
Long-Term Care Pharmacy: the Evolving Marketplace and Emerging Policy Issues

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EXECUTIVE SUMMARY

Long-term care (LTC) pharmacies provide essential prescription medications, medication therapy management, and other consultative services to nearly two million seniors in America's skilled nursing facilities (SNFs) and assisted living facilities (ALFs). The typical patient has multiple chronic conditions and relies heavily on multiple prescription medications to manage their healthcare needs.

As demographic changes drive greater demand for long-term and post-acute care in the nation's healthcare delivery system, LTC pharmacies will play a growing role managing the medication and clinical needs of seniors with increasingly complex medical conditions and greater needs for effective medication therapy and management.

Current and evolving payment systems, however, are increasing financial pressure on independent LTC pharmacies, raising significant questions as policymakers shape the future of healthcare delivery for individuals receiving care and services in LTC settings.

LTC Pharmacies Play Key Role in Patient Care, New Payment and Delivery Models

The mission of LTC pharmacies is to ensure patients receive the right medications, in the right doses, at the right time. Achieving this mission is increasingly complex and crucial to facilitating the efficient, high-quality outcomes demanded by patients, providers, and payers under new payment and delivery models such as accountable care organizations (ACOs), bundled payments, and value-based purchasing.

Success in these models means improving patient outcomes and reducing unnecessary costs, particularly those associated with avoidable hospital admissions. Given these goals and the importance of LTC pharmacy to effective care for seniors, Congress and the Administration should understand the clinical impact and challenges facing LTC pharmacies in the rapidly evolving healthcare delivery system.

LTC Pharmacies Distinct from Retail Pharmacies, with Higher Costs to Dispense

Distinct from more commonly known retail pharmacies, LTC pharmacies are not open to the public and do not sell convenience items. With no ancillary income streams, they rely solely upon revenue from dispensing prescriptions and providing consultative services. LTC pharmacies also have higher operating costs due to a myriad of legal and regulatory mandates. In particular, the National Community Pharmacists Association estimates that the cost to dispense for LTC pharmacies is 25 percent more than retail pharmacies.

The process to dispense medications differs substantially from retail pharmacies, which provide medications directly to consumers after confirming payer coverage. In contrast, LTC pharmacies must coordinate with the facility, provider, and payer to review each

prescription, compare against known medications, verify coverage, meet rigorous packaging and delivery requirements, and stand ready to deliver medications at all times.

Further, LTC pharmacies must comply with extensive Medicare and Medicaid Conditions of Participation, meet state licensing and related requirements pertaining to LTC services, and satisfy other regulatory and professional practice standards. As a result, the cost of dispensing drugs for use in LTC settings is markedly higher for LTC pharmacies due to these additional compliance needs.

LTC pharmacies must incur these costs to meet their three primary objectives:

- Maintain responsibility for a wide array of pharmacy services for residents in SNFs and ALFs.
- Facilitate and support regulatory compliance by LTC facilities, particularly related to patient safety and drug administration efficacy.
- Offer an efficient and effective method to protect vulnerable patients and improve the quality of their care, especially given that LTC facility residents are high utilizers of prescription medications.

LTC Pharmacy Sector Highly Fragmented

Roughly 50 percent of the LTC pharmacy sector is controlled by two publicly traded companies, with the larger serving 33.8 percent of the market. The rest of the market is highly fragmented. More than 1,000 other independent LTC pharmacies^a operate in the U.S., with the largest of this group serving roughly 2 percent of the market and the average independent serving less than 0.02 percent. In addition, vertically integrated companies own subsidiaries at multiple levels—including prescription drug plans (PDPs), pharmacy benefit managers (PBMs), and LTC and retail pharmacies.

Independent LTC Pharmacies Strained by Prevailing Reimbursement Model

Medicare, particularly Medicare Part D, pays for the lion's share of prescriptions for seniors in LTC facilities. This dominance is significant since a confluence of factors has led to falling Part D reimbursement, particularly for generic drugs. Notably, the two largest LTC pharmacies appear able to avoid certain reimbursement methods and instead utilize more consistent ones. Conversely, independent LTC pharmacies believe that PDPs and PBMs have increasingly reduced their reimbursement, trends they argue have accelerated with greater horizontal and vertical integration among health plans, PDPs, PBMs, pharmacies, and drug manufacturers.

^a Throughout this report, "independent" LTC pharmacies refers to non-publicly traded LTC pharmacies.

