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**AN OVERDUE NEED:**

**THE FEDERAL DEFINITION OF LONG TERM CARE  
PHARMACY**

*The need for and benefits of a legislative definition of LTC pharmacy*

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*Compiled by King & Spalding LLP on behalf of the Senior Care Pharmacy Coalition (SCPC)*

## **I. INTRODUCTION: The Growing Value of Long-Term Care Pharmacy**

Today there are more than 1.4 million Americans living in a long-term care (LTC) facility and nearly a million more reside in other types of residential community care facilities. As America's population ages over the next 25 years, a growing number of seniors will require LTC services and supports in an increasingly diverse array of settings – nursing facilities, assisted living facilities, continuing care retirement communities, residential care settings, outpatient settings and at home through home health and other home-and-community-based services. These patients suffer from multiple chronic health care conditions and rely on prescription medications to help manage their conditions and improve the quality of their lives. These patients rely on their continuing relationships with key health care providers across settings to receive appropriate care and services.

The specialized services and clinical oversight only independent LTC pharmacies provide necessarily will be required beyond the historic boundaries of a nursing home's walls. This patient population takes an average of eight prescription medications each day and takes 11 to 13 prescription medications each month. In the very near future, even greater coordination of care, particularly during care transitions, is essential to avoiding unnecessary care and treatment, including the risk of adverse medical and prescription medication events. Greater care management across settings and during care transitions increasingly will be crucial to controlling health care costs as well.

With a growing, dynamic healthcare marketplace rightly placing a premium on quality care, positive outcomes, reduced hospital readmissions and more efficient use of taxpayer dollars, independent LTC pharmacies are an increasingly significant 'value-added' component in the LTC continuum. In ongoing efforts to eliminate errors, continuously improve quality and consistently reduce causes, many LTC pharmacies also have invested heavily in pharmacy-based and remote dispensing technologies. These systems provide a variety of alerts and other information, which help the clinical staff nurse make informed, real time decisions – while still maintaining ownership, care, custody and control of both the equipment and the medications until a registered pharmacist receives a patient-specific prescription. Such technological advances will be essential in diversifying care settings for traditional LTC patients.

The value-added services LTC pharmacies provide also are the most efficient method of providing medications to LTC patients, regardless of setting. LTC pharmacies spread costs over multiple care settings at a fraction of the cost creating such pharmacies and providing related consultative services would cost if located at every facility and community-based care and treatment site. To facilitate this improved care, the federal government should streamline and standardize regulatory requirements imposed on LTC pharmacies. Unfortunately, that is not occurring, and LTC pharmacies are subject to differing and in some cases potentially conflicting regulations from a number of federal regulatory agencies with jurisdiction or authority over them.

The obvious next step demands that the federal government enact a statutory definition of LTC pharmacy that will compel consistency across the relevant regulatory agencies and better enable LTC pharmacies to follow geriatric and chronic care populations across settings. In doing so,

however, Congress must also address the rapidly diversifying LTC marketplace to assure that LTC pharmacies play an increasing role in care management for patients traditionally served in nursing homes and that also recognize the ways in which LTC pharmacies should operate in a future driven by diverse value-based purchasing models of health care delivery.

## **II. BACKGROUND**

For over five decades, long-term care pharmacy has played a crucial role in ensuring that residents of skilled nursing facilities (SNFs), nursing facilities (NFs) and other LTC settings receive appropriate medication therapy.<sup>1</sup> LTC pharmacies have played an essential role not only in providing timely and emergency dispensing of medication, but also in fulfilling key nursing facility obligations to perform drug regimen reviews and more recently medication therapy management. Over the decades, CMS has acknowledged the key role that LTC pharmacy fills in the LTC ecosystem, and specifically in providing medication services to nursing homes and their residents. Dating at least to the Nursing Home Reform Act of 1987, federal law and regulation have acknowledged that LTC pharmacies are the appropriate entities to provide required nursing facility medications and drug regimen review.

Over time, LTC pharmacy has grown to over five percent of the nation's prescription drug spend.<sup>2</sup> Yet, the sector's role in providing medications to LTC residents, and the essential services that LTC pharmacy provide for the nation's oldest and most frail patients, remain largely unknown in the federal policy sphere.

