

Long Term Care Guidance

March 16, 2005

This document is provided as guidance to assist Medicare Part D plans in formulating policies for the implementation of CMS requirements regarding pharmacies providing products and services to Long Term Care (LTC) facilities. This guidance is organized to address pharmacy performance and service criteria, convenient access standards, formulary considerations, and other beneficiary protections that Part D plans should consider as they develop their prescription drug benefit offerings for institutionalized LTC Medicare beneficiaries. As defined by the final regulation for the Medicare drug benefit, LTC facilities include skilled nursing facilities as defined under Title XVIII of the Social Security Act (the Act), or a medical institution or nursing facility for which Medicaid makes payment throughout a month as defined under Title XIX of the Act.

I. LTC Pharmacy Performance and Service Criteria

Part D plans will be required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting) and any other standard terms and conditions established by the plan for its network pharmacies.

CMS has developed the following minimum performance and service criteria for pharmacies providing LTC service, based on widely used best practices in the market today and with input from various CMS divisions and external stakeholders. We expect that these performance and service criteria will be incorporated into an addendum to a Plan's standard network contract for those pharmacies that would like to be designated LTC network pharmacies.

Performance and Service Criteria for Network LTC pharmacies (NLTCPs)

1. *Comprehensive Inventory and Inventory Capacity* -- NLTCPs must provide a comprehensive inventory of Plan formulary drugs commonly used in the long term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by federal and state law for controlled substances. This is not to be interpreted that the pharmacy will have inventory or security measures outside of the normal business setting.
2. *Pharmacy Operations and Prescription Orders* -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering

and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.

3. *Special Packaging* -- NLTCPs must have the capacity to provide specific drugs in Unit of Use Packaging, Bingo Cards, Cassettes, Unit Dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.
4. *IV Medications* -- NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.
5. *Compounding /Alternative Forms of Drug Composition* -- NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.
6. *Pharmacist On-call Service* -- NLTCP must provide on-call, 24 hours a day, 7 days a week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.
7. *Delivery Service* -- NLTCP must provide for delivery of medications to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCP must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine "dispensing".
8. *Emergency Boxes* -- NLTCPs must provide "emergency" supply of medications as required by the facility in compliance with State requirements.

9. *Emergency Log Books* -- NLTCP must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident's medication order and drug administration.
10. *Miscellaneous Reports, Forms and Prescription Ordering Supplies* -- NLTCP must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.

The CMS performance and service criteria are not intended to be exclusive or exhaustive. Rather, they are intended to be minimum requirements for becoming a network LTC pharmacy. While payment terms for LTC pharmaceutical and dispensing services are subject to negotiations between the Plan and its network LTC pharmacies, we note that payment to LTC pharmacies under Part D may only cover drug ingredient costs and dispensing fees as defined in the final regulations at 42 CFR § 423.100. The elements above, not including the cost of drugs, would all be legitimate costs to reflect in the dispensing fee. Specialized services provided in the administration of drugs after they are dispensed and delivered from the LTC pharmacy are specifically not covered by the Part D benefit.

II. Convenient Access

As stated earlier, Part D plans will be required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting) and any other standard terms and conditions established by the plan for its network pharmacies. Once a Part D plan has negotiated an agreement with an LTC pharmacy, the LTC pharmacy becomes a network provider and is eligible to serve the plan's enrollees who reside in LTC facilities.

We expect that each LTC facility will select one or possibly more than one eligible NLTCP to provide Medicare drug benefits to its residents. A facility can continue to contract exclusively if it chooses, however, the features to promote competition described above will likely give each facility access to a broader range of potential LTC pharmacies than is the case today. CMS will continue to assist LTC facilities in making informed choices for LTC pharmacy services and finding the best fit for their operational needs. On a voluntary basis, pharmacies that are interested in participating in LTC network contracting under the CMS stated performance and service criteria may be listed on the CMS website. CMS expects to provide pricing and access information to beneficiaries and their representatives as soon as it is available.

Part D plans must demonstrate that they have a network of participating LTC pharmacies that provide convenient access to LTC pharmacies for LTC residents who are Part D enrollees. There

are essentially 4 action steps that a Part D applicant plan sponsor must complete in order to assure CMS that it will provide convenient access for its enrollees to NLTCPs. They include:

1. *Workplan* – An applicant must provide a work plan in its March 23, 2005 application that describes its strategic approach and milestones toward the completion of LTC contracting by July 15, 2005. Part D applicants must work aggressively to complete their LTC pharmacy contracting so that they can provide convenient access to NLTCPs for their enrollees, and they will also need as much time as CMS can reasonably allow them in 2005 to do this. With that in mind, CMS will evaluate and provide feedback if necessary on this work plan. We will look for elements that concern:
 - a. Identifying NLTCPs and conducting outreach;
 - b. Offering the contract along with arrangements for discussion / negotiation, and approximate timeframe for coming to closure;
 - c. Tracking progress; and
 - d. Assessing progress to modify approach as necessary

NOTE: CMS provided in February 2005, a file of all the LTC facilities, their locations and bed capacity to assist plans in their strategic planning and contract negotiations with LTC pharmacies.

