The Pharmacist Activist

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Editorial

If *CMS* and *AMP* do not Turn Pharmacists into Activists, What Will?

The debacle of the implementation of the Medicare prescription drug program is fresh in our memories and is continuing. The program was very poorly designed, developed, and implemented by the Administration, Legislature, Centers for Medicare and Medicaid Services (CMS) leadership, and pharmacy benefit managers (PBMs). However, it could have been much worse were it not for the dedicated and capable efforts of pharmacists, even though many of these pharmacists were financially disadvantaged by their participation in the program. The services of pharmacists were recognized by the Secretary of Health and Human Services Michael Leavitt who noted that the efforts of pharmacists "...have been nothing short of heroic...They have been selfless, compassionate, and committed to service." You would think that such words would at least be associated with extended appreciation, even if patients and pharmacists were not rewarded with a better Medicare prescription program. However, the Administration and CMS are apparently determined to add insult to injury for pharmacists by changes they are making in the Medicaid prescription program.

One, if not the most, threatening challenge community pharmacy (and, therefore, the entire profession of pharmacy) has ever faced is scheduled to be implemented soon. In spite of strong opposition from pharmacy, the Deficit Reduction Act (DRA) was signed into law in early 2006, and provides for substantial reductions in reimbursement to pharmacies for generic drugs dispensed in the Medicaid program. The CMS projects a reduction in pharmacy revenues of $2 billion annually by 2011. In late 2006, the CMS published its rule to implement the changes and, on June 18, 2007, announced that the final regulation will be published on July 2, and will become effective on September 1, 2007. In a news release (June 20), the National Community Pharmacists Association (NCPA) noted that, if implemented as proposed, the planned Medicaid cuts "...will result in the demise of thousands of independent community pharmacists, and the loss of pharmacy access for millions of Medicaid patients."

The planned reductions in the reimbursement for generic prescription drugs are to be based on the determination of the average manufacturer price (AMP) for a generic drug on which a Federal Upper Limit (FUL) formula will be based. This approach is flawed from the start because, in its rush to abandon average wholesale price (AWP) as a fictitious number, the CMS wants to use AMP that is a more problematic fictitious number, the specific determination of which has been challenged.

The CMS has acknowledged that it expects a "significant impact on some, small independent pharmacies." This statement alone is sufficient reason for this program to be rejected! Rather than implement a program that will discriminate against and harm these pharmacies and the patients served by them, changes must be made now to address this recognized issue, instead of waiting until later to assess the damage that has resulted.

Several government offices (e.g., U.S. Government Accountability Office [GAO], Office of the Inspector General [OIG]) have

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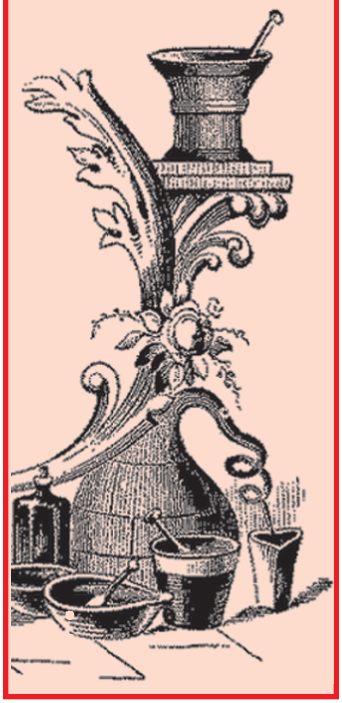

evaluated the financial impact of the changes that are planned, and the results of these studies are alarming. In a June 15 letter to the U.S. Small Business Administration, the American Pharmacists Association (APhA) notes that "The GAO study found that estimated reimbursement calculations, based on the new AMP-based calculation, for 77 of the most frequently dispensed generic medications would be on average 36% below the actual acquisition costs for community pharmacies." The APhA letter also includes findings of the OIG study of the reimbursement for high expenditure drugs that reported that "19 of the 25 medications that it studied had average pharmacy acquisition costs that would have been higher than the new FUL and 12 of these 19 drugs had average pharmacy acquisition costs that would have been more than double the new reimbursement limit."

