The Pharmacist Activist

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The Medicare Prescription Benefit??

Which of the following has been used to describe the Medicare prescription program?

a. confusing	o. an embarrassment
b. excessively complicated	p. an awful mess
c. overwhelming	q. a horror story
d. plagued by problems	r. a disservice to the elderly and disabled
e. catastrophic	s. a tangle of rules
f. outrageous	t. a public health emergency
g. chaos	u. running roughshod over patients and pharmacists
h. dangerous	v. placing lives at risk
i. complex beyond understanding	w. medication roulette
j. a debacle	x. favors special interests
k. a disgrace	y. a drug bill written by and for lobbyists and their clients
l. a disaster	z. all of the above.
m. a fiasco	
n. a crisis	

This 26-choices question is a lot easier than the many questions with just four or five choices on the exams we took in college. Most would quickly conclude that the sad but correct choice is "z" — all of the above. I did not need a thesaurus or have to do a long search to come up with the choices. I have read or heard them all. Indeed, the list could be much longer — I just stopped when I ran out of letters for the choices. We have witnessed how what started out as a well-intentioned idea (i.e., helping the elderly and disabled afford needed medications) has been seriously damaged by politics, greed, manipulation, and inept planning at the highest levels.

Contents

Discussion

Ezopiclone (Lunesta-Sepracor) is a hypnotic that is structurally unrelated to other agents that have been used in the treatment of insomnia. It is the S-isomer of zopiclone, a racemic mixture that is available in certain other countries but has not been marketed in the United States...

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(Medicare cont.)

As the Medicare prescription program and associated budgetary provisions were being designed, pharmacists and our associations identified many problems. As the program has been implemented, these problems occurred one after another. The Secretary of Health and Human Services Michael Leavitt said the problems were "unanticipated." However, the problems were anticipated by pharmacists. We were ignored!

It has been stated by some of those with primary responsibility for the program that it has been implemented effectively and without problems for many patients. However, hundreds of thousands of patients have encountered important and inexcusable problems. The responsibility for resolving the problems has fallen on community pharmacists and the staff of the Centers for Medicare and Medicaid Services (CMS) who were given the challenge of implementing a seriously flawed program. Many states have had to adopt emergency measures to avoid even worse problems.

Secretary Leavitt has noted that the efforts of pharmacists "…have been nothing short of heroic…. They have been selfless, compassionate, and committed to service." This is a wonderful tribute, but it doesn't pay the bills. Many community pharmacists have incurred huge expenses without knowing whether and when they will be compensated for product costs and dispensing fees.

Administrative costs (e.g., the time and extra personnel to resolve problems) are staggering! And the most noble thing of all is that these pharmacists have been willing to make these efforts to assist their patients in a program that has financial terms/restrictions for pharmacies that are so inequitable that it will force many of them out of business.

Pharmacists must demand equitable compensation for the medications and services provided, and should refuse to participate in the plans that do not provide such. We should demand compensation for the administrative costs incurred in resolving the problems created by others. We must hold our legislators accountable and actively support and work for the election of only those candidates who are committed to the provision of high-quality, comprehensive health care/pharmaceutical services for their constituents, and equitable compensation for pharmacists.

Included in this newsletter is a copy of my letter to my senator, Rick Santorum. If any sections of this letter can be useful to you in your communications with your legislators, please feel free to use them–verbatim if you wish.

- Daniel A. Hussar

Senator Rick Santorum
511 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Santorum:

I am in receipt of your letters in response to my communications voicing concerns regarding the Medicare and Medicaid prescription drug programs. Your letters include the following statements in bold type:

"Please be assured that I understand that community pharmacists play a vital role in ensuring the health and safety of American healthcare consumers."

"Moreover, as small businesses, community pharmacies are an important component of both the Commonwealth's and our nation's economies."

"Rest assured, I will be sure to keep your concerns in mind as I work to ensure that community pharmacists receive adequate reimbursement for their work."

However, your votes on the pertinent legislation and budget proposals are not consistent with the statements above. Not only can I not "rest assured" based on your comments but my concerns now are even greater. It is unclear to me whether you have been misinformed or do not understand some of the consequences of the legislation you have supported, and/or whether you have chosen to ignore the concerns that I and other pharmacists and organizations have communicated to you.

