The Pharmacist Activist

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Editorial

CVS Caremark's Participation in Medicare Prescription Programs should be TERMINATED!

What if CVS Caremark conducted an audit of a non-CVS pharmacy and learned that the pharmacy was charging patients higher prices for prescriptions dispensed in a particular program than the prices identified in the terms of the agreement of participation? What penalties would be imposed? Would the pharmacy be permitted to continue its participation in the program? My expectation is that CVS Caremark would terminate the participation of that non-CVS pharmacy from its program, even if the higher prices resulted from an error, and were not intentional.

A recent situation provides an opportunity to observe how an experience for which CVS Caremark is at fault is handled. I first became aware of this situation from an article in the May 28, 2010 issue of *The Wall Street Journal* (by Mark Maremont; page B4), titled, "CVS Cites Drug-Price Error." The article begins:

"Many customers of CVS Caremark Corp.'s SilverScript Medicare prescription-drug programs have been paying higher prices than they were promised when they signed up for the plans in late 2009.

CVS blames the problem on a computer error, which it says caused prices for brand-name drugs to be listed about 4% lower than they should have been. It says the error appeared in data CVS supplied to the Medicare website that allows senior citizens to do comparison shopping between prescription insurance plans."

Subsequent comments in the article include the following:

"The inaccurate information...made the CVS plans seem more attractive than they should have been. Medicare recipients paid the higher actual prices when purchasing the drugs at the store.

CVS notified the federal regulator, the Centers for Medicare and Medicaid Services, about the problem in January. A Medicare spokesman said regulators worked with CVS to craft a response plan, under which CVS would offer a refund for the price difference, but only to consumers who specifically requested that."

"CVS sent letters of apology to customers starting in late March. A letter reviewed by *The Wall Street Journal* didn't mention the possibility of a refund but directed a recipient with questions to call a toll-free number to discuss 'your options.'"

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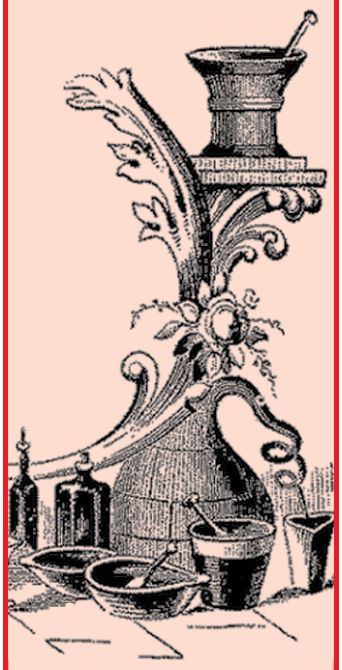

The Computer Error

There is a long-standing observation to the effect that it is not computers that make errors but rather it is the people who program and operate them. The attempt by CVS Caremark to explain this situation away by claiming "computer error" is disingenuous. Are we to believe that CVS Caremark's computers are so sophisticated that they make errors all on their own and that there are no employees who are at fault and accountable? Did the Centers for Medicare and Medicaid Services (CMS) not request a more detailed explanation? But this is just the first of numerous questions that should be asked. Other questions that come quickly to mind include the following:

- How was the error identified and why did it take as long as three months for it to be identified? Were intentional deception and fraud ruled out?
- How many consumers signed up for the plans for which CVS Caremark placed inaccurate information on the website?
- For what errors/violations does CMS have the authority to impose penalties on pharmacy entities participating in the Medicare prescription program? Did CMS impose any penalties on CVS Caremark?
- Why did it take almost three months from the time the inaccurate information was removed from the website for CVS Caremark to begin sending letters of apology to the customers affected?
- Why did the letter of apology not make mention of a refund when this was supposed to be part of the response developed in consultation with CMS?
- To what extent does the difference between the inaccurate advertised prices and the actual prices affect how quickly patients reach the donut hole in the Medicare program?

CMS Must Act!

CVS Caremark's letter of apology directed individuals to call a toll-free number. *The Wall Street Journal* article relates one such experience:

"An affected consumer who recently called CVS's toll-free number said he was told he could file a 'grievance' to seek a refund for brand-name drugs bought up to that date, but only if he had a printout of the original inaccurate pricing information from the Internet."

"A CVS spokeswoman said that consumer's experience wasn't in line with company policy to provide a refund if asked."

The failure of CVS Caremark to identify the opportunity for a refund in its letter to its customers, as well as its request for documentation from those who call the toll-free number, represent the height of arrogance. CVS Caremark knows the identity of every participant in the programs in which it provided information that was not accurate. It should have taken the initiative to provide a refund to these individuals. Not only did it not do that, but it also avoids providing timely and clear information through which its customers can pursue this possibility. It is now up to the CMS to take firm actions and I urge the following:

1. The CMS should conduct a thorough investigation of this situation that, at the least, would address the questions and issues identified earlier.
2. The CMS should terminate CVS Caremark's participation in Medicare prescription programs and impose other pertinent penalties.
3. The CMS should communicate pertinent information regarding this situation to the Federal Trade Commission (FTC) that is currently investigating allegations of anticompetitive practices on the part of CVS Caremark.

The lower inaccurate prices posted on the Medicare website by CVS Caremark provided it with an unfair advantage over other organizations that were recruiting patients for Medicare prescription programs. This error undoubtedly resulted in many individuals selecting the CVS Caremark program (only to be charged more) when they might have selected another program if accurate information had been provided. There appears to have been no consideration as to how this unfair advantage in a competitive marketplace should be addressed.