In its June 20 news release, NCPA also refers to the OIG report and notes "that once a dispensing fee to cover the cost of doing business is factored in, reimbursement for only 1 of the 25 drugs studied will allow community pharmacies to recover their basic operating costs." Also addressing the OIG report, the National Association of Chain Drug Stores (NACDS) issued a news release (June 14) calling for swift action to fix the Medicaid prescription reimbursement issue.

This is the challenge that faces the profession even though NCPA, APhA, and other associations and individual pharmacists have had ongoing dialogue with CMS officials, legislators, etc. Clearly, we must have more involvement and more activism if we are to prevent the implementation of a program that has devastating implications. We must not permit the same agencies/individuals whose efforts were so abysmal in the Medicare prescription program to dictate the policies and terms of the Medicaid program.

What must be done?

A course of action must be developed quickly and I recommend that it include at least the following components:

1. The NCPA, APhA, and NACDS must insist with one voice that the current plans regarding the Medicaid prescription program be rescinded or substantially revised in a manner that is equitable and acceptable to community pharmacists. Although NACDS is not a pharmacist membership association, its member companies employ tens of thousands of pharmacists who should be requested to individually support the position taken by the associations These associations must develop a coordinated strategy with respect to communicating with legislators and CMS and Administration officials, developing legislative proposals as necessary, and requesting the involvement of thousands of their pharmacist members.

2. Pharmacists must actively support our professional associations. Every independent community pharmacist (owners and employee pharmacists) should be a member of NCPA and, preferably, also of APhA. Every chain pharmacist who is not a member of NCPA should be a member of APhA or both organizations. State and local pharmacy associations must also be strongly supported. Our associations must be able to speak and act from a position of strength, and that strength is directly related to the number and level of involvement of its members.

3. All pharmacists, whether we are in a community pharmacy or have another responsibility in the profession, should be involved in preventing the implementation of the planned changes in the Medicaid prescription program. Not only are we supporting our colleagues in community pharmacies for whom the threat is most urgent, but we are also helping to prevent serious consequences for the entire profession. At a time when our profession is strongly promoting expanded roles for pharmacists in areas such as medication therapy management, we cannot permit the implementation of programs that impose a substantial reduction in reimbursement to pharmacists for medications and services provided to such a large segment of our population.

4. We must enlist the support of the patients served in the Medicaid program, as well as the agencies and individuals who serve them in an advocacy capacity.

5. We must demand an equitable professional fee to dispense a prescription and provide related services. I recommend a fee of $15.00 for a prescription for a generic drug (with the fee to be adjusted on an annual basis), with the drug product cost to be reimbursed at actual acquisition cost (AAC).* Because of antitrust legislation, professional associations are limited in addressing recommendations regarding specific fees, and it is all the more important that individual pharmacists take a strong stand in efforts to attain equitable fees.

6. AAC should be used in reimbursing the cost of drug products to pharmacies.* However, the agreement of pharmacists to accept AAC for their drug costs must be accompanied by a commitment to provide an equitable professional fee, and an appropriate mechanism to address the very high costs to maintain an inventory of numerous expensive drugs.

As individuals and as associations, we have a lot to do quickly. We need strong associations and many more pharmacist activists. What will your role be? And if you do not get involved, who should be? If CMS and AMP do not turn pharmacists into activists, what will?

Daniel A. Hussar

*For additional information to support these recommendations, please see my editorial, "Pharmacy Must Demand Fair and Immediate Payment for Medications and Services," in the March 2007 issue of *The Pharmacist Activist* that may be accessed at **www.pharmacistactivist.com**.

New Drug Review

Rotigotine
(Neupro – Schwarz Pharma; UCB)
Antiparkinson Agent

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
in a scale of 1 to 5, with 5 being the highest rating

Indication:

For transdermal use for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease.

Most important risks/adverse events:

Formulation contains sodium metabisulfite and should not be used in patients with a history of hypersensitivity to sulfites; falling asleep suddenly (sleep attacks) without warning and while engaged in normal activities; hallucinations; symptomatic hypotension and syncope; elevation of blood pressure and heart rate; weight gain and fluid retention; compulsive behaviors (e.g., urge to gamble); should not be applied to the same application site more than once every 14 days; heat may increase absorption of drug and transdermal system should not be exposed to external sources of direct heat; backing layer contains aluminum and transdermal system should be removed prior to magnetic resonance imaging or cardioversion to avoid skin burns; action may be reduced by the concurrent use of a dopamine antagonist (e.g., antipsychotic agents).