These integrated companies may have incentives to provide more favorable reimbursement to their subsidiaries or to tailor payments to maximize their profits. This environment creates financial challenges, particularly under the prevailing payment model for generic medications under Medicare Part D—Maximum Allowable Cost (MAC) pricing, which may not account for the actual costs LTC pharmacies bear to dispense each medication.

A rapidly aging population, rising use of generics, generic price inflation, and negotiating and contract administration tactics by PBMs are exacerbating adverse financial trends, creating significant challenges for independent LTC pharmacies. In addition, independent LTC pharmacies believe that subjective network adequacy requirements mean PDPs can exclude independent pharmacies from their network, while claiming they satisfy the requirements. This threat of exclusion contributes to downward pressure on prices.

Other recent and proposed federal policy changes aggravate the challenges that independent LTC pharmacies face. For example, mandatory short-cycle dispensing, implemented to reduce medication waste of brand-name drugs, means LTC pharmacies need to dispense two 14-day supplies to cover a comparable number of days as a single 30-day supply. Because of fixed costs to dispense, delivering multiple prescription packs compounds the effect of already inadequate dispensing fees. Interviews with independent LTC pharmacies suggest that, collectively, these issues strain the independent LTC pharmacy business model and may impede the ability of LTC pharmacies to fulfill their mandate.

To preserve choice, and to ensure that elderly SNF and ALF patients continue to receive the LTC pharmacy clinical services that help advance high-quality patient care and cost-savings objectives, policymakers should consider how to address the unique needs and roles of LTC pharmacies as they seek to streamline, standardize, and make more transparent the drug pricing and distribution process.

INTRODUCTION: THE VALUE OF LONG-TERM CARE PHARMACIES

LTC pharmacies serve a crucial role in the care continuum, managing medications for vulnerable, medically complex residents of SNFs and ALFs. With the typical SNF patient receiving 8 to 10 different medications each day, effective delivery of pharmacy services is essential to the overall care and services patients receive.^{1, b} LTC pharmacies, through their consultant pharmacists, manage medications and related pharmacy services, and review residents' clinical needs to ensure that patients receive the right medications at the right time. These services begin upon receipt of each prescription and continue after dispensing the drug.

Although LTC pharmacies serve these important roles, confusion persists. Unlike retail pharmacies, most consumers have not interacted with or received services from LTC pharmacies; therefore, the substantial differences in service models are not broadly understood. While retail pharmacies mainly focus on dispensing medications, LTC pharmacies are more engaged in clinical care delivery.

OVERVIEW OF LTC PHARMACIES

LTC pharmacies serve the medication needs of institutional LTC patients. The two most common LTC providers are SNFs and ALFs, which offer continuing care and supervision to patients who need rehabilitation services and/or long-term residential care. LTC pharmacies have evolved to support the special needs of these LTC providers and their residents. Specific to the SNFs, LTC pharmacies process prescriptions, dispense and deliver medications, provide ongoing medication management and clinical consulting both before and after dispensing the drug, and assist with medical records management, narcotics reviews, and medication disposal.¹ Pharmacies must also stock and maintain emergency/interim kits in facilities to ensure that patients can receive an immediate dose of a medication when care dictates. **Figure 1** lists these services. In addition, LTC pharmacies employ consultant pharmacists who are responsible for medication dispensing and management services as well as medical record and medication reviews for the patients in these LTC facilities.

^b The estimated number of medications per resident per day comes from a report prepared by The Lewin Group for the Centers for Medicare & Medicaid Services in 2004. Interviews with LTC pharmacies suggest that higher patient acuity means the average number of medications dispensed per resident per day has increased to 10 to 12.