As described in detail below, in 1987, as part of comprehensive nursing home reform, Congress and CMS modernized the statutory and regulatory requirements for the provision of pharmacy services to nursing home residents. More current changes took place in 2003, when Congress enacted the Medicare Modernization Act (MMA), creating the Medicare prescription drug benefit (otherwise known as the Part D program). The enactment of Part D had a major effect on LTC pharmacy, shifting approximately 1 million "dual eligible" nursing home residents (those eligible for both Medicare and Medicaid) who had previously been receiving prescription medications under Medicaid into the Medicare program. Unfortunately, because Congress at the time did not clearly understand the role of LTC pharmacy, it did not define the term in statute but instead ordered CMS to study the role that LTC pharmacy played in the drug distribution process. This mandate resulted in the 2005 "Lewin" study,<sup>3</sup> and ultimately, in a very modest and

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<sup>1</sup> Both the statute and the regulations use "skilled nursing facilities" to refer to facilities qualified to provide care and services to Medicare beneficiaries and use the term "nursing facilities" to refer to facilities qualified to provide care and services to Medicaid beneficiaries. For purposes of this White Paper, the terms "nursing home" or "nursing facility" refers to skilled nursing facilities and nursing facilities, as well as facilities regulated under state law as nursing homes.

<sup>2</sup> See IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S. 2015* at 45 (April 2016), available at: <http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>; *see also* [http://becomeahealthmart.com/Websites/becomeapharmacy/images/Whitepaper-Becoming\\_a\\_Long-Term\\_Care\\_Pharmacy.pdf](http://becomeahealthmart.com/Websites/becomeapharmacy/images/Whitepaper-Becoming_a_Long-Term_Care_Pharmacy.pdf) (indicating average number of prescriptions per patient has increased from 9 in 2011 to 12 in 2015). *See also* <http://news.morningstar.com/articlenet/article.aspx?id=564139> for additional statistics related to anticipate trends in LTC pharmacy.

<sup>3</sup><https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/LewinGroup.pdf>. This report, which pre-dates implementation of the Part D program,

vague definition of “long term care pharmacy.” Over the last decade, however, the absence of a clear definition has resulted in a wide range of conflicting federal regulations affecting LTC pharmacy, particularly by Agencies other than CMS.<sup>4</sup>

Section III, below, sets out the various current and proposed federal regulatory definitions of LTC pharmacy, or federal regulations affecting LTC pharmacy. As is evident, the federal agencies are inconsistent in their application of the term or understanding of how (and where) LTC pharmacy operates. Following that analysis, Section IV addresses how the practice of LTC pharmacy may change in the future as the healthcare market transitions to a performance/value based reimbursement system. Section V then summarizes the state of the varying definitions and calls for development of a single definition that can be used across all federal agencies for consistent regulation and oversight of the sector today and into the future.

### **III. Federal Definitions of Long-Term Care Pharmacy**

Although the LTC pharmacy sector has existed for decades and provides approximately five percent of all prescription drugs dispensed in America today, there is no meaningful statutory definition of the term “long term care pharmacy” in federal law. As a result, a panoply of federal regulations across multiple regulatory agencies has been proposed, and in several cases finalized, regulations that define both LTC facilities and pharmacies inconsistently and which have created confusing and in some cases unreasonable and potentially irreconcilable obligations on LTC facilities and pharmacies.

Most significant is the Medicare definition the Center for Medicare and Medicaid Services (CMS) established for LTC pharmacies to be eligible to participate in Part D pharmacy networks. While the Part D regulations include a brief definition of LTC pharmacy, the Part D Manual contains a more extensive description of the different and unique functions that LTC pharmacies perform. These distinguish LTC pharmacy from retail and other types of pharmacy, and detail many of the specific services LTC pharmacies must provide, effectively outlining the many of the value-added services LTC pharmacies provide.

In addition, the CMS’ Medicare and Medicaid Requirements of Participation for nursing facilities augment the key elements that define a LTC pharmacy, including an extensive list of required pharmacy services each nursing facility must satisfy either directly or through contractual relationships with independent LTC pharmacies. In virtually all cases, nursing facilities satisfy these requirements through contracts with LTC pharmacies. In any case, however, the pharmacy services Requirements of Participation add further parameters to help define LTC pharmacies.

