The Pharmacist Activist

Volume 12, No. 6 • June 2017

Editorial

Our Profession's Own Pharmacy Care Administrator (PCA): Part 2

Honest, Simple, Clear, Fair, Transparent!

The editorial in the May issue of *The Pharmacist Activist* included my observations and recommendations regarding the development of a pharmacy care administrator (PCA) program that would be owned and administered by the profession of pharmacy. Although I have addressed this concept in previous commentaries, the continuing and escalating concerns about the current PBMs and their programs have resulted in strong and extensive support for the development of a superior program that would give the highest priority to the provision of the highest quality pharmacy care and services for patients and the optimal use of medications. Thus, this editorial becomes "Part 2" of what may become an even longer series of editorials on this topic.

In just one month since I wrote the previous editorial there have been numerous additional examples of the problems inherent in the current PBMs and their programs, including the following:

- An investor has criticized the alliance in which Mallinckrodt uses Express Scripts as the exclusive distributor for its drug Acthar and alleges that this results in excessively high prices.

- Express Scripts is suing Kaleo for what it claims are unpaid *rebates* in the amount of $14.5 million. Many pharmacists have probably not even heard of Kaleo and the lawsuit involves rebates for just one product, Evzio, a formulation of naloxone. The amount of $14.5 million represents just the alleged *unpaid* rebates; the amount of the rebates the company paid is not disclosed. The lawsuit does reveal, however, that Express Scripts receives at least two different types of rebates – a "formulary rebate" and a "price protection rebate."

- My wife and I obtain our medications at our local independent pharmacy even though we often receive communications from CVS Caremark, the administrator of the prescription benefit plan, that we can save money by obtaining 90-day supplies of maintenance medications from the Caremark mail-order pharmacy or a local CVS Pharmacy.

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Within the last week both of us have received telephone calls from employees of CVS Caremark who promote specific cost savings if we were to use a CVS pharmacy instead of our current pharmacy. When we ask if the caller is a pharmacist, the response is "no." When we ask how they are aware of specific medications for which we have prescriptions that we understand to be confidential information, they respond that as employees of CVS Caremark they are entitled to have access to that information. This practice of CVS Caremark trying to steal patients from other pharmacies is not new, but their promotions are even more aggressive and what I consider to be a blatant conflict of interest and unprofessional conduct must be challenged more vigorously.

- CVS and Cigna have announced what they describe as a new health care and drug coverage model. In his message to me in which he identifies the subject as, "CVS & Cigna adopt diluted, distorted means of pharmacy care," Dan Hoffman, the President of Pharmaceutical Business Research Associates (a consultancy located in Glenmoore, PA), provides the following astute assessment:

  "Here's an irritating example of how insurers and chain pharmacies combine to generate profit by exploiting a genuine need that prostitutes a service and shortchanges the public. People covered by Cigna who seek to fill prescriptions at CVS stores will be encouraged to call a Cigna 800 number. At the other end, a Cigna employee will seek to provide some diluted, less informed version of pharmacy counseling while also enrolling the vulnerable consumer in one or another Cigna program. CVS pharmacists thereby have the temptation to conduct some counseling at the counter removed so as not to obstruct their workflow. As a result, CVS's assembly line approach to community pharmacy gets strengthened, Cigna gets access to a captive market, and consumers get denied the benefit of a genuine, in-person, pharmacy consult."

Pharmacy's own PCA

As noted in my May editorial, most previous efforts to persuade, legislate, and sue for positive changes in prescription benefit plans have resulted in failures, long delays, and/or frustration. Individually or together, pharmacists have little chance to achieve positive change in conflicts with giant pharmaceutical companies, insurance companies, and PBMs with huge resources. In my opinion, the most viable, and perhaps the only, option is for the profession of pharmacy to establish, own, and administer its own pharmacy care administration program that is clearly superior to current programs.

Let's begin by identifying qualities that we would want to characterize our new and superior PCA. Words such as "honest, simple, clear, fair, and transparent," come quickly to mind and are seemingly unambiguous. Now think of the largest PBMs and determine how many of those five words would accurately describe their programs. Time's up and I can guess your answer! Qualities that one should be able to expect to define any program, or working or personal relationships, are not only ignored, they are abused! A commitment to these qualities would be welcomed and supported, by patients, pharmacists, and the government programs/employers/unions who are assuming some of the costs for prescription benefit plans. And this commitment is just the starting point for the program parameters that will provide pharmacy care and services for patients that will result in more effective and safer use of medications and achieve positive therapeutic outcomes. Considering the many billions of dollars that the PBMs and health insurance companies currently extract for themselves from funding committed for prescription programs, pharmacy's new PCA will be cost-effective.

Learning from experience

There have been previous well-intended initiatives to develop better prescription benefit programs but, for the most part, these efforts have been limited and/or not been successful, at least in reaching a size that would make them competitive with the programs that are now

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New Drug Review

Ocrelizumab

(Ocrevus – Genentech) *Agent for Multiple Sclerosis*

New Drug Comparison Rating (NDCR) = 5
(important advance)
in a scale of 1 to 5 with 5 being the highest rating

Indication:
Administered intravenously for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis (MS).

Comparable drug:
Interferon beta-1a (e.g., Rebif).

Advantages:
- Is the first drug to be shown to be effective in the treatment of primary progressive multiple sclerosis (PPMS);
- Is more effective than interferon beta-1a in the treatment of relapsing MS;
- Has a unique mechanism of action (is a CD20-directed cytolytic antibody);
- Is administered less frequently (every 6 months compared with 3 times a week with interferon beta-1a).

