



**LTCPA**

Long Term Care  
Pharmacy Alliance

September 26, 2006

Cynthia Tudor, Ph.D.  
Director, Medicare Drug Benefit Group  
Center for Beneficiary Choices  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244

Dear Dr. Tudor:

**Re: Comments on Draft Medicare Part D Manual—Chapter 6**

The Long Term Care Pharmacy Alliance (LTCPA) represents the leading providers of comprehensive pharmacy services to residents of long-term care (LTC) facilities. Our members provide pharmacy services to over 60 percent of America's nursing home residents.

We appreciate the opportunity to comment on Chapter 6 of the Medicare Drug Benefit Manual draft distributed by CMS on September 12.

As you are aware, residents of LTC facilities are the most vulnerable members of the Medicare beneficiary population. The average nursing home resident is 84 years old, has nearly 8 different diagnoses and consumes approximately 9 concurrent medications. Further, more than half of all LTC residents have some level of cognitive impairment, and over two-thirds are dually eligible under Medicaid and Medicare.

Prior to January 2006 the majority of these residents received their prescription drug coverage under the State Medicaid programs. LTCPA supported maintaining this relationship when the MMA was being debated, primarily because of issues related to formulary coverage. Therefore, Part D issues related to formulary requirements are especially important to our industry.

Our comments will be organized according to the outline in the draft document:

**10.12 Multiple Source Drugs:** Under previous practice, the manner in which generic drugs were dispensed was fairly simple; if a generic alternative existed it

would be dispensed. Some states have substitution laws that are mandatory (substitution must take place) while others are permissive (subject to patient acquiescence and pharmacist professional judgment). Newly-devised arrangements between drug plans and manufacturers have complicated the process. Some plans have mandated that the brand be dispensed in lieu of the generic since the negotiated price for the brand is more favorable, at least during the initial 6 months of exclusivity of the first generic.

While we understand the economic argument for making this policy, CMS has not anticipated the extent to which this policy is, or is not, consistent with state substitution laws. For example, some states require that a generic drug be dispensed. In cases where ambiguity exists, CMS should clarify what standard is to be followed.

**Recommendation:** CMS should provide direction as to the need to observe State drug substitution laws when they may appear to conflict with plan requirements.

**10.4 Extemporaneous Compounds:** Although we understand the reason CMS believes it can only cover the portion of a compound that includes a Part D covered drug, we are uncertain of the practical implications of issuing a claim for such a compound without running afoul of other regulations (e.g., false claim act). We would appreciate more clarity around this process.

**Recommendation:** CMS should clarify and illustrate the process for the correct submission of claims for compounded drugs when not all ingredients are covered under the Part D benefit.

**10.5 Medical Supplies Associated with the Injection of Insulin:** CMS has issued guidance in 2006 that stipulates that plans must provide coverage of needle safety devices in institutional settings. We believe that policy should be included in this section.

**Recommendation:** CMS should cover the requirement for the coverage of needle safety devices in section 10.5.

**20.2.2 Plan Due Diligence in Prior Authorization of Part B vs. Part D Coverage Determination:** The Part B/ Part D status of drugs utilized in nursing homes has been a continuing source of confusion between LTC pharmacies and drug plans. While the ideal solution would be to declare all non-Part A drugs, with the exception of infusion drugs, dispensed to LTC residents to be covered under Part D, we recognize that CMS may not feel it has the authority to make that determination. However, since nebulizer drugs are never covered under Part B for residents of nursing homes, we believe CMS could include a provision in the manual declaring that all claims for nebulizer drugs, where the

location code on the claim form indicates the drug is being dispensed in an LTC facility, be considered by the plan to be covered by Part D.

Although we appreciate the efforts CMS has made to attempt to facilitate proper identification of non-Part B drugs, we point out that the CMS approach requires the prescriber to make a notation on the prescription. Since orders for LTC residents are not generally transmitted on a prescription, but rather a physician's order, this solution has not generally been adopted in the LTC setting.