2. *Performance and Service Criteria* – An applicant must ensure that its NLTCP contracts include the performance and service criteria drafted by CMS and presented in Section I of this paper. When the applications arrive, CMS will examine the plan's NLTCP contracts to determine if such criteria is included. These criteria are essential to providing appropriate pharmacy service to institutionalized beneficiaries.
3. *Contract With Any Willing Provider* – An applicant must attest that it will provide contracts to any willing pharmacy that meets the standard terms and conditions of the network contract and the performance and service criteria stated in Section I of this guidance.
4. *Convenient Access Requirements* – An applicant must attest that it will ensure that all of its future Part D enrollees who are institutionalized can routinely receive their Part D benefits through the plan's network of pharmacies. In other words, the plan may not rely on the out-of-network benefit to meet the convenient access standard. We would expect that the plan would seek to enter into a network contract with a pharmacy serving the LTC facility as soon as practicable.

In addition, by August 1, 2005, the plan must provide a list of NLTCPs. As part of this listing, the plan must describe how these pharmacies will adequately provide the Part D benefit to all the plan's future enrollees who are institutionalized.

In performance years CMS will look at enrollment and disenrollment rates for institutionalized beneficiaries by plan, as well as complaints data and utilization data for patterns that suggest inadequate access. We will also use MDS data and enrollment files to identify institutionalized beneficiaries and link them to LTC pharmacies in a plan's

network to determine whether there is enough LTC pharmacy network capacity by plan to assure the plan's institutionalized enrollees have access to their Part D benefit.

III. Formulary

Plans must accommodate within a single formulary structure the needs of long term care residents by providing coverage for all medically necessary medications at all levels of care. The use of a special long term care formulary violates the requirement that plans offer a uniform benefit because LTC beneficiaries may not have access to the same drugs available to other beneficiaries, or vice versa. Coverage of all medically necessary medications may include, but is not limited to, alternative dosage forms such as liquids that can be administered through feeding tubes, intravenous medications, or intramuscular injections. Access to necessary medications for long term care residents may be provided through formulary inclusion, utilization management tools, or exceptions processes. Appropriate access to long term care medications should be provided in such a way as to not substantially discourage enrollment by certain part D eligible individuals.

Part D plans are required to establish an appropriate transition process for new enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary. Elements of what constitutes an acceptable transition process are described in separate guidance.

CMS recommends that Part D plans develop and implement a policy and procedures that ensure the beneficiary's drug history is known to the Part D plan when there has been a change in the beneficiary's LTC pharmacy provider.

IV. Exceptions and Appeals

In the final rule, we streamline the grievance, coverage determination, and appeals processes, which will ensure that long term care residents receive quick determinations regarding the medications they need. As part of these requirements, we expect Part D plan sponsors to consider the special circumstances that are applicable to enrollees who are residents of LTC facilities when making medical necessity coverage determinations based on an enrollee's health condition. These special circumstances may include, but are not limited to, the interrelationship between the LTC facility, the attending physician, and the LTC pharmacy, as well as applicable laws and regulations governing the operation of, and care furnished by, an LTC facility.

Each Part D plan sponsor must have procedures in place for addressing the needs of Part D enrollees who reside in LTC facilities, with particular attention to situations where there is a disparity between the Part D requirements and the Medicare Conditions of Participation (COP) for LTC facilities. Part D sponsors must clearly articulate the financial responsibility of the plan in such situations. In circumstances where current enrollees have an immediate need for a non-formulary Part D drug, we recommend that plan sponsors consider a one-time temporary or emergency supply process as a method of ensuring that such enrollees do not have a coverage gap while processing an exception or appeal request.

Since an enrollee in a long term care (LTC) facility may have cognitive, mental or physical impairments that may preclude the enrollee's ability to participate in the coverage determination and appeals processes, it is important to note that the regulations allow an appointed representative to act on the enrollee's behalf. An appointed representative can be any individual (or entity) chosen by an enrollee or authorized under State or other applicable law to act on his or her behalf in obtaining a coverage determination or with any level of the appeals process. For instance, an enrollee may choose an agent of the LTC facility, such as a registered nurse or case manager, to act as his or her appointed representative.