Long Term Care Pharmacy Alliance

Testimony of the Long Term Care Pharmacy Alliance to the Senate Special Committee on Aging

Chairman Smith, Ranking Member Senator Kohl, and Members of the Committee, I appreciate this opportunity to testify on behalf of the Long Term Care Pharmacy Alliance regarding the implementation of the new Medicare Part D benefit, and the transition for beneficiaries dually eligible for Medicaid and Medicare. The Long Term Care Pharmacy Alliance (LTCPA) represents the nation's leading providers of pharmacy services to residents of long term care facilities, including nursing facilities, intermediate care facilities and assisted living facilities. LTCPA's members provide these services to over 60 percent of all nursing home residents in the United States.

My name is Wendy Gerlach, and I am the Director of Pharmacy Operations in Wisconsin for a company called Roeschen's Omnicare, a leading provider of pharmaceutical care for seniors. Each and every day, Omnicare's experienced staff of pharmacists serve residents in skilled nursing, assisted living and other healthcare facilities, comprising approximately 1,071,000 beds in 47 states, with one goal in mind: to help ensure the health of the senior population in a cost-effective manner. Wisconsin alone had a total of 403 nursing homes in 2003 serving over 36,000 residents, almost 64 percent of which are currently paid for by Medicaid. Though we don't have specific numbers of dual eligibles in Wisconsin, we do know that almost 92 percent of these nursing home residents are over the age of 65 and therefore the majority of the 64 percent of these residents on Medicaid are likely dually eligible, and will therefore be impacted by this transition from Medicaid to Medicare.[*] These nursing home residents will experience monumental change in the way they receive prescription drug benefits on January 1, 2006. Despite efforts by Congress and CMS to blunt the impact of this change, we believe there is more to be done to assure that the nation's most vulnerable citizens continue to have access to necessary prescription drugs.

As you may know, there are approximately 1.6 million nursing home residents in the United States. This population is disproportionately old and frail. The average nursing home resident is approximately 84 years of age, suffers, on average, from eight, and sometimes more distinct diseases and consumes approximately nine or more different medications concurrently. In addition, the incidence of cognitive impairment among nursing home residents approaches 75 percent, rendering personal participation in their care relatively meaningless.

Medicaid currently provides prescription drug coverage for approximately 70 percent of nursing home residents. An additional 15 percent of nursing home residents are admitted following a qualifying stay at an acute care hospital, therefore their care including prescription drugs is covered under Medicare Part A. Under the Part A benefit, nursing

[*] http://dhfs.wisconsin.gov/provider/pdf/03nh&r.pdf

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homes are paid a global payment that includes the cost of prescribed drugs. The remaining 15 percent of nursing home residents pay for their prescription drugs from their own resources or from third-party insurance. These residents typically are spending their resources down to the level at which they will eventually qualify for Medicaid.

It is important to distinguish the special pharmacy services provided to long term care residents from outpatient retail pharmacy services. Long term care residents are not your typical "cash and carry" ambulatory pharmacy customers. Instead, they require pharmacies that can dispense their drugs in special packaging, 24 hours a day, to the nursing facility where a nurse will directly administer the drug to the patient in a safe and effective manner.

Under federal regulations, nursing homes have the primary responsibility for assuring that their residents receive appropriate pharmacy services. Nursing facilities generally comply with this obligation by contracting with specialized long term care pharmacies to provide services that help the facility provide the highest level of pharmacy care at reasonable cost.

The long term care pharmacy industry provides these services, including:

- **Specialized packaging**: The simple fact that nursing home residents are not able to administer their own medications necessitates the development and maintenance of systems that clearly identity the drug; the patient for whom it is prescribed; and the frequency of administration. These systems typically revolve around the concept of the unit-dose packaged medications. Long term care pharmacies package each medication in a system that segregates each dose and accounts for each dose administered. This system has resulted in the lowest rate of dispensing errors in the pharmacy industry.

- **Scheduled Delivery**: Once again, the residents we serve do not come to us, we must go to them. Therefore, each long term care pharmacy provides scheduled routine delivery service to each facility it serves. Generally, these deliveries are made twice each day. The delivery consists of boxes of medicine, compartmentalized for each resident.

- **Emergency Deliveries**: Since residents may be admitted at odd hours and residents may be prescribed treatments in response to a physician's intervention, the pharmacy must be ready to provide prescribed drugs between the scheduled delivery hours. This often necessitates the use of contracted couriers or contracted alternative pharmacies that can respond immediately to necessary medications. It is not unusual for a pharmacy that services 5000 nursing home residents to have more than 700 such emergency deliveries in a 30-day period.

- **Emergency Kits and Interim Supplies**: Pharmacies generally supply nursing facilities with emergency kits of lifesaving drugs in order to respond to medical emergencies. They also supply small amounts of commonly used drugs to provide immediate service to newly-admitted residents.