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describes a LTC environment that no longer exists, due in large part to the shift in payment for dual eligibles from Medicaid to Medicare and ultimately proved to be of very limited utility in constructing an appropriate regulatory regime for LTC pharmacies. For a more recent treatment of the state of LTC pharmacy, *see* Avalere Health, Long-Term Care Pharmacies: The Evolving Marketplace and Emerging Issues (October 2015), available at [www.seniorcarepharmacies.org](http://www.seniorcarepharmacies.org).

<sup>4</sup> CMS officials themselves have conflicting understandings the Part D Manual provisions. For example, in 2015 during a FDA “Listening Session” on August 28, 2015 concerning a proposed FDA guidance document, Jeffrey Kelman, M.D., Chief Medical Officer for CMS, openly stated to an FDA panel that there was no federal definition of “LTC pharmacy” anywhere in federal law, regulation or sub-regulatory guidance, despite the clear definition in the Part D Manual.

## **A. Medicare Part D Statute, Regulation, and Guidance**

### (i) Statute and Regulation

As noted above, neither the MMA nor any other provision of Title XVIII of the Social Security Act, defines “long-term care pharmacy” under the Part D - Voluntary Prescription Drug Benefit Program provisions. However, the Part D regulations contain a brief definition of the term “long-term care pharmacy” as “a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility’s residents.” 42 C.F.R. § 423.100. This short, single sentence is the sole federal regulatory definition existing in today.

### (ii) Part D Manual

Although the regulatory definition is somewhat circular and does not include any definitional characteristics of a LTC pharmacy other than being in a contractual relationship with a nursing home, the Part D manual provides extensive guidance regarding the minimum performance and service criteria for long-term care pharmacies, which include:

- (1) **Comprehensive Inventory and Inventory Capacity** – NLTCPs<sup>5</sup> 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.

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<sup>5</sup> CMS uses the phrase NTLCPs, which stands for “Network Long Term Care Pharmacies.” For purposes of this analysis, there is no distinction between network and out-of-network pharmacies.

- (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.<sup>6,7</sup>

The guidance further explains that “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 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.”<sup>8</sup>

## **B. Nursing Home Reform Act of 1987**

### *(i) Statute and Regulations*

As noted above, the requirements for delivery of medications to LTC residents does not itself stem from the MMA, but instead from the Nursing Home Reform Act of 1987, which ultimately was combined into and passed under the Omnibus Budget Reconciliation Act of 1987.

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<sup>6</sup> *Centers for Medicare and Medicaid Services*, Long-Term Care Guidance (March 16, 2005), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf>.

<sup>7</sup> *Centers for Medicare and Medicaid Services*, Medicare Prescription Drug Benefit Manual Ch. 5, Part 50.5.2, “Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCs)” (Sept. 20, 2011), available at [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5\\_093011.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf). See also Center for Disease Control, National Center of Health Statistics, Long-Term Care Providers and Services Users in the United States: Data from the National Study of Long-Term Care Providers, 2013–2014 (Feb. 2016) Appendix A, available at [http://www.cdc.gov/nchs/data/series/sr\\_03/sr03\\_038.pdf](http://www.cdc.gov/nchs/data/series/sr_03/sr03_038.pdf) (Defining LTC pharmacy services as including “filling of and delivery of prescriptions. Pharmacist services are provided by “the licensed pharmacist(s) who a facility is required to use for various purposes, including providing consultation on pharmacy services, establishing a system of records of controlled drugs, overseeing records and reconciling controlled drugs, and/or performing a monthly drug regimen review for each resident” (CMS form 671). Definition for pharmaceutical services is not provided in CMS’ State Operations Manual”). Several private entities have also used the CMS criteria in their definitions of LTC pharmacy, including Managed Health Care Associates [http://www.mhainc.com/uploadedFiles/Content/Resources/Avalere\\_LTC%20Pharmacy%20the%20Evolving%20Marketplace%20and%20Emerging%20Policy%20Issues....pdf](http://www.mhainc.com/uploadedFiles/Content/Resources/Avalere_LTC%20Pharmacy%20the%20Evolving%20Marketplace%20and%20Emerging%20Policy%20Issues....pdf) and McKesson, *supra*, [http://becomeahealthmart.com/Websites/becomeapharmacy/images/Whitepaper-Becoming\\_a\\_Long-Term\\_Care\\_Pharmacy.pdf](http://becomeahealthmart.com/Websites/becomeapharmacy/images/Whitepaper-Becoming_a_Long-Term_Care_Pharmacy.pdf).