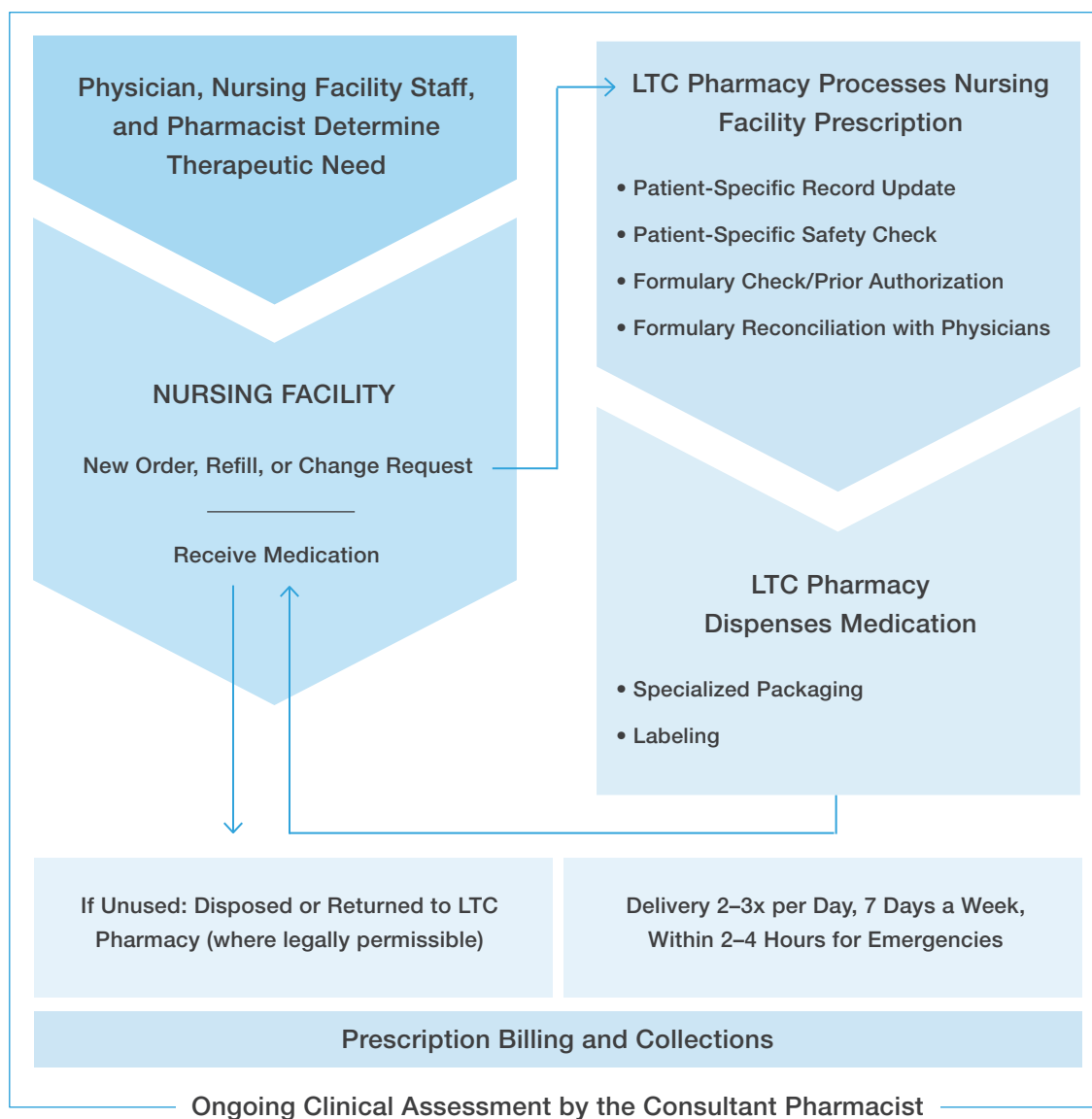
Figure 1: LTC Pharmacy Services¹

PREScription PROCESSING	DISPENSING AND DELIVERY	MEDICATION MANAGEMENT	RETURN/REUSE AND DISPOSAL
• Create medication record • Clarify medication order • Respond to emergency medication orders • Perform drug utilization reviews • Perform holistic clinical review of the patient • Maintain and provide entire medical record for the facility on a monthly basis	• Package medications in unit doses • Prepare IV therapy solutions in USP 797 clean rooms • Ensure proper labeling • Provide timely delivery 24-hours-per-day/7-days-per-week • Maintain consignment inventory in emergency/interim kits, floor stock	• Perform quality assurance checks • Conduct narcotics reviews • Supply medication carts • Perform consultant pharmacist services • Inspect facility inventory to ensure proper storage and handling	• Accept return of unused medications • Provide biomedical waste services for all returned medications • Assist in disposal of controlled and non-controlled substances • Reuse only where allowed under specific circumstances

LTC pharmacies are typically closed-door facilities that do not have public-facing operations, but rely solely on revenue from filling and delivering prescriptions and providing other clinical, medication-related, patient-facing services within institutional settings.