I am an advocate for initiatives that will help needy individuals obtain medications and other health care services. However, I and many others are of the strong opinion that the recent and proposed changes in the Medicare and Medicaid prescription programs are a disservice to many of the individuals whom these programs are supposed to serve. In addition, they are having a devastating financial impact on local pharmacies.

You refer to reports that indicate that there are overpayments of billions of dollars for prescription drugs in these programs, and the administration and most legislators have chosen to address this situation by reducing the compensation provided to pharmacists. The studies that are the basis for these reports have serious flaws and the conclusions are extremely misleading. Just as bad is the preoccupation with the small amount of compensation that pharmacists receive that is above their costs to purchase the medications. This increment of compensation is a very small fraction of the total cost of a prescription, yet it has inappropriately received the exclusive attention of the administration and most legislators. There is also a failure to recognize the inadequacy of the dispensing fees provided to pharmacists and the financial restrictions under which pharmacists must practice. As examples of the latter, pharmacists must purchase medications at prices that are established by the manufacturers/distributors of the drugs and, if they provide medications in prescription drug benefit programs, they must accept dispensing fees and product cost compensation that are determined/dictated by government agencies, insurance companies, or managed care programs. Pharmacists are precluded by antitrust laws from negotiating the financial terms in which they can participate in these programs. The antitrust laws need to be revised to permit pharmacists and other health professionals and their organizations to negotiate equitable terms of participation in such programs, and I urge your support for this initiative.

In my opinion, the Medicare prescription program has been poorly designed and poorly implemented, although I do wish to acknowledge and commend the dedicated efforts of many staff of the Centers for Medicare and Medicaid Services (CMS) who were given the challenge of implementing a flawed program. As all are now aware, hundreds of thousands of patients have experienced problems with the program. In his Secretary's One Month Progress Report on the Medicare Prescription Drug Benefit, Secretary of Health and Human Services Michael Leavitt acknowledges problems but says they were unanticipated. The problems were not unanticipated. Pharmacists and our associations anticipated and identified these problems, and communicated our concerns. We were ignored!

In his report Secretary Leavitt makes the following very complimentary comments about pharmacists:

"The efforts of pharmacists over the last month have been nothing short of heroic…They have been selfless, compassionate, and committed to service."

This accolade is appreciated but is of no consolation when the CMS, the administration, and many legislators have developed and are implementing a program with financial terms that will result in many independent pharmacies going out of business or having to decline to participate.

The following comment in Secretary Leavitt's report is misleading, if not inaccurate:

"Most (pharmacists) have negotiated payment terms with the health plans that are different than those they are accustomed to."

It is the health plans that establish the payment terms and they offer them to pharmacists on a "take it or leave it" basis without the opportunity for negotiation. As noted above, pharmacists are precluded from getting together to negotiate payment terms, nor are their professional organizations able to do this on their behalf. The fact that Secretary Leavitt has made this comment, however, raises the question as to whether some pharmacists are being provided the opportunity to negotiate payment terms that are not known or available to other pharmacists. If this situation does exist, it would be the small independent pharmacies (i.e., small businesses) that are clearly at the greatest disadvantage. I wish to ask that you seek clarification of this situation from Secretary Leavitt.

The problems resulting from the changes in the Medicare and Medicaid programs have necessitated emergency action and funding in many states to help patients obtain needed medications. A statement attributed to Dr. McClellan of CMS indicates that these states will be reimbursed for their costs for the medications, as well as for any administrative costs that states had incurred in operating stopgap programs.

Patients have been told not to leave their pharmacy without their medication and many pharmacies have dispensed thousands of dollars worth of medications without specific assurance of whether or when they will be compensated. Many pharmacists have experienced cash flow crises for which immediate relief is needed. It is encouraging that Dr. McClellan has assured the states that they will be compensated for administrative costs, as well as drug product costs. Pharmacists are entitled to no less but I am not aware that anyone in CMS, the administration, or legislature is addressing this.

This is an opportunity for you to take a leading role in recognizing the services, time, and expense that pharmacists have committed to avoid even greater problems in the implementation of the changes in the Medicare prescription program. In addition to providing assurance of compensation on a timely basis to pharmacists for their drug product costs and dispensing fees, there must also be compensation for pharmacists to recover some of their extraordinary administrative costs. Although it falls far short of the actual administrative costs incurred by pharmacists, I recommend, as a starting point, that pharmacies be provided an administrative fee of $25 for every patient in the Medicare program who obtains prescriptions in that pharmacy. I urge you to initiate the administrative and/or legislative actions necessary to do this, and I am confident that you and your colleagues will be able to identify the needed financial resources.

