requirements of 42 CFR 423.505(i) regarding relationships with pharmacies or other providers, related entities, contractors, subcontractors, and first tier and downstream entities.

50.5 - Long-Term Care (LTC) Pharmacy Access

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

As described in section 50.5.1, Part D sponsors must demonstrate that their contracted pharmacy network provides convenient access to LTC pharmacies for enrollees who reside in an LTC facility. Part D sponsors must offer standard LTC pharmacy network contracts to all LTC pharmacies operating in their service area that request such contracts. These standard contracting terms and conditions must include the performance and service criteria for LTC pharmacies specified in section 50.5.2 below.

50.5.1 - Convenient Access to LTC Pharmacies

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors 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 the performance and service criteria in section 50.5.2 (and relevant State laws governing the practice of pharmacy in the LTC setting), as well as any other standard terms and conditions established by the Part D sponsor for its network LTC pharmacies (NLTCPs). Once a Part D sponsor has negotiated an agreement with an LTC pharmacy, the LTC pharmacy becomes an NLTCP and is eligible to serve the sponsor's enrollees who reside in LTC facilities.

CMS expects 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 with a single LTC pharmacy 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 was the case before the implementation of the Part D benefit. An NLTCP that serves a particular LTC facility must provide the same services, as delineated in its contract with a Part D sponsor, to all of that sponsor's enrollees who reside in that LTC facility.

Part D sponsors may not rely on OON access to meet the LTC convenient access standard. All of a Part D sponsor's enrollees who reside in an LTC facility must be able to routinely receive their Part D benefits through the plan's network of LTC pharmacies in order for a Part D sponsor to be in compliance with CMS' LTC convenient access standard.

In addition, Part D sponsors may not rely upon beneficiary special enrollment periods (SEPs) to circumvent the LTC convenient access requirement. Although individuals moving into, residing in, or moving out of an institution are entitled to an SEP, and dually eligible individuals are entitled to an ongoing SEP for as long as they are eligible for Medicaid benefits, it is not acceptable for Part D sponsors to rely on this beneficiary option in lieu of contracting with a sufficient number of pharmacies to ensure that a beneficiary can remain in his or her current plan for as long he or she resides in an LTC facility in the Part D sponsor's service area. Ultimately, all beneficiaries – including those who reside in LTC facilities – should have available to them the full array of plans operating in their area.

Part D sponsors must demonstrate that they have a network of contracted LTC pharmacies that provide convenient access to LTC pharmacies for enrollees who reside in LTC facilities. In order to demonstrate convenient access to LTC pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions, a list of all contracted LTC pharmacies. In addition, Part D sponsors are required to submit an updated list of all contracted LTC pharmacies as part of the annual Part D reporting requirements developed in accordance with 42 CFR 423.514 and OMB 0938-0992.

CMS will evaluate whether Part D sponsors provide convenient access to LTC pharmacies through analysis of these submissions. Specifically, CMS will use these lists to verify that Part D sponsors have contracts in place with LTC pharmacies that serve the LTC facilities where their beneficiaries reside. Part D sponsors should have processes in place to ensure beneficiaries residing in LTC facilities are being served by an LTC network pharmacy.

CMS expects LTC pharmacy contracting activity will be ongoing as Part D sponsors continue to identify LTC facilities and LTC pharmacies, and as they examine their auto-enrollment assignments and incoming enrollments. To the extent that a beneficiary is enrolled in a Part D sponsor's plan that does not have a contract with an LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a Part D sponsor to take is to contract with the facility's contracted LTC pharmacy or – if that pharmacy will not sign a contract – with another LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary.

50.5.2 - Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCPs)

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

In order to participate in Part D sponsor LTC pharmacy networks, a pharmacy must be capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting), as well as any other standard terms and conditions established by the Part D sponsor for its network pharmacies. The following minimum performance and service criteria for pharmacies providing LTC services are based on widely used best practices in the market. These performance and service criteria must be incorporated into an addendum to a Part D sponsor's standard network contract for those pharmacies that would like to be designated 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 as requiring the pharmacy to 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. NLTCPs must be responsible for return for destruction 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 units 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** – NLTCPs must provide on-call, 24-hour-per-day/7-day-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** – NLTCPs must provide for delivery of medications to the LTC facility up to 7 days each week (up to 3 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, NLTCPs 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** – NLTCPs 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** – NLTCPs 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.

To qualify as an LTC pharmacy for a Part D sponsor's LTC pharmacy network, a pharmacy must currently have the capacity – either by itself or through subcontracts with other entities – to meet all these performance and service criteria, even if an LTC facility that pharmacy serves does not need a particular service subsumed under those performance and service criteria. Pharmacies subcontracting with other entities to meet the performance and service criteria must ensure that they comply with all relevant Part D requirements, including all performance and service criteria for the provision of LTC pharmacy services. However, it will ultimately be up to LTC facilities and their contracted LTC pharmacy(ies) to determine which of these specific items or services a nursing facility needs. In other words, an LTC pharmacy must be capable of meeting all the aforementioned performance and service criteria at the time it contracts with a Part D sponsor, but it will not be required to provide all those services to LTC facilities if those facilities do not have a need for those certain services.

These performance and service criteria are not intended to be exclusive or exhaustive. Rather, they are intended to be minimum requirements for becoming an NLTCP. While payment terms for LTC pharmaceutical and dispensing services are subject to negotiations between the Part D sponsor and its NLTCPs, CMS notes that payment to LTC pharmacies under Part D may only cover drug ingredient costs and dispensing fees as defined in section 20.6. 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.