Recourse for Pharmacists

Many pharmacists have reasons to contend that they are victims of abusive auditing practices by CVS Caremark, as well as other administrators of prescription

(Continued on Page 4)

New Drug Review

Pitavastatin calcium (Livalo – Kowa; Lilly)

Lipid-Regulating Agent

New Drug Comparison Rating (NDCR) = 2

(significant disadvantages) in a scale of 1 to 5, with 5 being the highest rating

Indications:

As adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol (LDL-C), apolipoprotein B, triglycerides, and to increase high-density lipoprotein cholesterol in patients with primary hyperlipidemia or mixed dyslipidemia.

Comparable drugs:

Atorvastatin (Lipitor), fluvastatin (e.g., Lescol XL), lovastatin (e.g., Mevacor), pravastatin (e.g., Pravachol), rosuvastatin (Crestor), simvastatin (e.g., Zocor).

Advantages:

- Lower risk of drug interactions (compared with atorvastatin, lovastatin, and simvastatin);
- May be administered at any time of day (compared with fluvastatin, lovastatin, and simvastatin).

Disadvantages:

- Extent of reduction of LDL-C with the maximum recommended dosage is lower than with the maximum recommended dosages of atorvastatin, rosuvastatin, and simvastatin;
- Labeled indications are limited (e.g., compared with atorvastatin and simvastatin that have been demonstrated to reduce the risk of myocardial infarction, stroke, and revascularization procedures in patients with clinically evident coronary heart disease, as well as in patients without clinically evident coronary heart disease but who have multiple risk factors for such);
- Concurrent use with cyclosporine is contraindicated.

Most important risks/adverse events:

Contraindicated in patients with active liver disease that may include unexplained persistent elevations in hepatic transaminase concentrations (liver function tests should be performed before and at 12 weeks following initiation of treatment and increases in dosage, and periodically [e.g., semiannually] thereafter; caution should be exercised in patients with a history of liver disease or who consume substantial quantities of alcohol); contraindicated during pregnancy (Pregnancy Category X) and in nursing mothers; action may be increased by cyclosporine and concurrent use is contraindicated; myopathy/rhabdomyolysis (patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness; treatment should be discontinued if markedly elevated creatine kinase concentrations occur; risk of myopathy is increased by the concurrent use of a fibrate or lipid-lowering doses of niacin); action may be increased by the concurrent use of lopinavir/ritonavir (Kaletra), erythromycin, and rifampin (use with lopinavir/ritonavir is not recommended; dosage of pitavastatin should be reduced when used concurrently with erythromycin or rifampin).

Most common adverse events:

Back pain (4%), constipation (4%), diarrhea (3%), myalgia (3%).

Usual dosage:

2 mg once a day to initiate treatment; blood lipid concentrations should be determined when initiating treatment and after four weeks, at which time the dosage may be adjusted accordingly; maximum recommended dosage is 4 mg once a day; in patients with moderate renal impairment or with end-stage renal disease receiving hemodialysis, the recommended initial dosage is 1 mg once a day and the maximum dosage 2 mg once a day; in patients treated with erythromycin, the dosage should not exceed 1 mg once a day and, in patients treated with rifampin, the dosage should not exceed 2 mg once a day.

plans. These pharmacists, as well as our professional organizations, should monitor this situation involving CVS and CMS very closely. If CVS Caremark escapes with no penalty or only a minor one, it must not be permitted to engage in auditing practices that are any stricter than those it is willing to accept when it makes the error. One of the noteworthy parts of the response plan on which CVS consulted with CMS is that the offer of a refund would be for the price difference between the inaccurate and actual prices. If an error is made in a non-CVS pharmacy in a prescription program administered by CVS Caremark, is the pharmacy held responsible for the specific dollar amount that the error might be considered to represent, or the entire cost of a prescription that consists primarily of the cost of the drug product?

The auditing practices of CVS Caremark in non-CVS pharmacies must not be allowed to be any more rigid and punitive than what it experiences as a consequence of its error in the Medicare program. Pharmacists who experience excessive and abusive auditing practices by CVS Caremark should use this situation as an example in challenging its actions. If pertinent, the feasibility of a class-action challenge should be explored. Some pharmacists have been successful in challenging unjust decisions/actions in small-claims court. Pharmacists and our professional associations must also give a very high priority to the enactment of federal legislation that will permit pharmacists to work and act together to negotiate the terms of prescription benefit programs.

Daniel A. Hussar

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

NEWS - Line PUBLISHING

New Drug Review (cont.)

Products:

Tablets – 1 mg, 2 mg, 4 mg.

Comments:

Pitavastatin is a 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor (statin) with properties that are generally similar to those of the other statins. In comparative studies, the percent reduction of LDL-C with the maximum recommended dosage of pitavastatin (4 mg once a day) was noninferior to atorvastatin (20 mg once a day) and simvastatin (40 mg once a day), and greater than with pravastatin (40 mg once a day). Higher dosages of the latter agents were not evaluated in these studies. Pitavastatin is metabolized to only a limited extent via cytochrome P450 metabolic pathways, and is less likely than lovastatin, simvastatin, and atorvastatin to interact with other medications via this mechanism.

Daniel A. Hussar

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