Disadvantages:
- Is administered by intravenous infusion under the supervision of a health professional (whereas interferon beta-1a is self-administered subcutaneously or intramuscularly);
- Often causes infusion reactions;
- More likely to be associated with occurrence of infections;
- May be associated with an increased risk of malignancy.

Most important risks/adverse events:
Contraindicated in patients with active hepatitis B virus infection; infusion reactions (e.g., dermatological events, dyspnea, bronchospasm, hypotension; contraindicated in patients with a history of a life-threatening infusion reaction to the drug; patients should be observed during the infusion and for at least one hour following the completion of the infusion); infections (e.g., respiratory infections, herpes infections; however, in the clinical trials there were no reports of progressive multifocal leukoencephalopathy [PML] or reactivation of hepatitis B virus infection); use of live or live-attenuated vaccines during treatment is not recommended; increased risk of malignancies including breast cancer.

Most common adverse events (and incidence in patients with PPMS):
Upper respiratory tract infections (49%), infusion reactions (40%), skin infections (14%), lower respiratory tract infections (10%), cough (7%).

Usual dosage:
Administered by intravenous infusion; initial dose – 300 mg over at least 2.5 hours, followed two weeks later by a second 300 mg dose; subsequent doses – 600 mg as a single infusion over at least 3.5 hours every 6 months; patients should be pre-medicated with 100 mg of methylprednisolone (or an equivalent corticosteroid) intravenously approximately 30 minutes prior to each infusion and with an antihistamine (e.g., diphenhydramine) approximately 30-60 minutes prior to each infusion.

Product:
Injection – single-dose vials containing 300 mg/10 mL (should be stored in a refrigerator); intended dose should be withdrawn and diluted into an infusion bag containing 0.9% Sodium Chloride Injection to a final drug concentration of approximately 1.2 mg/mL (i.e., 300 mg in 250 mL, 600 mg in 500 mL).

Comments:
Multiple sclerosis affects approximately 400,000 people in the United States. Relapsing MS is the most common form of the disease in which patients experience relapses that are followed by remissions of varying duration. Approximately 15% of patients with MS have primary progressive disease (PPMS) that is characterized by steadily worsening function sometimes without early relapses and remissions. The disease-modifying drugs for MS (i.e, interferon beta [e.g., Rebif, Plegridy, Avonex], glatiramer acetate [e.g., Copaxone], natalizumab [Tysabri], alemtuzumab [Lemtrada], fingolimod [Gilenya], teriflunomide [Aubagio], dimethyl fumarate [Tecfidera]) are of value in reducing the frequency and severity of relapses, but are of limited benefit in more severe disease.

Ocrelizumab is a humanized monoclonal antibody that, like the chimeric monoclonal antibody rituximab (Rituxan), is directed against CD20-expressing B-cells. In two studies in patients with relapsing MS conducted over 96 weeks, it was more effective than interferon beta-1a (Rebif) in reducing annualized relapse rate and in increasing the number of patients who were relapse-free. In a placebo-controlled study in patients with PPMS for 120 weeks, it lengthened the time to worsening of disability and is the first drug to be demonstrated to be effective for PPMS.

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dominant. We must evaluate and learn from these experiences, and the perspectives of certain of the individuals who have been involved with these programs can be of great value. Former employees, including whistleblowers, of the large PBMs, who have knowledge of the deceptive and abusive tactics that characterize these programs, would have important recommendations that would contribute to the development of a new program that would be characterized by integrity and transparency.

In my May editorial I recommended that the leadership of the American Pharmacists Association (APhA) and the National Community Pharmacists Association (NCPA) convene a task force of individuals with the needed expertise regarding the development of a new PCA, and I have had a very preliminary discussion in this direction. However, it will take some time for these organizations to have the appropriate discussions and approvals for such an initiative. Therefore, it would be advantageous to more quickly convene a meeting of interested individuals to discuss ideas and strategies, and to initiate recommendations.

Ownership of the new PCA

With respect to the ownership of the new PCA, we can start by considering what must *not* be permitted to occur. The PCA must not be owned by venture capitalists or other investors, a chain pharmacy, a pharmaceutical company, or other entity whose highest priority is the financial return, and who might sell the program/company when they consider it financially advantageous to do so.

Although the new PCA might be started on a local or regional basis, the goal should be to have a national program. Unless there are legal or other restrictions, a national pharmacists association could develop and own the program. Ownership by one national association would be the least complex strategy, but a potential exists for collaboration and an ownership structure that would involve two or more associations. Perhaps this opportunity might even provide the motivation for the national associations to develop an organizational structure that would better serve the needs of the profession.

Another option would be to have the participating pharmacists own the program. There are approximately 22,000 independent pharmacies in the United States and having a large number of pharmacists sharing the cost of ownership could make it an affordable investment for most individual pharmacists. Although not all of the pharmacists who own these pharmacies would be interested in participating and/or be in a position to provide the scope of pharmacist services that would be required in the program, I expect that a large majority of independent pharmacists would want to participate. Indeed, the most important question for them could well be whether they could afford not to participate. A network of a large number of independent pharmacies that have a shared ownership in a PCA has exciting potential. The number of pharmacies and their geographical distribution will be greater than the largest of the chain pharmacies. I would also like to think that sharing in the ownership of the PCA would provide the basis for the network of these pharmacies to be able to negotiate the terms and compensation for their participation in the other programs administered by PBMs and insurance companies.

The more I think of these possibilities, the more enthusiastic I become about the opportunities for positive outcomes for patients and pharmacists. And I do believe that dreams can become reality!

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