



LTCPA

Long Term Care
Pharmacy Alliance

September 18, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

**Re: Comments on Medicare Prescription Drug Benefits Manual—
Draft of Chapter 5**

Dear Dr. McClellan:

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

We are pleased to have the opportunity to comment on the September 5 draft of Chapter 5 of the Medicare Prescription Drug Benefit Manual:

Section 20.6—Dispensing Fees:

Costs associated with special packaging and delivery for residents of non-LTC facilities: The LTCPCA endorses this policy and believes that extension of these services to residents of assisted living facilities serves an important function. However, it is not clear what criteria plans are required to use to evaluate an individual's need of special services.

Recommendation: We believe it would be helpful to beneficiaries, plans and pharmacies if CMS clarified that a physician's attestation that a beneficiary residing in a non-LTC setting requires specialized services serve as adequate proof that a beneficiary should receive these services.

Section 30.4—Pharmacy Waiver/Reduction of Cost-Sharing and Applicability toward TrOOP: Given the experience in plan recognition of appropriate cost sharing levels for institutionalized dual eligibles in 2006, we would like to suggest that CMS clarify that the failure to collect cost sharing from individuals improperly determined to be subject to such cost sharing not be determined to have had this cost sharing waived. Further, as plans reconcile cost sharing as a result of retroactive cost sharing determinations, CMS should instruct plans that the cost sharing adjustments for long-term care residents should be paid to the responsible long-term care pharmacy and not to the beneficiary.

Recommendation: CMS should take this opportunity, in this section or others, to clarify that dual-eligible cost sharing adjustments for institutionalized beneficiaries be reconciled with the dispensing pharmacy, rather than with the beneficiary.

Section 50—Access to Covered Part D Drugs: CMS proposes that sponsors notify CMS of any substantive change in their pharmacy networks that may impact their ability to maintain a network. However, this standard is insufficient, since it is up to the plan sponsor to determine what constitutes a substantive change. In fact, in the long-term care environment, the loss of a single pharmacy serving 10,000 beds could easily threaten the network integrity of a plan and render it unresponsive to the convenient access standard.

Recommendation: CMS should require plans, annually, to submit long-term care pharmacy network information, including service capacity, to CMS for a review of convenient access compliance.

Section 50.5—Long-Term Care (LTC) Pharmacy Access: This section tells plan sponsors that they must “offer” standard contracts to all LTC pharmacies in the region. The clear intention of the MMA was that network contract relationships would result from voluntary negotiation between plan sponsors and the pharmacies. If a sponsor can fulfill its obligation by simply offering a standard contract the purpose of the statutory language is not met. This, along with other provisions outlined below, serves to discourage plans from negotiating with pharmacies in good faith.

Section 50.5.1—Convenient Access to LTC Pharmacies: CMS states, in this section, that plans may not rely on SEPs to meet the convenient access standard. However, in the final rule, CMS notes that the rationale for providing an SEP for institutionalized beneficiaries includes situations in which the LTC pharmacy serving the facility is not a network member of

the plan in which the beneficiary is enrolled. Also, it is not clear how reliance on the SEP benefits the plan sponsor. If the beneficiary can use her SEP to obtain access to a plan that includes the pharmacy serving the facility in place of the plan in which she is currently enrolled that would seem to provide a benefit to the beneficiary, not the plan.

The process CMS describes for vetting the LTC pharmacy network is, as previously noted, deficient in that it does not allow for a determination of network adequacy. For example, if a plan has 10 pharmacies in network, with each pharmacy having an average capacity to serve 500 beds, it would not be as robust as a network with 7 pharmacies, each capable of serving 10,000 residents. The analysis must include some measure of pharmacy capacity in order to be meaningful.

Finally, CMS proposes that the remedy for not having an adequate number of long-term care network pharmacies is for the nursing facility to allow access by a network pharmacy. As you are aware, nursing facilities generally contract with individual pharmacies as a matter of safety and quality. A single point of responsibility helps the LTC facility control quality and provides a measure of reproducibility in operations. Short-circuiting this practice serves only to provide additional negotiating power to the plan sponsor, at the expense of patient care.

Recommendation: Since the majority of residents served by LTC pharmacies are Part D beneficiaries, pharmacies have tremendous incentives to negotiate fairly with plan sponsors. CMS should modify this section to require an annual analysis of LTC pharmacy network adequacy and revise the policy in a manner that encourages fruitful negotiations between plan sponsors and LTC pharmacies.

Section 50.5.3 Other LTC Contracting Terms and Conditions and Uniformity of Benefits: Although CMS begins this section with a passing reference to non-interference in negotiations between plan sponsors and pharmacies, it continues the narrative by attempting to interfere in direct opposition to the clear non-interference language of the MMA.

CMS refers to contract provisions that explicitly conflict with statutory and regulatory requirements, and goes further to warn that these provisions may be harmful to beneficiaries. In Example 1, CMS suggests that providing extended beneficiary transition periods conflicts with the “uniform benefit” requirement of the Act. However, the provision to which CMS refers relates to the bidding model for plan submission, not to this

example. CMS also suggests that these voluntary agreements may result in increased program costs. However, these costs should be reflected in the plan bid, submitted by the plans for CMS approval. Suggesting that these provisions may adversely affect program costs would appear to be somewhat disingenuous.

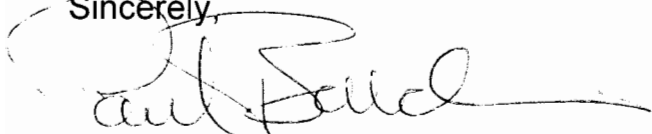
In Example 2, CMS takes issue with waiver of prior authorization requirements, suggesting that this conflicts with the requirement for cost-effective utilization management programs. Again, since the plans' utilization management program is explained to CMS in its annual contracting documents, it would seem that CMS could take issue with the plan's application, rather than with the agreement to suspend these edits to residents of LTC facilities. Again, CMS misstates the uniform benefits provisions of the Act in reference to these practices.

Recommendation: CMS should withdraw the portion of Section 50.5.1 that references special protection provisions for LTC residents that result from voluntary agreements between LTC pharmacies and plan sponsors. The justification that this practice conflicts with provisions of the statute and regulations is false and misleading.

Section 50.8.1—Any Willing Pharmacy Requirement: CMS notes in this section that the determination as to whether a pharmacy has been offered an opportunity to participate in the network is fact-specific question that should be left to the parties. However, the statute does not make a distinction or restrict the period in which the any willing provider provision is in force.

Recommendation: CMS should not limit the time period within which a pharmacy may be permitted to exercise the any willing provider provision of the statute in determining accepting an agreement to participate in the plan network.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Baldwin", written over a faint circular stamp or watermark.

Paul Baldwin
Executive Director