<sup>8</sup> Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, Section 50.5, available at: [https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/memopdbmanualchapter5\\_093011.pdf](https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/memopdbmanualchapter5_093011.pdf).

That statute and its implementing regulations specifically touched upon LTC pharmacy without ever using the term. The law does not define long-term care pharmacy nor do the regulations.<sup>9,10</sup> However, the regulations do provide that skilled-nursing facilities and nursing facilities, as defined under 42 C.F.R. § 483.5, must provide certain “pharmacy services,” which include:

- The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.
- **Procedures.** A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.
- **Service consultation.** The facility must employ or obtain the services of a licensed pharmacist who – (1) provides consultation on all aspects of the provision of pharmacy services in the facility; (2) establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and (3) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
- **Drug regimen review.** The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.
- **Labeling of drugs and biologicals.** Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.
- **Storage of drugs and biologicals.** In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys. The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.<sup>11</sup>

In July 2015, CMS published a proposed rule that would result in significant changes to the Conditions for Participation for skilled nursing facilities and nursing facilities, which include proposed revisions to the regulations regarding the provision of pharmacy services. Under these revised provisions, CMS proposes to require additional review of medical charts, additional

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<sup>9</sup> See Omnibus Budget Reconciliation Act of 1987, P.L. 100-203 (Dec. 22, 1987), available at [https://www.ssa.gov/OP\\_Home/comp2/F100-203.html](https://www.ssa.gov/OP_Home/comp2/F100-203.html).

<sup>10</sup> 54 Fed. Reg. 5316 (Feb. 2, 1989).

<sup>11</sup> 42 C.F.R. § 483.60.



documentation and drug regimen reviews and revisions to the definition of irregularities, the provisions concerning the use of psychotropic drugs, and PRN orders, and additional requirements on the pharmacy-physician relationship.<sup>12</sup> The proposed regulatory changes applicable to nursing homes are not expected to affect the elements of any definition of LTC pharmacy.

(ii) *State Operations Manual*

Although the Nursing Home Reform Act did not define long term care pharmacy, the Nursing Home State Operations Manual (SOM) published by CMS provides guidance to surveyors of long-term care facilities,<sup>13</sup> includes standards for review for LTC facilities, interpretive guidelines, and specific “F-Tag” (or facility compliance requirement enforcement) numbers denoting specific deficient practices and non-compliance with regulations and guidance. Similar to other OBRA 1987 documents, the SOM does not provide a definition for long-term care pharmacy. However, Interpretive Guideline F-425: Pharmacy Services provides additional guidance related to pharmacy services that LTC facilities should provide. For example, CMS provides the following guidance to nursing home surveyors in F-425 as follows:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist;
- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, and to guide development and evaluation of the implementation of pharmaceutical services procedures;
- The licensed pharmacist helps the facility identify, evaluate, and address/resolve pharmaceutical concerns and issues that affect resident care, medical care or quality of life such as the:
  - Provision of consultative services by a licensed pharmacist between the pharmacist’s visits, as necessary; and
  - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]); and

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<sup>12</sup> Center for Medicare and Medicaid Services, Proposed Rule “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” 80 Fed. Reg. 42,168 (July 15, 2015).

<sup>13</sup> See Centers for Medicare and Medicaid Services, State Operations Manual (Publication No. 100-07), *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html>. The major pharmacy-related F-Tags include: F-Tag 309: Quality of Care; F-Tag 329: Unnecessary Drugs; F-Tag 332-333: Medication Errors; F-Tag 425: Pharmacy Services; F-Tag 428: Medication Regimen Review; and F-Tag 431: Storage, Labeling, and Controlled Medications. Note that the term “long-term care facilities” does not, under federal law, include assisted living facilities.