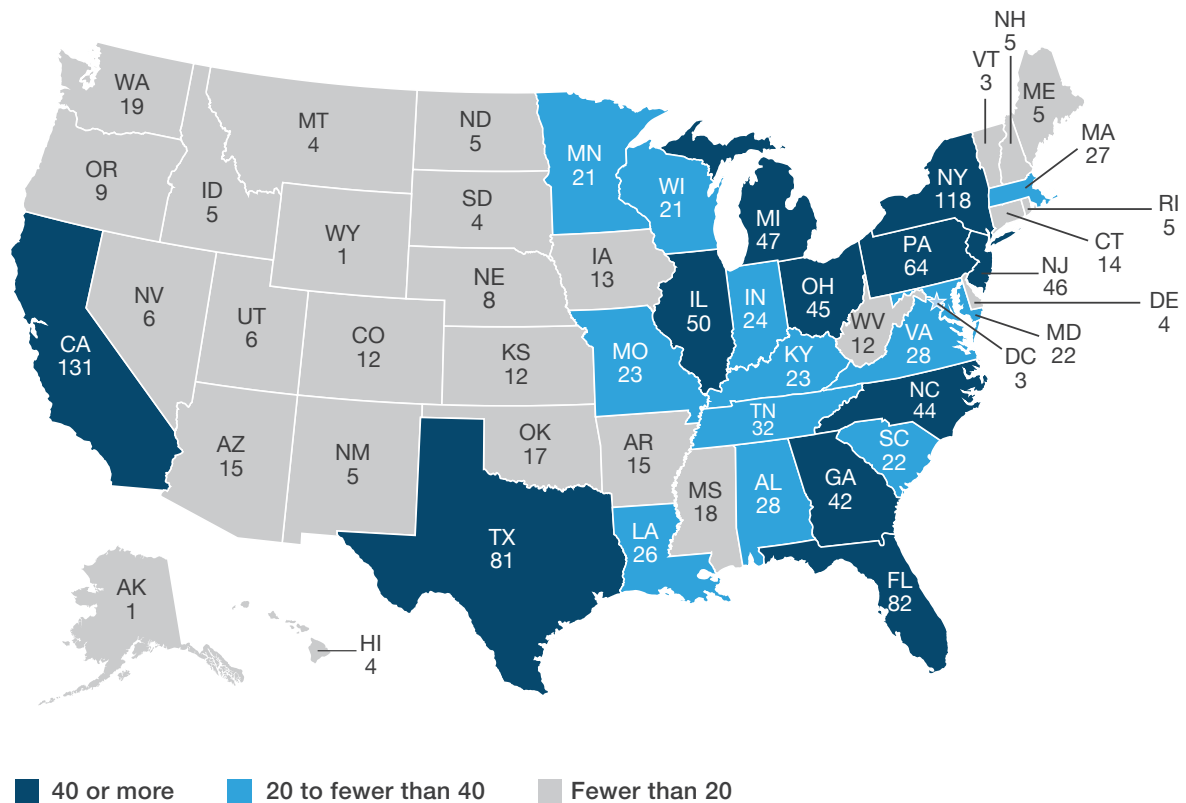
Figure 2 illustrates the LTC pharmacy's process in dispensing medications to residents of an SNF.

Figure 2: Process Map for LTC Pharmacy Prescriptions¹



In 2013, 1,282 LTC pharmacies operated in the U.S., with the majority in California, the Midwest, the Mid-Atlantic, and the South (**Figure 3**).^{2, 3, 4}

Figure 3: Geographic Distribution of LTC Pharmacies in the U.S. in 2015²



Each of the over 1,200 LTC pharmacies must comply with numerous regulations. First, through contracts with SNFs, LTC pharmacies must assume the responsibility of and comply with federal regulations that are part of the Conditions of Participation for SNFs to receive Medicare and Medicaid funding.¹ In addition, LTC pharmacies must satisfy Medicare Part D network pharmacy standards to be eligible for payment from PDPs. Finally, LTC pharmacies must comply with state-level standards of practice related to the specific services provided within the nursing facility.¹ **Figure 4** outlines various regulations and standards of practice that affect LTC pharmacy operations. In addition to complying with these regulations, LTC pharmacies are subject to other regulations that apply to all pharmacies—retail and LTC.

Figure 4: Influence of Federal Regulation on LTC Pharmacy and Consultant Pharmacist Standards of Practice^{1, 5}