**Recommendation:** We believe CMS should require plans to accept Part D claims for nebulizer drugs for residents whose claim form demonstrates that they reside in an LTC facility.

**20.4 Application of General Exclusion Provisions:** CMS notes in the draft that Part D vaccines may only be excluded when their administration is not reasonable and necessary for the prevention of illness. This will be the overwhelming majority of cases in the nursing home environment. Requiring a prior authorization or tiering in this environment is inappropriate.

**Recommendation:** Require plans to cover Part D vaccines in nursing homes without requiring prior authorization or tiering.

## **Formulary Requirements**

### **30. 1.1 Pharmacy and Therapeutics Committee Membership:**

The LTCPA has commented in earlier formulary documents, and reiterates in this document, that we believe each P&T Committee should have at least one physician member certified as a Certified Medical Director. Further, we believe, because of the special expertise involved, each plan should have a pharmacist that has special certification in geriatric pharmacy, such as that offered through the Commission for Certification in Geriatric Pharmacy.

**Recommendation:** Require each plan P&T Committee to have at least one certified medical director and a certified geriatric pharmacist. This will provide the special expertise required to review the appropriateness of the formulary for residents of LTC facilities.

**30.1.4 P&T Meeting Administration:** Given the importance of the construction and maintenance of the plan formulary to Medicare beneficiaries in general and to residents of LTC facilities in particular, we believe it is important for the minutes of each meeting of the P&T committee to be public documents.

**Recommendation:** We encourage CMS to require plans to make minutes of meetings of their P&T committee available for public review.

**30.1.5 Formulary Management:** CMS proposes that the P&T committees be required to establish and document procedures to assure appropriate drug review and inclusion. This is a very important consideration, which the LTCPA heartily endorses. However, we believe CMS should require this information to be easily accessible on the plan web site.

**Recommendation:** Require the P&T committees to publish, on their web site, the procedures by which formulary determinations are made.

### **30.2.3 Formulary Benefit Management Tools; Long-Term Care**

**Accessibility:** CMS captures the importance of requiring plans to include dosage forms commonly used in LTC facilities. Our early experience in the implementation of the benefit demonstrated that plans had little experience in managing benefits for institutionalized beneficiaries. Several had not included unit-dose NDCs on their payment files and frequently needed to update their list of payable drugs to accommodate this need.

**Recommendation:** We believe CMS should maintain this language without significant edits.

**30.2.5 Six Classes of Clinical Concern:** LTCPA believes CMS has taken the prudent approach in requiring the plans to not implement prior authorization or step therapy requirements for enrollees currently taking a referenced drug. If the plan cannot determine at the point of sale that an enrollee is not currently taking a drug, plans should treat enrollees as currently taking the drug. This is an important beneficiary protection.

**30.2.7 Formulary Performance and Content Review:** CMS intends to review based on the methodology outlined in the draft document. While much of this content is very appropriate, we stress that CMS needs to review formularies specific to their potential impact on beneficiaries in institutional settings. In this case, it is appropriate for CMS to solicit review guidance from specialty organizations such as the American Society of Consultant Pharmacists and the American Medical Directors Association.

CMS also suggests that it doesn't intend to require inclusion of drugs on formularies when the drugs in question are covered primarily under Part B. In this case, we encourage CMS to consider the impact on LTC residents, since coverage rules vary depending on place of service.

**Recommendation:** Solicit professional guidance from long-term care specialists in reviewing plan formulary submissions in order to determine the potential discriminatory impact on residents of nursing homes.

**30.4 Transition: General Observations:** The unwillingness of many plans to implement CMS guidance with respect to transitional coverage was among the biggest obstacles faced by LTC pharmacy during the implementation of the drug benefit in 2006. Requests for transitional coverage were routinely denied and overrides of denials were difficult to obtain. We, like CMS, believe that an appropriate transition policy, rigorously enforced, is essential to providing effective access in the LTC environment.