50.5.3 - Other LTC Contracting Terms and Conditions and Uniformity of Benefits

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

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 conditions are "reasonable and relevant," since these are fact-specific questions that are best left between negotiating parties. Thus, for example, CMS generally does 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.

LTC pharmacies may propose other terms and conditions 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. Following are several examples of such terms and conditions. While these examples are not exhaustive – and others may exist with similar effects – 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.

> **Example 1**: Requirements for a longer transition period than the plan has provided for in its transition process submission to CMS.
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> As described in section 30.4.4.2 of chapter 6, all plans must offer a temporary supply of non-formulary drugs of at least 31 days with multiple refills during a 90-day transition period 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 CMS' regulations, plans cannot agree to a differential transition policy for some of their LTC enrollees. Transition policies must be applied uniformly to all similarly situated 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.
>
> **Example 2**: 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 CMS' regulations, plans cannot apply prior authorization or other utilization management edits differentially to a subset of their LTC enrollment.
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> **Example 3**: Waivers of certain 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 CMS' regulations mean that plans cannot apply DUR edits differentially to a subset of their LTC enrollees. All plan benefits must be applied uniformly to all similarly situated enrollees.

Part D sponsors 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 Part D sponsors 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, there are instances in which it is appropriate or legally required under CMS' Part D guidance for Part D sponsors to establish standards that differentiate between enrollees residing in LTC facilities and ambulatory patients.

For example, it is perfectly acceptable for Part D sponsors 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, Part D sponsors 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.

50.5.4 - Access to LTC Pharmacies for Enrollees Residing in Institutions for Mental Disease (IMDs), Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), and LTC Hospitals

(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

To the extent that an ICF/MR or IMD designated by a State as an institution has, as an inpatient, any institutionalized individuals – which means any full benefit dual eligible individual for whom payment is made under Medicaid throughout a month, as provided in section 1902(q)(1)(B) of the Act – it falls within CMS' regulatory definition of the term "LTC facility." There exists a statutory Federal financial participation exclusion under Medicaid affecting residents of IMDs between the ages of 22 and 64. However, the IMD exception to the definition of "medical assistance" under section 1902(q)(1)(B) of the Act does not apply to individuals who are age 65 and older. Thus, all elderly full-benefit dual eligibles who are inpatients in an IMD designated by the State as an institution for a full month are considered institutionalized individuals for that month. Long-term care hospitals are also medical institutions and are considered LTC facilities if they have as inpatients any institutionalized individuals.

CMS also clarifies that as medical institutions, hospitals (including long-term care hospitals) that receive payments under section 1902(q)(1)(B) of the Act can meet the definition of an LTC facility. As discussed in section 20.2.1 of chapter 6, to the extent that inpatients in these hospitals exhaust their Part A inpatient days benefit, and payment is no longer available under Part A or Part B for drugs that would otherwise meet the definition of a Part D drug, such drugs are Part D drugs.

This means that Part D sponsors must ensure that they provide convenient access to network LTC pharmacies for:

- All of their enrollees residing in a long-term care hospital or in an IMD or ICF/MR designated by the State as an institution, and in which any institutionalized individuals

reside (although living in an institution that does not meet the definition of an LTC facility does not preclude an individual from enrolling in Part D).

- All of their enrollees who are inpatients in a hospital that is a "medical institution" under 1902(q)(1)(B) of the Act – and therefore would meet the Part D definition of an LTC facility – and whose Part A benefits have been exhausted.

Part D sponsors will not be compliant with CMS' LTC convenient access standard if they do not provide access to covered Part D drugs via an LTC pharmacy in their network for all of their enrollees who reside in LTC facilities.

Many ICFs/MR, IMDs, and LTC hospitals utilize in-house pharmacies and, particularly in the case of ICFs/MR and IMDs, such pharmacies are State run and operated. In some States, licensing laws preclude facilities from obtaining prescription drugs and LTC services for their residents from anyone but the facility's in-house pharmacy. States may not be able to agree to certain standard clauses in some LTC standard contracts because of constitutional and legal restraints on States. Part D sponsors should be prepared to readily negotiate with States to address these issues. To the extent that Part D sponsor contracting efforts involve communication with State run and operated pharmacies, CMS encourages Part D sponsors to coordinate their efforts through a single point of contact at the State level. Refer to the following Web site for lists of State contacts for IMDs and ICFs/MR:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_PartDContacts.asp#TopOfPage

50.5.5 - Post-Consumption Billing

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS interprets the term "post-consumption" billing as billing that is performed after a drug is dispensed and consumed by an enrollee, usually at the end of the month or the beginning of the next month. While post-consumption billing is not typical in retail pharmacy, certain LTC pharmacies utilize post-consumption billing procedures. A significant advantage of this type of billing is reduction in waste because only those drugs actually consumed by an individual are billed. Post-consumption billing arrangements are permissible under the Part D program and should be accommodated by sponsors, assuming they are managed in a manner that is compatible with all other Part D requirements (i.e., for a formulary drug used for a medically accepted indication) and in a manner that provides for an accurate calculation of TrOOP expenditures (for example, via a single claim, Point-of-Sale transaction, HIPAA compliant format (i.e., *v.* NCPDP 5.1 *or v .D.0*)).

Network pharmacies are responsible for verifying that drugs dispensed to the beneficiary are covered under the beneficiary's Part D plan. Because network pharmacies utilizing post-consumption billing will not submit the first claim to a Part D plan until after the drug has been dispensed, the pharmacy must employ another mechanism for verifying coverage in advance of dispensing.

50.6 - I/T/U Pharmacy Access

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