FEDERAL LAW MANDATES	• Provide pharmaceutical services to meet the needs of each resident • Decrease medication errors and adverse drug events and report any irregularities • Ensure proper medication selection • Monitor drug interactions, overmedication, and undermedication • Properly label and store drugs and biologicals
MEDICARE PART D LTC PHARMACY REQUIREMENTS	• Comprehensive inventory and inventory capacity • Pharmacy operations and prescription orders • Special packaging • IV medications • Custom compounding • Pharmacist on-call service (24/7) • Delivery service (24/7) • Emergency medications (24/7) • Emergency log books • Miscellaneous reports, forms, and prescription ordering supplies
CMS LTC REQUIREMENTS	LTC Pharmacy Services • Specialized medication carts, emergency drug supplies, and equipment to assist in the storage, control, and dispensing of medications • Preparation of computerized medical records for facilities (medication administration records, physician's monthly order sheets, treatment records, etc.) • Specialized services such as intravenous and infusion therapy services • Emergency back-up systems • Pharmacy policies and procedures • Facility and resident-specific reports Consultant Pharmacist Services • Drug regimen reviews • Medication therapy management • Counsel patients • Present in-services and attend policy meetings

The lion's share of LTC pharmacy payments are from Medicare, with the distribution and reimbursement system varying by type of insurance. In general, for Medicare Part A the SNF bills the Centers for Medicare & Medicaid Services (CMS) for the prescription and then pays a negotiated fee-for-service rate to the LTC pharmacy. The pharmacy or group purchasing organization (GPO) also negotiates with pharmaceutical manufacturers or wholesalers on the price of supplying the drug. For Medicare Part D, LTC pharmacies negotiate reimbursement rates and manufacturer rebates with PBMs. **Figures 5 and 6** detail the distribution and reimbursement system for Medicare Parts A and D. A smaller share of LTC pharmacy reimbursement comes from state Medicaid programs, private or self-pay, and Medicare Part B.

Figure 5: Medicare Part A Distribution and Reimbursement System for LTC Pharmacies