One of the things that pharmacists have learned from the Medicare debacle is that we have not been effective in helping to shape legislation in a direction that is most beneficial for patients and equitable for pharmacists. I and many other pharmacists intend to be activists in the upcoming elections in encouraging pharmacy students to register to vote and in encouraging patients and other citizens to support and vote for candidates who are committed to the provision of prescription programs that are easily understood and used by patients, and that provide equitable compensation for the services provided by pharmacists. In this letter I have provided recommendations through which you can be a leader in such efforts. I urge your prompt personal attention to these needs and opportunities, and look forward to your response.

Sincerely,
Daniel A. Hussar

New Drug Review

Eszopiclone (Lunesta)

New Drug Comparison Rating (NDCR) = 3
(no or minor advantage/disadvantage)
in a scale of 1 to 5, with 5 being the highest rating

Indications:
Treatment of insomnia.

Comparative drugs:
Zolpidem (Ambien; Ambien CR)

Advantages:
- Longer duration of action may be of benefit with respect to maintaining sleep and decreasing early morning awakening
- Labeling does not include a recommended limit with respect to duration of use (compared with the immediate-release formulation of zolpidem [Ambien])

Disadvantages:
- Longer duration of action may increase the likelihood of daytime sedation
- Unpleasant taste is a common adverse event
- Extensively metabolized via the CYP3A4 pathway with greater possibility of clinically important interactions with CYP3A4 inhibitors and inducers
- Pregnancy Category C (compared with immediate-release formulation of zolpidem [Ambien] that is in Category B; controlled-release formulation of zolpidem [Ambien CR] is in Category C)
- More expensive

Conclusions:
Neither eszopiclone (Lunesta) nor the controlled-release formulation of zolpidem (Ambien CR) has been demonstrated in comparative studies to be more effective or better tolerated than the immediate-release formulation of zolpidem (Ambien). Eszopiclone has a longer half-life and a longer duration of action than zolpidem which can be an advantage in improving sleep maintenance and decreasing early morning awakening, but a disadvantage in increasing the possibility of daytime sedation. Eszopiclone is the first hypnotic demonstrated to be effective and safe for a period of time as long as six months. However, the immediate-release formulation of zolpidem often has been used for the long-term treatment of insomnia.

For the treatment of insomnia characterized by difficulty with sleep onset and sleep maintenance, the immediate-release formulation of zolpidem is the best choice. If this product does not satisfactorily improve sleep maintenance or prevent early morning awakening, the use of eszopiclone or the controlled-release formulation of zolpidem should be considered.

Cost: (from Medi-Span Price Alert, February 15, 2006)
Lunesta--$4.04/tablet (1 mg, 2 mg, or 3 mg)
Ambien--$3.54/tablet (5 mg or 10 mg)
Ambien CR--$3.54/tablet (6.25 mg or 12.5 mg)

Discussion

Eszopiclone (Lunesta-Sepracor) is a hypnotic that is structurally unrelated to other agents that have been used in the treatment of insomnia. It is the S-isomer of zopiclone, a racemic mixture that is available in certain other countries but has not been marketed in the United States. The properties of eszopiclone are most similar to those of zolpidem (Ambien) that was initially marketed in 1993, and in late 2005 in a controlled-release formulation (Ambien CR). Neither eszopiclone nor zolpidem is a benzodiazepine (e.g., temazepam [e.g., Restoril]), but they are believed to act at gamma-aminobutyric acid (GABA)-receptor complexes at which the benzodiazepines interact, and they share many of the properties of the benzodiazepines.

Eszopiclone is indicated for the treatment of insomnia. Its effectiveness and safety in decreasing sleep latency and improving sleep maintenance have been demonstrated in studies in outpatients of up to six months' duration, as well as in sleep laboratory studies. Eszopiclone has a longer half-life and a longer duration of action than zolpidem, and may be more effective in improving sleep maintenance in some patients.

It is generally recommended that the use of a hypnotic be limited to seven to 10 days of treatment, and most hypnotics have been studied for periods of up to 28 or 35 days. The labeled indication for the immediate-release formulation of zolpidem, as well as for certain other hypnotics, is for the short-term treatment of insomnia, and the labeling notes that it should not be prescribed in quantities exceeding a one-month supply. In contrast, the labeling for eszopiclone and

(Discussion cont.)

the controlled-release formulation of zolpidem does not include a specific reference to "short-term" use or the quantity prescribed.