- The facility utilizes only persons authorized under state requirements to administer medications.<sup>14</sup>

CMS in the SOM guidelines also provides the definition of “pharmaceutical services” to clarify terminology related to “pharmaceutical services” and the management of each resident’s medication regimen for effectiveness and safety, as follows:

- The process (including documentation, as applicable) of receiving and interpreting prescriber’s orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, administering, monitoring responses to, using and/or disposing of all medications, biologicals, chemicals (e.g., povidone iodine, hydrogen peroxide);
- The provision of medication-related information to health care professionals and residents;
- The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and
- The provision, monitoring and/or the use of medication-related devices.<sup>15</sup>

The guidance also explains that the provision of pharmaceutical services is “an integral part of the care provided to nursing home residents. The management of complex medication regimens is challenging and requires diverse pharmaceutical services to minimize medication-related adverse consequences or events. The overall goal of the pharmaceutical services system within a facility is to ensure the safe and effective use of medications.”<sup>16</sup>

In a brief synopsis of the regulation to determine compliance, CMS states: “The Pharmaceutical Services, Procedures and Consultation requirement has four aspects. First, the facility must provide routine and/or emergency medications and biologicals or obtain them under an agreement described in 42 CFR 483.75(h). Second, the facility must have procedures for pharmaceutical services to meet the resident’s needs. The procedures must assure accurate acquisition, receipt, dispensing, and administration of all medications and biologicals. Third, the facility must have a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services. Fourth, the facility must follow applicable laws and regulations about who may administer medications.”<sup>17</sup> CMS’s criteria for compliance with F425 Pharmaceutical Services are as follows:

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<sup>14</sup> See Center for Medicare and Medicaid Services, State Operations Manual – Appendix PP, “Guidance to Surveyors for Long Term Care Facilities,” (Oct. 9, 2015), available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

A nursing facility [that is the nursing home and not the pharmacy] is in compliance with this requirement, if they provide or arrange for:

- a) Each resident to receive medications and/or biologicals as ordered by the prescriber;
- b) The development and implementation of procedures for the pharmaceutical services;
- c) The services of a pharmacist who provides consultation regarding all aspects of pharmaceutical services; and
- d) Personnel to administer medications, consistent with applicable state law and regulations.<sup>18</sup>

### C. Environmental Protection Agency

In 2015, the EPA issued a proposed rule, titled, “Management Standards for Hazardous Waste Pharmaceuticals.”<sup>19</sup> In the proposed rule, EPA defines “healthcare facility” to mean: “any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals.”<sup>20</sup> EPA further expands on this definition by stating that the definition includes, among others, long-term care pharmacies. *Id.* (“This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, **long-term care pharmacies**, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals. Thus, these proposed regulations will be applicable to any healthcare facility for human or animal which generates hazardous waste pharmaceuticals on its premises.” 80 Fed. Reg. 58,024 & 58,083 [Sept. 25, 2015]) (emphasis added).

In the preamble to the final rule, EPA notes the following: “this proposed definition is adapted from the definition of ‘health care’ that the Department of Health and Human Services (DHHS) promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).” *Id.* at 58,024. A review of that HIPAA definition, however, reveals no similarity to the EPA definition, and there is no relevance of the HIPAA definition to the scope of LTC pharmacy.

Importantly, the proposed EPA definition also includes within its scope assisted living facilities (ALFs), which will pose a significant (if not impossible) operational challenge to LTC pharmacy due both the absence of any other federal definition of what constitutes an ALF and

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<sup>18</sup> *Id.*

<sup>19</sup> See Environmental Protection Agency’s Proposed Rule, “Management Standards for Hazardous Waste Pharmaceuticals,” 80 Fed. Reg. 58,014 (Sept. 25, 2015).

<sup>20</sup> Proposed Rule 40 C.F.R. § 266.500.

how any pharmacy, much less LTC pharmacy, can exert control over medications sold to ALF residents. The EPA's broad over-regulation is an unfortunate example of misuse of the term LTC pharmacy without a clear understanding of defines an LTC pharmacy.