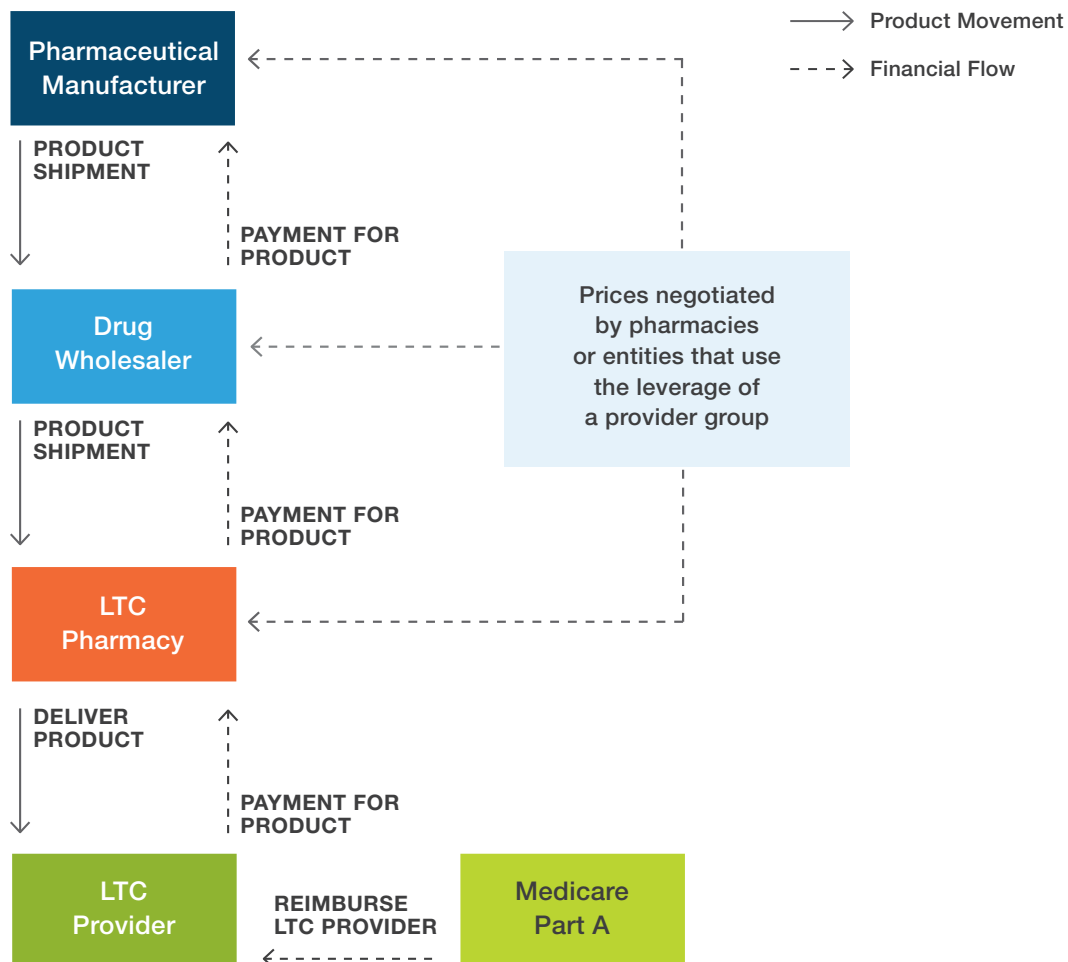
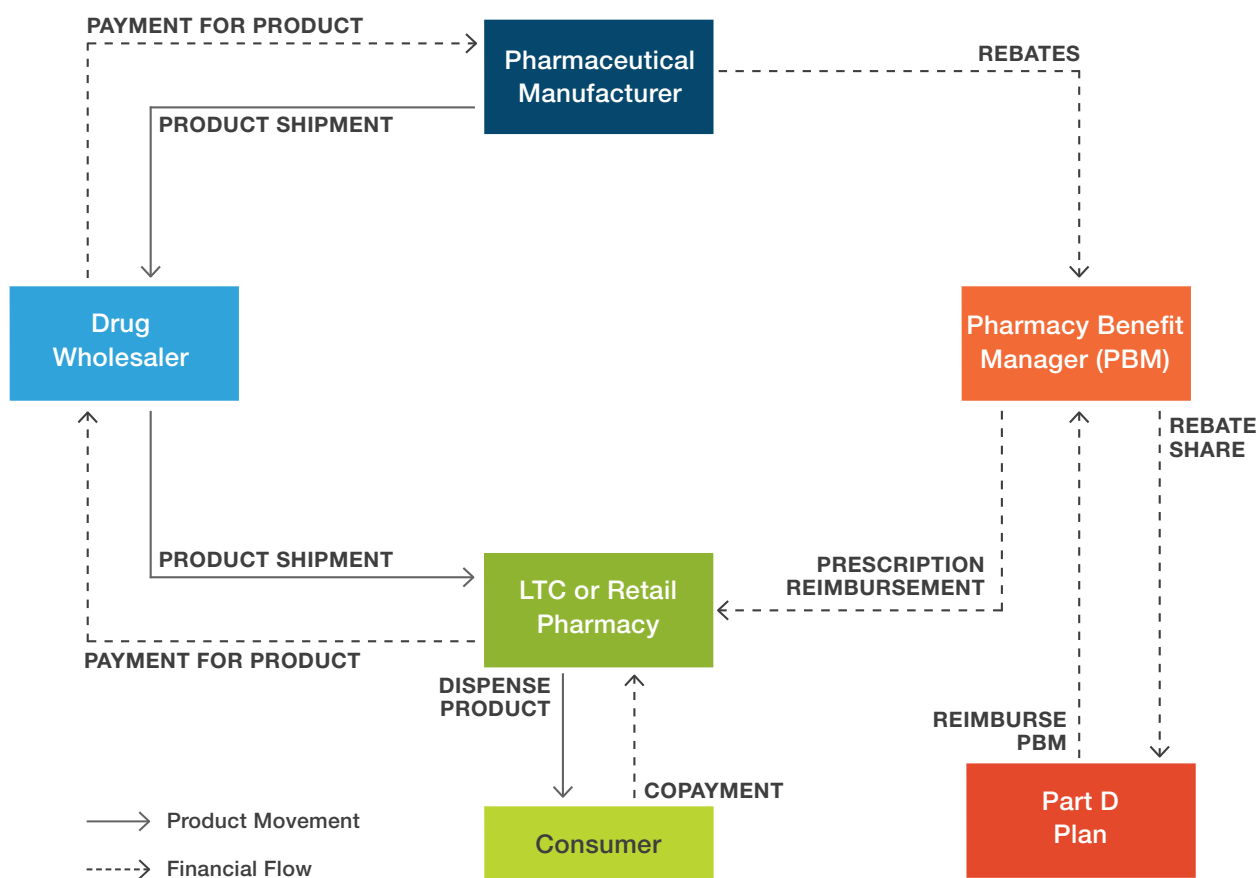


Figure 6: Medicare Part D Distribution and Reimbursement System for LTC Pharmacies



The basic reimbursement model for an LTC pharmacy is intended to account for ingredient costs plus “all operating costs incurred by the pharmacy to dispense the medication to patients in full compliance with all state and federal laws and provide a fair return on investment.”⁵ The payment for ingredient costs covers the cost of acquiring the drug from a wholesaler or pharmaceutical manufacturer. Average wholesale price (AWP), a predictable list-price benchmark, minus 10 to 20 percent is the most common methodology to determine ingredient cost for brand-name drugs.⁶ In contrast, Part D plans favor MAC pricing for generic drugs, which sets a payer-specific total reimbursement limit for each drug. Unlike AWP, no standard exists for calculating and updating MAC pricing, so the reimbursement amounts can vary greatly by payer. Notably, the majority of drugs dispensed by LTC pharmacies are generic. Other pricing methodologies, such as average sales price and estimated acquisition cost, may be used by other payers, including Medicare Part B and Medicaid, respectively.