The primary studies of eszopiclone were placebo-controlled and did not involve direct comparisons with zolpidem or other hypnotics. The immediate-release formulation of zolpidem has been used in some patients for long periods of time (e.g., years) without a loss of effectiveness or safety problems, and there are insufficient data from comparative studies to conclude that either eszopiclone or zolpidem has an advantage if long-term use is considered necessary.

The most commonly experienced adverse events in a six-week study of eszopiclone (and their incidence in non-elderly patients receiving doses of 2 mg and 3 mg) include unpleasant taste (17%/34%), headache (21%/17%), somnolence (10%/8%), dizziness (5%/7%), and dry mouth (5%/7%). Unpleasant taste has not been a problem with the use of zolpidem and the frequency of its occurrence with eszopiclone is a disadvantage for the new agent.

Because of the potential for eszopiclone to cause daytime sedation, it is recommended that the drug not be used in patients who are not able to get at least eight hours of sleep before they must be active again.

Like zolpidem, zaleplon (Sonata), and the benzodiazepines, eszopiclone has the potential to cause dependence and abuse, and is classified in Schedule IV. Particular caution should be exercised if one of these agents is considered for patients with a history of abuse of, or addiction to, drugs or alcohol. The central nervous system (CNS) depressant action of the hypnotics that is responsible for their beneficial effect in the treatment of insomnia is also responsible for one of their most important risks (ie, daytime sedation). Patients should not engage in potentially hazardous activities following administration of these agents, and they should be cautioned about the possibility of impairment of alertness, coordination, and judgment on the day following use of the hypnotic. The occurrence of daytime sedation ("sedative hangover") is more likely with eszopiclone than with zolpidem because of the longer duration of action of the new agent. The concurrent use of other medications having a CNS depressant action, as well as alcoholic beverages, is likely to result in an additive response and corresponding risk.

Except for the occurrence of CNS adverse events, most patients tolerate eszopiclone and zolpidem well. However, unlike zolpidem or the other hypnotics, eszopiclone has been associated with a high incidence of unpleasant taste. Eszopiclone and the controlled-release formulation of zolpidem are classified in Pregnancy Category C, whereas the immediate-release formulation of zolpidem is in Category B.

Eszopiclone and zolpidem are extensively metabolized via CYP450 pathways and are primarily eliminated in the urine as metabolites. Eszopiclone is metabolized to the greatest extent via the CYP3A4 pathway and is more likely to interact with other medications that are inhibitors or inducers of this pathway.

A lower dosage of eszopiclone should be used in patients who are also being treated with a potent CYP3A4 inhibitor (e.g., clarithromycin [e.g., Biaxin], itraconazole [e.g., Sporanox]).

Following oral administration, eszopiclone is rapidly absorbed. The consumption of a heavy high-fat meal results in slower absorption of the drug and a delay and/or reduction in its action on sleep onset. Accordingly, it should not be administered with, or shortly after, such a meal.

Because of the potential for eszopiclone to cause daytime sedation, it is recommended that the drug not be used in patients who are not able to get at least eight hours of sleep before they must be active again.

The recommended starting dosage of eszopiclone for most non-elderly patients is 2 mg immediately before bedtime. If the primary complaint is difficulty staying asleep, the dosage may be initiated at or raised to 3 mg.

The exposure (AUC) and half-life of eszopiclone are greater in patients over 65 years of age, and a starting dosage of 1 mg is recommended for elderly patients whose primary complaint is difficulty falling asleep. The dosage may be increased to 2 mg if needed. For elderly patients whose primary complaint is difficulty staying asleep, the recommended dosage is 2 mg. In patients with severe hepatic impairment or who are being treated concurrently with a potent CYP3A4 inhibitor, the recommended starting dosage is 1 mg.

Eszopiclone film-coated tablets are supplied in 1 mg, 2 mg, and 3 mg potencies.

Ramelteon (Rozerem) is another new hypnotic and has unique properties; however, it, as well as zaleplon, has a short duration of action and their benefit is limited to the treatment of insomnia characterized by difficulty in falling asleep.

- Daniel A. Hussar