#### **D. U.S. Food and Drug Administration**

Historically, the FDA has been granted oversight of medications in all pharmacies including LTC pharmacies. The Agency, however, has exercised enforcement discretion and deferred to State Boards of Pharmacy to regulate LTC pharmacies, particularly with respect to activities that are essentially the practice of pharmacy. Thus, for example, FDA has never enforced the Food, Drug and Cosmetic Act's (FDCA) repackaging limits on pharmacies in general, and LTC pharmacies in specific, instead relying upon the state Boards of Pharmacy for enforcement action when necessary.

In February 2015, in response to Congress enacting the Drug Quality and Security Act of 2013 (the DQSA), FDA proposed a draft guidance regarding repackaging by state-licensed pharmacies, Federal facilities, and facilities that register with FDA as outsourcing facilities under section 503B of the FDCA.<sup>21</sup> The draft guidance, titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities," provides that entities engaged in repackaging, which includes all pharmacies, would be subject to this guidance. In light of the broad definition of pharmacy, long-term care pharmacies are also subject to these provisions and are not exempt.

According to the draft guidance, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FDCA if the drug product is repackaged by a state-licensed pharmacy or federal facility in accordance with the following conditions:

- The drug that is being repackaged is a prescription drug product approved under section 505 of the FD&C Act, except as provided in section III.B of this guidance regarding repackaging unapproved drug products that appear on FDA's drug shortage list under section 506E.
- The drug product is repackaged in a state-licensed pharmacy, a Federal facility, or an outsourcing facility.
- If the drug product is repackaged in a state-licensed pharmacy or a Federal facility (but not an outsourcing facility), it is repackaged and distributed after (a) the receipt of a valid prescription for an identified, individual patient directly from the prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's chart in a health care setting, unless it is repackaged (but not distributed) in advance of receipt of such a prescription or a written order in a patient's chart in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy or the Federal facility repackaged pursuant to patient-specific prescriptions or written orders in a previous, consecutive 14-day period, and based on a history of receipt of prescriptions or written orders over a consecutive 14-day period for such repackaged drug products.

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<sup>21</sup> FDA Center for Drug Evaluation and Research, Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (February 2015).

- The drug product is repackaged by or under the direct supervision of a licensed pharmacist.
- Except as provided below for a single-dose vial, the drug product is repackaged in a way that does not conflict with approved drug product labeling. For a single-dose vial that is repackaged into multiple units, the drug product is repackaged in a way that does not conflict with the approved labeling, except for the statements designating the product as a single dose or single use product, and related language (e.g., discard remaining contents).
- The repackaged drug product is assigned a beyond-use-date (BUD) as described in the guidance.
- Except with regard to BUDs, which are addressed in the condition above, if the drug product is repackaged in a state-licensed pharmacy or a Federal facility:
  - If it is a non-sterile drug product, it is repackaged in accordance with U.S. Pharmacopeial Convention (USP) Chapter 795, and if it is a sterile drug product, it is repackaged in accordance with USP Chapter 797 (e.g., a sterile drug product is repackaged in an area with air quality that meets or exceeds ISO Class 5 standards);
- The drug product that is being repackaged does not appear on a list of drug products that have been withdrawn or removed from the market because they have been found to be unsafe or ineffective. For purposes of this provision, repackagers should refer to the list of drug products in 21 CFR 216.24, developed for use with sections 503A and 503B.
- The drug product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include administration of a repackaged drug product in a health care setting.
- The repackaged drug product is distributed only in states in which the facility repackaging the drug product meets all applicable state requirements.<sup>22</sup>

The FDA requirements prohibiting repackaging except in very limited circumstances directly conflict with the CMS requirement that LTC pharmacies provide prescription drugs in specialized packaging and that LTC pharmacies provide “emergency kits” (e-kits) to nursing homes to meet residents’ emergency medication needs. Many prescription drugs commonly used in nursing homes are not available for purchase in specialized packaging, and it is impractical for LTC pharmacies to be forced to repackage in limited quantities that will all be dispensed within 15 days (as proposed by the draft FDA guidance) or be required to secure FDA repackager licenses. Moreover, conversations with the FDA over the course of 2015 and 2016 related to its draft Guidance reveal that the absence of a clear definition of LTC pharmacy has impeded the FDA from appropriately regulating the LTC pharmacy sector. Stated differently, a clear federal definition of LTC pharmacy that included the specialized packaging requirements would have allowed the FDA in its draft of the Guidance to appropriately distinguish LTC

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<sup>22</sup> *Id.* at 5-8.

pharmacy repackaging from other retail and wholesale repackaging which is the real focus of the FDA's regulatory efforts.