- **Medication Administration and Treatment Records**: In order to properly document medical treatment ordered by physicians and the administration of prescribed drugs, the pharmacy often supplies documents that facilitate this process.

- **Specialized Therapeutic Monitoring and Intervention**: Under federal regulation, nursing homes are required to have each resident's medications reviewed by a pharmacist for proper identification of unnecessary drugs and potential adverse reactions. Nursing homes generally contract separately for this review, although it is frequently performed by an employee of the dispensing pharmacy.

Currently, the primary payer for pharmacy services for nursing home residents is the state Medicaid program. These programs, although functioning differently from state-to-state, have the advantage of local uniformity. That is, for 70 percent of the residents of any nursing facility, the payer (Medicaid) adheres to a common set of rules for coverage of medically necessary drugs. The importance of this is difficult to overstate. It has been well documented that variation in process is the enemy of quality. In addition, Medicaid operates under the general assumption that, while states may impose access restrictions such as preferred drug lists and prior authorization, the recipient is entitled to access to all medically necessary drugs. Therefore, in practice, we have found that nursing home residents typically get the drugs they need in a timely manner regardless of their preferred status under Medicaid.

We anticipate that the Medicare Modernization Act (MMA) will have a significant impact on long-term care pharmacy services. The philosophical foundation of the MMA is that the combination of market dynamics and consumer choice will result in higher quality at lower cost. This assumption is not unreasonable. The long history of quality improvements resulting from private sector competition is replete with examples of innovation and efficiencies that have advanced the American economy and resulted in better lives for each generation.

The Part D experiment, as applied to the 38 million Medicare beneficiaries who are not residing in long term care facilities, may also succeed in producing similar results. However, the Medicare beneficiaries who will achieve the most robust benefits will likely be those who can avail themselves of the competing choices and make conscious decisions as to the best option that will suit their individual needs. These beneficiaries will most likely have little, if any, cognitive impairment and will generally not be the frailest of the Medicare population. In short, the beneficiaries most likely to benefit the most will be the healthiest and most engaged cohort of the Medicare beneficiary pool.

Congress was generous in expanding low-income subsidies and cost sharing limitations to beneficiaries with incomes below 150 percent of the federal poverty level (FPL), with the most generous subsidies being reserved for beneficiaries below 135 percent of the FPL. Since Medicaid coverage generally begins at about 75 percent of the FPL, these subsidies will encompass a significantly higher percentage of long term care residents than the current 70 percent who currently qualify for full coverage under the Medicaid program. As a result, we expect that more than 80 percent of long term care residents will be exempt from any financial participation in support of the Medicare drug benefit.

Nevertheless, we remain concerned about the operational impact of the transition from the current model, in which Medicaid is the dominant authority in drug benefit delivery to the long term care population, to the new model where multiple prescription drug plans (PDPs) within each region will compete for Medicare beneficiaries. This transition is expected to result in a fragmented decision-making system within the nursing facility. An average-sized nursing facility of 150 beds could conceivably have residents of two or more PDPs, all operating under different formularies and exceptions processes. The resulting confusion could increase the risk of medical errors. The task of managing several formularies and exception processes over small resident populations not only creates administrative complexities, but also potential treatment problems. I hope that my testimony will help Congress and CMS identify potential areas of concern and possible solutions to mitigate this confusion.

Drugs Excluded from the Basic Part D Benefit

We are very concerned that the MMA specifically disallows coverage of certain drug classes in the standard benefit plan of a PDP. These mandatory exclusions include such classes as over-the-counter (OTC) drugs, benzodiazepines (used for the treatment of anxiety disorders), barbiturates (used for the treatment of some seizure disorders) and drugs for weight management. Although state Medicaid programs have the option of continuing coverage of these drugs, there is some uncertainty as to their willingness to do so. Impeding access to these products will almost certainly result in increased hospitalization and higher costs to the program.

Benzodiazepines

Benzodiazepines are a class of psychotropic medication used to treat anxiety, seizure disorders, panic attacks, and insomnia. All benzodiazepine medications marketed in the United States are available in generic form and are relatively inexpensive. Examples include diazepam (Valium), alprazolam (Xanax) and temazepam (Restoril).

No suitable alternative exists for these medications. Treatment of acute anxiety, panic attacks, certain types of seizures and other disorders will be difficult, if not impossible, without these medications. Dual eligible beneficiaries, especially those in long-term care settings may lose access to these medications. Approximately 1.7 million of the 6.4 million dual eligibles are estimated to be taking benzodiazepines. In nursing facilities, 12 percent of residents take benzodiazepines. Without coverage of these medications, physicians may turn to alternative medications that are more costly and/or more toxic, such as atypical antipsychotics and meprobamate (an older medication that is highly sedating and addictive).

Barbiturates

In addition, phenobarbital is a barbiturate widely used for seizures in the elderly. About 2 percent of nursing home residents are estimated to be taking these medications. This drug is currently excluded from coverage by the MMA statute.

