Q: To what extent should Part D sponsors consider adopting contracting terms and conditions in their long-term care (LTC) pharmacy contracts that go beyond the performance and service criteria in CMS's March 2005 LTC Guidance?

A: Part D sponsors must offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting certain performance and service criteria and any other standard terms and conditions established by the plan for its pharmacy network. Our March 2005 LTC Guidance delineates these ten performance and service criteria.

Outside of the minimum performance and service criteria, Part D sponsors and pharmacies may propose a number of contracting terms and conditions. With rare exceptions, CMS does not generally involve itself in determining whether standard contracting terms and condition are "reasonable and relevant," since these are fact-specific questions that are best left between negotiating parties. Thus, for example, we generally do not opine on contracting terms and conditions associated with compensation, billing, and business practices provided such terms and conditions are consistent with explicit Part D statutory and regulatory requirements.

It has come to CMS's attention that certain other terms and conditions are being proposed by LTC pharmacies in their negotiations with Part D sponsors as additional beneficiary protections. Such additional terms and conditions may be problematic because they explicitly conflict with statutory and/or regulatory requirements for the Part D program. Some of these proposed contracting terms and conditions not only conflict with CMS rules, but could even be harmful to beneficiaries, as described below. Following are several examples of such terms and conditions.

- Requirements for a longer transition period than the plan has provided for in its transition process submission to CMS. In 2006, all plans offer a temporary supply of non-formulary drugs of at least 60 days in the LTC setting. Some pharmacies may wish to extend that transition period to up to 180 days. However, given uniform benefits requirements under the statute and our regulations, plans cannot agree to a differential transition policy for some of its enrollees. Transition policies must be applied uniformly to all enrollees. Moreover, extending a transition period for some plan enrollees has cost implications for plans that may ultimately drive up costs to both beneficiaries and the Medicare program.

- Waivers of prior authorization or other utilization management edits for LTC facility residents. Plans must determine whether a particular drug is a Part D drug and, in addition, must establish cost-effect utilization management programs. Waivers of prior authorization management edits or other utilization management edits for some plan enrollees run counter to these program requirements. In addition, given uniform benefits

requirements under the statute and our regulations, plans cannot apply prior authorization or other utilization management edits differentially to a subset of their enrollment.

- Waivers of certain drug utilization review (DUR) requirements for LTC facility residents. Plans must optimize drug regimens, which requires an up-front and thorough review of enrollee drug files in order to ensure their safety (e.g., by preventing drug-drug interactions). In addition – and as stated above – uniform benefits requirements under the statute and our regulations mean that plans cannot apply DUR edits differentially to a subset of their enrollees. All plan benefits must be applied uniformly to all enrollees.

While the examples above are not exhaustive – and others may exist with similar effects – our intent is to clarify that, ultimately, all contracting terms and conditions must comply with Part D rules and requirements in order to protect the interests of beneficiaries and safeguard the integrity of the Medicare prescription drug program.

Clarification

On May 19, 2006, we posted the preceding question and answer (Q&A) to plans to provide guidance regarding certain LTC contracting terms and conditions that may be problematic because they explicitly conflict with statutory and/or regulatory requirements for the Part D program. Since we posted the Q&A, we have received many requests for further clarification and explanation regarding how plans should interpret this provision. We offer the following as additional guidance.

Plans may be out of compliance with uniform benefits requirements to the extent that they agree to particular contracting terms and conditions that have the net result of creating a non-uniform benefit for plan enrollees residing in LTC facilities serviced by network LTC pharmacies whose contracts with plans may not include these same provisions. Plan benefits must also be applied uniformly across all enrollees (both those who reside in the community and those residing in LTC facilities) when there is no justification for applying different rules to enrollees residing in LTC facilities. However, CMS recognizes that there are instances in which it is appropriate or legally required under our Part D guidance for plans to establish standards that differentiate between enrollees residing in LTC facilities and ambulatory patients.

For example, it is perfectly acceptable for plans to adopt alternative standards applicable only in the LTC setting when clinically justified, legally required, or otherwise justified based on characteristics unique to beneficiaries residing in LTC facilities, such as extended transition periods for enrollees residing in LTC facilities or prior authorization or other utilization management requirements (for

example, those that distinguish between Part B and Part D covered drugs given that some drugs covered for use in the home under Part B are not covered by Part B in LTC settings). However, plans cannot agree to differential benefits which would result in a non-uniform benefit among enrollees in LTC facilities, such as an extended transition period, certain utilization management edits, or different drug utilization review protocols that are limited to those LTC enrollees who obtain their Part D drugs from a specific LTC pharmacy. Plan benefits must be applied uniformly to all similarly situated enrollees, meaning that all enrollees residing in LTC facilities must be subject to the same rules.