Most common adverse events:

Application site reactions (37%), nausea (38%), somnolence (25%), dizziness (18%), headache (14%), vomiting (13%), insomnia (10%).

Usual dosage:

2 mg once a day (per 24 hours) initially and, based on clinical response and tolerability, the dosage may be increased weekly by 2 mg/24 hours to the maximum recommended dosage of 6 mg/24 hours; if it is necessary to discontinue treatment, the daily dosage should be reduced by 2 mg/24 hours every other day until the drug is completely withdrawn.

Products:

Transdermal systems (patches) – 2 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours.

Comparable drugs:

Pramipexole (Mirapex), Ropinirole (Requip).

Advantages:

- Less frequent administration (once a day compared with three times a day for treating Parkinson's disease);
- Gradual release from transdermal formulation may result in less variation in concentration and clinical benefit;
- Gradual release from transdermal formulation may reduce the occurrence of adverse events that may be associated with peak concentrations multiple times a day with other agents.

Disadvantages:

- Has not been directly compared with pramipexole and ropinirole;
- Indications are more limited (pramipexole and ropinirole are also indicated for the treatment of advanced Parkinson's disease in conjunction with levodopa, as well as in the treatment of restless legs syndrome);
- Often causes application site reactions;
- Should not be used by patients with a history of hypersensitivity to sulfites.

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The Pharmacist Activist
661 Moore Rd., Suite 100, King of Prussia, PA 19406

Author/Editor
Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia

Publishers
Christopher J. Polli • G. Patrick Polli II

Assistant Editor
John Buck

Publications Director
Jeff Zajac

Graphic Artist/Designer
Joe Monte

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The Pharmacist Activist
661 Moore Rd., Suite 100
King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

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New Drug Review (cont.)

Comments:

Rotigotine appears to act primarily to stimulate dopamine D2 receptors in the brain, and its properties are most similar to those of pramipexole and ropinirole. These three agents are designated as non-ergoline dopamine agonists, whereas agents like bromocriptine (e.g., Parlodel) are ergot derivatives that may be associated with additional serious adverse events.

Rotigotine is unique among the antiparkinson agents as it is the first to be supplied in a transdermal (patch) formulation for topical application. It is specifically indicated for the signs and symptoms of early-stage idiopathic Parkinson's disease, and its effectiveness was demonstrated in placebo-controlled studies. The gradual release of the medication from the transdermal formulation may result in less variation in concentration and clinical benefit, and avoidance of some of the adverse events that may result from the peak concentrations occurring three times a day with the use of pramipexole and ropinirole. However, rotigotine has not been directly compared with these agents.

Both pramipexole and ropinirole are also indicated for the treatment of advanced Parkinson's disease in conjunction with levodopa, as well as in the treatment of restless legs syndrome. Although rotigotine is being studied in these conditions, they are not labeled indications at the present time.

The use of each of the dopamine agonists is associated with numerous warnings and precautions. Some patients have fallen asleep suddenly (sleep attacks) without warning and while engaged in normal activities such as driving or talking. The risk of such episodes is greater if a patient is also taking other sedating medications or consuming alcoholic beverages. Patients must be advised of this risk and cautioned not to engage in activities such as driving, operating machinery, or working at heights until they have determined how they respond to the medication.

Rotigotine is applied once a day which is a more convenient regimen than those for pramipexole and ropinirole that are administered three times a day. This and the other advantages it may provide are related to the formulation in which it is used rather than the properties of the drug itself. However, the formulation also is the source of some disadvantages as there is a high incidence of application site reactions (37%) and the product should not be used in patients with a history of hypersensitivity to sulfites. Overall, the new product is sufficiently different from its predecessors that it may provide a useful alternative for patients in whom effectiveness, safety, and/or compliance is less than optimal with current treatments.

Daniel A. Hussar