A separate professional or dispensing fee is intended to pay for the various administrative and professional services, specialized packaging materials, and 24-hours-per-day/7-days-per-week delivery services—among other behaviors required by state and federal law.⁷ The median cost for an LTC pharmacy to dispense a prescription is \$13.54, which is largely constant regardless of the number of doses or days supplied.⁸ For many years, “payers underpaid pharmacies for the dispensing fee component but made up the difference by overpaying for the ingredient component.”⁸ However, researchers have noted that payers have corrected the ingredient cost imbalance without addressing dispensing fees, thereby threatening the sustainability of LTC pharmacies.⁸ Under Part A, LTC pharmacies receive payment for the additional professional services and supplies directly from SNFs, although the substantial pressures SNFs have faced with reductions in Part A payments has made negotiating payments sufficient to cover these costs increasingly difficult.⁹ Under Part D, interviewees indicate that dispensing fees paid by PDPs and PBMs are consistently less than the cost to dispense, with fees declining in recent years.

UNDERSTANDING DIFFERENCES BETWEEN LTC AND RETAIL PHARMACIES

While retail pharmacies mainly focus on dispensing medications, LTC pharmacies are more engaged in specialized pharmacy services, medication delivery, and ongoing monitoring. In contrast, retail pharmacies fill prescriptions and provide new medication counseling directly for patients at store counters, but do not provide the same clinical services as LTC pharmacies. Unlike closed-door LTC pharmacies, retail pharmacies also sell other products unrelated to medications. Retail pharmacies include chain drugstores, independent drugstores, supermarkets with pharmacies, and mass merchants with pharmacies. In 2013, 62,300 retail pharmacies operated across the U.S., including 23,600 chain drugstores, 20,800 independent drugstores, 9,400 supermarkets with pharmacies, and 8,500 mass merchants with pharmacies.¹⁰

Federal regulations require SNFs to employ or obtain the services of a consultant pharmacist who bears a significant responsibility for providing medication-related expert services, such as medication and medical record reviews.¹¹ The American Society of Consultant Pharmacists defines them as “*pharmacist[s] who [are] paid to provide expert advice on the use of medications by individuals or within institutions or on the provision of pharmacy services to institutions.*”¹² In the majority of cases, SNFs contract with consultant pharmacists working in LTC pharmacies or independent consultant pharmacists. Notably, retail pharmacies do not have consultant pharmacists on staff, since similar requirements do not exist in the retail space.

Consultant pharmacists focus on medication use among senior populations within hospitals, SNFs, ALFs, psychiatric hospitals, hospice, and home- and community-based care settings.¹² SNFs must provide pharmacy services that “assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologics” to meet the needs of each of their residents.¹¹ Working with facility medical records, producing facility and resident medication reports, and implementing broader pharmacy policies and procedures for the LTC facilities all fall within the skillset and purview of consultant pharmacists and pharmacies. Each of these elements can require considerable effort, with associated costs. For example, providing intravenous and infusion therapy services requires the LTC pharmacy to build a clean room, conduct weekly batch tests, and submit to regular inspections.

CMS has established detailed regulatory and pharmacy practice requirements that elaborate on each of these services and the degree to which pharmacy services interact with other requirements imposed on SNFs.¹³ In addition, in July 2015, CMS proposed substantial changes to the conditions of participation for SNFs, including the regulations governing the provision of pharmacy services.¹⁴ If finalized, LTC pharmacies would need to offer increased services related to medical record and drug regimen reviews, psychotropic medications, PRN orders, and drug irregularities; in effect expanding significantly the scope of LTC pharmacy responsibilities.