**30.4.1.3 Transition Timeframes:** Although CMS has indicated that it expects plans to provide a temporary supply any time during the first 90 days of a beneficiary's enrollment in a plan, there is no mention of extending this time period for LTC residents. Since LTC residents may be required to change several drugs to accommodate the plan formulary, and since not all these drugs can be changed simultaneously, we believe it is appropriate to request a longer transition period for resident of LTC facilities.

**Recommendation:** Require plans to provide a 180-day transition period for residents of LTC facilities.

**30.4.1.4 Edits for Transition Fills:** CMS lays out the requirements for dealing with dose-optimization edits. This is an important issue worth a brief discussion. While we understand the economic basis for implementing dose optimization, plans must understand that drugs metabolize very differently in the very old. Physicians typically use smaller doses, dosed more frequently, in order to manage potential adverse reactions.

Further, CMS discusses the need to notify the beneficiary if any edits are overridden at the point of sale only during the transition, the beneficiary needs to be notified in order to arrange either a modification of the prescription or to arrange for a medical exception request. In the LTC environment, this notice often has little meaning for the beneficiary. We believe it is critically important for plans to notify either the facility nursing staff or pharmacy when this occurs so that an appropriate action can be initiated to either seek a change in the prescription or to initiate a medical exception request.

**Recommendation:** Require plans to notify pharmacies of temporary transitional coverage in addition to the beneficiary for LTC residents.

**30.4.1.6 Transition Notices:** We agree that beneficiaries need to be notified as quickly as possible about the temporary nature of their transitional supplies. However, while informing the beneficiary may be useful, it is far more important that the dispensing pharmacy be made aware that the supply is temporary in order to help manage the medical exceptions process or initiate a move toward a formulary alternative.

In addition, CMS should outline the process by which a beneficiary can advise either CMS or the PDP of a change of address from the one listed by the plan. Frequently, the address for the beneficiary is listed as the home address prior to the move to the facility. Therefore, several beneficiaries in LTC will not get the mail in a timely manner.

**Recommendation:** Include the pharmacy in the notification process and allow for a process by which a change of address can be implemented.

**30.4.1.7 Public Notice of Transition Process:** A frequent problem encountered in the early stages of implementation was that the plan did not abide by its published transition policy. In some cases the plan, when contacted by telephone, was not aware of the transition requirement. CMS should require plans to post their transition policies, for both retail and LTC, in a prominent place on their web sites.

**Recommendation:** Require plans to post transition policies prominently on their web sites and provide a plan contact to resolve differences between plan implementation and their published information.

**30.4.3 Current Enrollee Transitions:** We strongly support the requirement that plans be required to implement transition policies for beneficiaries who experience a level of care change (e.g., entering a nursing home from the community). However, we believe CMS, in the final document should go beyond encouragement and require plans to have level-of-care changes included in the list of areas where transition exceptions are to be provided,

CMS also notes the need to allow overrides of the “early refill” edits that are common among nursing home residents. We support the CMS draft language in this section.

**Recommendation:** Level-of-care changes should be covered under the mandatory transition policies for Medicare beneficiaries.

**30.4.4 Emergency Supply for Current Enrollees:** CMS language in this section is entirely appropriate, especially as it relates to LTC residents. Assurance that the beneficiary will not be left without access to a necessary drug while the plan makes a coverage determination is critical to the continuity of care and we encourage CMS to retain the language in this section.

**30.4.6 Transition Process in the LTC Setting:** We support the draft language; however we encourage CMS to extend the mandatory transition period for residents of LTC facilities from 90 days to 180 days.

**Recommendation:** Extend the LTC transition period to 180 days

CMS has made significant improvements in this document over other Part D formulary documents and the agency is to be commended for its efforts. We do believe, however, that there remain several things CMS can do to optimize the quality of the formulary development and management process and we encourage the agency to take this opportunity to do so.

Sincerely,

Paul Baldwin  
Executive Director