Weight Loss

Unintentional weight loss can occur in individuals with cancer, AIDS, or other medical conditions. A number of medications are used to treat weight loss in these populations. Nursing facilities have a publicly reported quality measure on weight loss that tracks their ability to manage this condition in their residents. Without access to medications to treat this condition, nursing facilities and their residents will be adversely impacted when Medicare Part D is implemented.

Over-The-Counter Drugs

Many OTC drugs are a necessary adjunct to maximize the benefit from prescription agents. Iron supplementation is needed with the erythropoetic therapies Procrit® and Aranesp®. Calcium supplementation is necessary with osteoporosis therapies such as Actonel® and Miacalcin.® Acetaminophen is considered first line therapy for the treatment of mild to moderate musculoskeletal pain in the elderly. Stool softeners are necessary to prevent opioid-induced constipation. When OTC medications are a necessary concomitant therapy, there is risk of therapeutic failure when the covered entity is used alone.

The potential loss of this coverage with the implementation of Part D will lead to cost shifting to an already burdened elderly population residing in LTC facilities. When OTC drugs become out-of-pocket costs, Medicare recipients will likely request the physician to prescribe a more expensive covered prescription medication at an additional cost to the program.

Recommendation

Therefore, we recommend that dually eligible beneficiaries be assured access to these excluded drugs. Since full-dual eligibles remain Medicaid beneficiaries, we believe that either states should remain obligated to cover excluded drugs for this population, or that Congress must strike the MMA provision prohibiting PDPs from covering these drug classes.

Enrollment

I know that enrollment is a concern we share with others on the panel who have testified. Medicaid will not be an option for coverage for dually eligible beneficiaries as of January 1, 2006. Though the vast majority of long term care residents will be within the Medicare Part D subsidized population, it is imperative that these beneficiaries are enrolled in a PDP by January 1, 2006. CMS has worked hard to address this issue and has provided continued assurance that these beneficiaries will be automatically enrolled into a PDP, and will of course have the option to enroll in their own choice of PDP, perhaps beginning as early as September of this year.

We applaud CMS' commitment to enrollment, but must emphasize that the nursing facility staff and long term care pharmacy must be involved for enrollment to be successful. The nursing facility can ensure that its residents are aware of the PDPs that include the long-term care pharmacy in its network of providers. In addition, nursing facilities and long-term care pharmacies must be notified somehow of the PDP in which the resident is enrolled so that all concerned caregivers understand which plan will be responsible for each resident.

Otherwise, the facility and pharmacy could be left not knowing what formulary and exceptions process to follow, or what entity to bill.

Transition to Part D Formularies

Many interested parties have expressed concern that moving medically complex patients from a list of well-tolerated and effective drugs to alternatives necessitated by adherence to a plan formulary will present serious challenges. We join in that concern. Imagine a common scenario in which nursing home patient is on 8 different drugs, and 3 of those drugs turn out to not be on the PDP's formulary beginning January 1, 2006. If the nursing facility switches all 3 of the patient's non-formulary drugs at once, and an adverse event occurs, it will be difficult if not impossible to determine which drug caused the adverse event. CMS has recognized this as a priority and has communicated that it will require plans to establish a transition process and that CMS will review this process for reasonableness. We strongly encourage CMS to issue very specific guidelines that PDPs must follow in this regard. LTCPA offers the following recommendations for Congress and the Administration that we believe will help minimize the inherent risk of such a massive transition by maintaining a consistent formulary for long term care residents:

- The preferred option is to require a robust formulary for residents of long term care facilities. This option would be most consistent with the Medicaid benefit currently enjoyed by nursing home residents.
- The next option is to create an exceptions process that allows for a pharmacist to override a formulary restriction, subject to retrospective review. This option assures that the patient, at least initially, gets the prescribed drug without delay. A pharmacist would be allowed to dispense a drug and be assured payment from the PDP until the retrospective review is conducted.

Conclusion

To summarize, LTCPA makes the following recommendations to CMS and to Congress as we work together to make the transition from Medicaid to Medicare Part D as smooth as possible for dually eligible beneficiaries.

1. Maintain access to excluded drugs either by requiring state coverage, or by striking the MMA provision excluding coverage of certain drug classes.

2. Facilitate enrollment of nursing home residents by notifying beneficiaries, nursing facilities and long term care pharmacies of the PDP in which beneficiaries are enrolled.

3. Create a clear standard for PDPs that is available to all interested parties with regard to nursing home residents that will assure access to medically necessary drugs, and will mitigate the risks of switching multiple medications at once.

In closing, we believe CMS is diligently working to assure that beneficiaries are not jeopardized during the transition to a Part D benefit and look forward to working closely

with Congress and CMS to identify and work through potential areas of concern. We thank the Committee for the opportunity to provide testimony for this important hearing and pledge our continued support in your efforts to assure a successful implementation of this program.