#### **E. U.S. Pharmacopeial Convention (“USP”)**

The USP does not provide a definition of long-term care pharmacy.

#### **F. Other Relevant Definitions**

Although not germane for the purposes of this federal analysis, it is worth noting that there are relevant federal agencies that do not use the term LTC pharmacy and relevant states that have their own definitions of LTC pharmacy. In brief, they are as follows:

- **Occupational Safety and Health Administration:** The Occupational Safety and Health Act of 1970 does not define “long-term care pharmacy” nor do the implementing regulations (29 C.F.R. Part 1910. OSHA does regulate LTC pharmacies generally, as it would other work sites. Although OSHA has unique regulations specific to nursing homes, none of those regulations affect LTC pharmacy.
- **National Association of Boards of Pharmacy:** In the August 2015 National Association of Boards of Pharmacy’s Model State Pharmacy Act and Model Rules of the NABP, the association defines “institutional pharmacy” to mean “any place that is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmacist Care to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as “Drugs”) are Dispensed, Compounded, and Distributed.”<sup>23</sup>
- **State Definitions:** At least 29 states regulate long-term care pharmacies under the broader category of institutional pharmacies, which also includes hospital pharmacies, penal institution pharmacies and hospices. There are 12 states with distinct regulations for long-term care pharmacies.

#### **IV. Looking Forward: Emerging LTC Pharmacy Care Models**

Beyond the conflicting definitions in today’s regulation and sub-regulatory guidance, any definition of LTC pharmacy must anticipate emerging new care models and the expected transition from today’s “fee for service” ingredient cost plus dispensing fee model to a value based care model. Stated differently, LTC pharmacy in the future may be compensated based upon improvements in outcomes due to medication management, reduced rehospitalizations, the prevention of adverse health conditions (such as falls, dehydration, and other preventable medical conditions), and other similar metrics. It is likely that drug utilization review (DUR) and other medication management tools will play a greater role in care, and in compensation, than is the case today.

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<sup>23</sup> National Association of Boards of Pharmacy, “Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)” (August 2015).

At the same time, it is possible that today's "one nursing home-one pharmacy" model may also change due to an increasingly shorter average lengths of stay in nursing facilities and an increased movement shifting patients to less expensive sites of care such as assisted living facilities, residential facilities or home care. Given the anticipated reduction in lengths of stay and a potential reduction in the number of nursing home beds in the country, combined with the increase in alternative care models through ACOs and bundled post-acute care arrangements, LTC pharmacy already has begun migrating to a "follow the patient" model of care. Given the number of medications LTC patients require regardless of setting and the important role pharmacy consulting services play in maintaining health and reducing adverse health events, it is entirely appropriate that LTC pharmacies continue managing medications and providing related services to LTC patients regardless of setting. Further, with the ascendancy of intermediaries between the payers, the care facility and the pharmacy, and with the emphasis on risk-sharing, pharmacy may find itself being asked to bear risk for some component of drug spend, with a potential upside payment for intensive medication utilization management.<sup>24</sup>

To operate within this emerging new environment, LTC pharmacy will have to demonstrate the value of its services – both to earn its compensation, and to develop and satisfy appropriate metrics to demonstrate it is a quality provider eligible for the payer's (and increasingly the intermediary's) "network pharmacy" arrangement. A pharmacy "star rating" system may emerge by which pharmacies, like nursing homes, can be measured by payers and intermediaries.

