

It is important that state program officials recognize the need to effectively utilize pharmacist and physician expertise in the selection of drugs used in PDLs. If the P&T Committee has access to clinical experts to advise on drug selection, then the task of the P&T Committee can be more effectively focused on the practice of medicine.

Drug Exclusion Lists

The second critical issue is to have a robust process for dealing with drug exceptions. It is important to ensure the state has already established, through legislation if possible, that the Federal Food and Drug Administration's (FDA's) "AB" rating of generic drugs is the gold

standard for measuring the substitutability of generic pharmaceuticals for their brand name counterparts.

The exclusion of drugs in such categories as mental health, oncology, diabetes, AIDS or other areas are often tied to the mistaken position, frequently promoted by patient groups and manufacturers, that generic versions of therapies in these categories may not offer the same safety and efficacy as the brand counterparts. This issue has been repeatedly addressed by the FDA, which has confirmed the substitution of all brand name drugs were an equivalent generic version is available.

For example, products associated with the treatment of mental health and other neurological conditions, such as epilepsy, are often considered for exclusion. It is important to note that of the top 15 drugs used to treat mental illness, generic versions are currently available for five, and five additional brand drugs are expected to soon have generic competition. There are currently over 60 major drugs available to treat a variety of mental health issues. The potential for exclusion of drugs in this one category could have significant impact on opportunities to lower health care expenditures.

In considering the issue of exclusions, Massachusetts recently concluded that as much as 47% of prescription drugs covered under Medicaid could be classified as mental health therapies. Similar arguments have previously been made about other cancer and cardiovascular drugs, where no scientific data supports their exclusion.

As a result, the exclusion of any prescription drug product should be based solely on conclusive, sound scientific and clinical data. This is critical for ensuring that PDL decisions are not susceptible to efforts by special interests to exploit loopholes in the PDL structure and P& T Committee process.

All products excluded from a state's PDL are always available to a Medicaid beneficiary through prior authorization. Medicaid prior authorization is based on medical need, not product cost. States are required to ensure that requests are handled within 24 hours and, in fact, states are handling requests within the same day. Further, states must ensure that the pharmacy can dispense up to a 72 hour supply, any time a medication requiring prior authorization is prescribed in an emergency so that there are never access issues when excluded medications are medically necessary. When a medication has generic equivalents, identified by the FDA's "AB" rating process, prior authorization should be the method used to screen for those rare cases where the branded version is necessary. As an example, when Illinois began using physician-based prior

authorization for "brand medically necessary" prescriptions, exceptions were reduced by more than 80 percent.

Numerous States Have Implemented PDLs

In 2000, Georgia's state Drug Utilization Review Board enacted a preferred drug list to be used in the following state-funded programs: Medicaid, PeachCare for Kids, Board of Regents for higher education health insurance benefits and State Health Benefit Plan for state employees. The list was created by the Drug Utilization Board and Express Scripts, the state's pharmacy benefit manager (PBM) and is composed of both brand and generic drugs. Under Georgia's plan, all generic drugs are automatically considered preferred. When a new generic equivalent becomes available for a brand on the preferred list, the brand version loses preferred status.

Georgia officials expect to achieve significant savings from the plan, which began in 2001 after the state suffered budget shortfalls in Georgia's Medicaid and State Health Benefit Plan due to a 20 percent increase in pharmaceutical spending.

Kansas Governor Bill Graves (R) signed a law in 2002 allowing the Department of Social and Rehabilitation Services to create and maintain a PDL. Similar to Georgia's program, Kansas limits reimbursement to generic drugs unless the physician indicates the brand or other drug is absolutely necessary.

In Massachusetts, where according to the state Division of Medical Assistance, Medicaid spent about $968 million on prescription drugs last year for roughly 933,000 people - a 16.8 percent increase over the previous year, state lawmakers enacted legislation that will now require Medicaid patients to fill prescriptions with generic medicines. The program, which went into effect August 2002, institutes a preferred drug list of generic medicines and physicians are given the authority to override the list when medically necessary. While too early to quantify actual savings, officials predict significant returns.

Michigan Governor John Engler (R) signed legislation in 2001, creating the Michigan Pharmaceutical Best Practices Initiative to develop a PDL. Under the plan, the Michigan Therapeutics Committee was appointed to compile a list of drugs that are "best in class." "Preferred drug lists are the most effective tools available to states" to control spending on prescription drugs, said Gov. Engler. "Michigan's new program saves $800,000 each week -- or $42 million this year," he continued.

Vermont has begun implementing a PDL. The state began by requiring prior authorization for non-preferred acid reducers, anti-inflammatory, and narcotic analgesic medications. From

March 11, 2002 through September 30, 2002, the state reduced expenditures by 26.3 percent ($2.9 million) for these three drug classes. The Vermont PDL now includes 32 classes of drugs, and they have been negotiating supplemental drug rebates and an additional factor in determining the net cost of each product in the classes in their PDL process.

Barr Laboratories Prepared to Help

As one of the leading developers, manufacturers and marketers of high quality, lower cost generic pharmaceuticals in the United States, Barr Laboratories, Inc. is committed to helping states implement programs to more effectively manage escalating health care expenditures.

Barr also has extensive experience in working with the majority of this nation's states to assure that new programs -- designed to lower pharmaceutical costs and increase access to important medicines -- are structured to prevent special interests from capitalizing on loopholes that reduce the potential pharmaceutical savings these programs are designed to create.