Notwithstanding these changes, there will be several core building blocks of LTC pharmacy practice that both enable pharmacies to meet these emerging care models and continue to distinguish LTC from retail pharmacy services. LTC pharmacy should anticipate that retail pharmacy, facing the same challenges, would adopt a "retail version" of DUR and medication management processes to establish its own quality metrics. However, there will remain several unique distinguishing features of LTC pharmacy (many of which can be found in the Part D Manual definition and the Medicare and Medicaid Requirements of Participation today) that will continue to separate it from other types of pharmacy providers into the future. It will be including these elements in any new statutory definition, as well as be sufficiently flexible to allow for emerging market trends, will be crucial to assuring that LTC patients receive appropriate medication and pharmacy management services.

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<sup>24</sup> The health care delivery system is evolving rapidly, with various intermediaries emerging as a result of the Affordable Care Act and related initiatives by CMS, which the private sector is using to revise reimbursement systems. A common theme is inserting an intermediary between the payer and the provider. Such intermediaries include ACOs, bundle holders under bundled payment system, pharmacy benefit managers for pharmacy services and "conveners."

## V. Conclusion

Federal regulation today contains a widely divergent set of actual and proposed definitions of LTC pharmacy. In several important instances, the definitions conflict with each other, and create the proverbial “Hobson’s choice” for pharmacies to comply with CMS regulations, FDA regulations, or EPA regulations. Particularly if several of the pending regulatory and sub-regulatory proposal are finalized as proposed, it will be impossible for LTC pharmacies to meet some of the different requirements without violating others. More importantly, the improvements in patient outcomes, quality of care, and elimination of medication errors achieved over the past 25 years may be lost, particularly if the proposed FDA regulatory guidance is adopted and specialized medication packaging services and provision of emergency medications are hindered or prevented due to unnecessary and overly burdensome FDA Repackaging Guidance requirements.

The most comprehensive and most accurate federal definition of LTC pharmacy is found in the CMS Part D Manual, which memorializes (perhaps in somewhat outdated terms) the scope and practice of LTC pharmacy in a manner that ensures quality patient care today and into the future. The Part D Manual provisions could serve as the starting point for the development of a federal statutory definition of the term. In contrast, the EPA’s definition – effectively any pharmacy that delivers drugs used in a nursing home or assisted living facility – is inaccurate and overly broad, and serves to confuse the issue.

The Part D Manual definition may also be adaptable to future models of LTC pharmacy, as both the LTC industry and the pharmacy sectors migrate to a value-based reimbursement model. It is likely that over the coming five years the existing fee-for-service or ingredient cost/dispensing fee model will change, and that payers and intermediaries will overwhelmingly stand between pharmacies and payers, particularly Medicare. Similarly, it is likely that reimbursement may migrate toward a value-based model, where the attendant services such as DUR, specialized packaging, and even emergency delivery services will drive medication dispensing and reimbursement practices. Moreover, as nursing home patient stays continue to decrease, and patients are moved to lower-intensity alternative care sites including home care, LTC pharmacy may develop a “follow the patient” pharmacy model. Any definition will need to be flexible enough to accommodate these changes.

What is clear today is that the sector cannot continue without a federal statutory definition that addresses today’s needs and tomorrow’s care models. At issue is not just regulatory certainty for pharmacies, but the quality of medication therapy that those pharmacies are able to provide to LTC residents. Drug utilization review, specialized medication packaging, 24/7/365 pharmacist availability, emergency delivery, and onsite “e-kits” are crucial to resident care in nursing facilities. Each is a standard service offering by a LTC pharmacy today. Yet, in the absence of a definition that makes this clear, other agency regulation and guidance may put these services at risk.

Congress should have adopted a clear definition in 2003 when it enacted the MMA. At the time, however, Congress did not clearly understand what role pharmacy played in LTC, or how the Part D program would impact beneficiaries in nursing homes and other LTC settings. Since that time, the LTC pharmacy sector, and the agencies that regulate it, have gained a significant



appreciation for both the benefits of this specialized sector and the operational requirements needed to provide the enhanced pharmacy services. Even without the conflicts being created across agencies today, it is time that Congress adopt a clear definition of the sector. Given that the FDA and EPA today (and other agencies and care models in the future) are or will be expanding regulations that encompass the LTC pharmacy sector, a clear definition is needed so that patients may continue to enjoy the protections and quality care being provided today and policymakers may appropriately address this specialized segment of the pharmacy sector.