In addition to significant service differences, reimbursement differs for retail and LTC pharmacies. Retail pharmacies do not receive payments related to Part A, and consequently do not need to negotiate with SNFs. While retail pharmacies have a similar payment and distribution model for Part D, LTC pharmacies must comply with additional state and federal requirements. This compliance increases the cost to dispense relative to retail pharmacies. According to the National Community Pharmacists Association, compliance with these requirements and provision of additional services leads to a cost to dispense for LTC pharmacies that is 25 percent^c more than retail pharmacies.¹⁵ Advocates argue that reimbursement should account for costs to dispense, but independent LTC (and independent retail) pharmacies have significantly less negotiating power with PBMs than most large, publicly traded pharmacies due to their smaller market shares and areas of operation.^{16, 17} In addition, according to interviews with LTC pharmacies, costs extend beyond dispensing and ingredients.

Federal regulations require quick turnaround on prescriptions for LTC residents, which can lead to LTC pharmacies bearing some of the risks and costs of initial doses. LTC pharmacies try to adjudicate claims as they process prescriptions, but due to the quick

c The National Community Pharmacists Association calculated this figure by comparing results of a survey of LTC pharmacies conducted by researchers at Virginia Commonwealth University and Midwestern University to costs to dispense for retail pharmacies reported in a pair of studies completed by Alabama and Oregon.

turnaround time they are sometimes unable to do so. In these cases, the pharmacy may dispense prescriptions quickly only to subsequently discover the drug was not on the PBM's formulary and, therefore, not reimbursed. Interviews suggest this results in considerable bad debt. For example, one organization indicated this bad debt equaled one percent of revenue. Interviewees noted that a potential solution—the submission of test claims to verify coverage—has costs due to claims processing fees imposed by PBMs. In addition, PBMs may require LTC pharmacies to repay a portion of the reimbursement if MAC pricing changed after adjudication. Interviewees also said that attempting to resolve claims requires significant staff resources, with several departments dedicated to determining the patient's payer, following up with payers and providers to secure authorization, and billing patients, payers, and the facility. Because most retail pharmacies collect payment as they dispense medications, they may not face the same challenges.

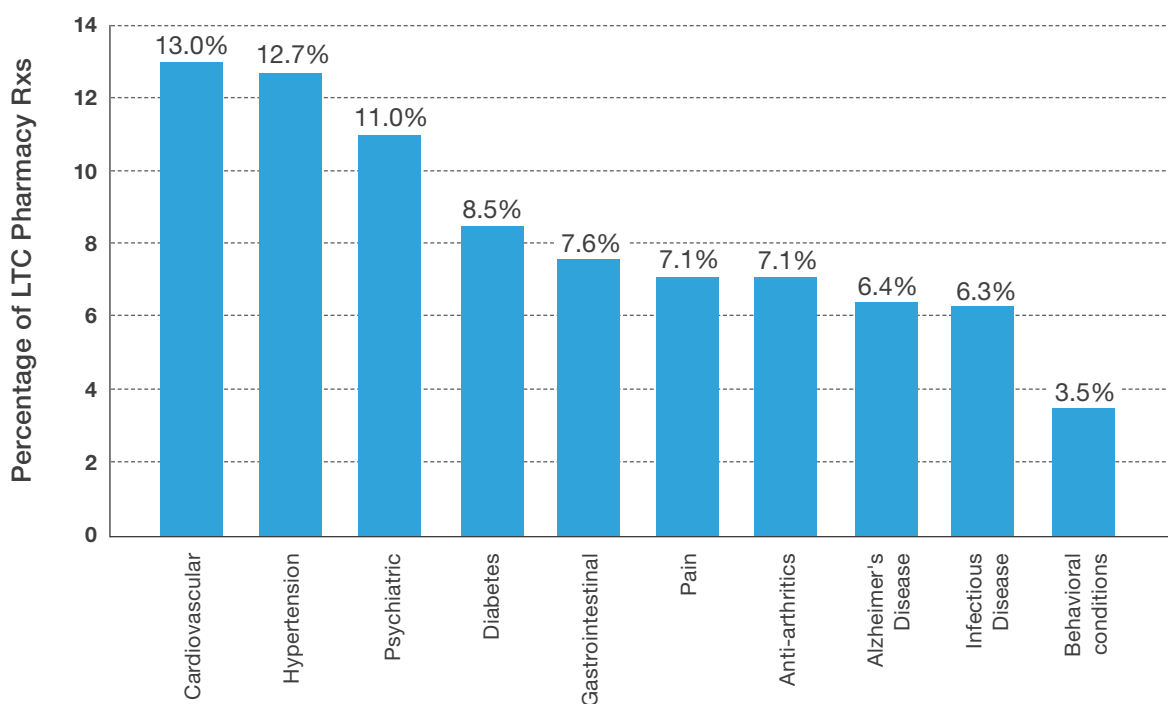
Along with dispensing medications, LTC pharmacies must provide a wide array of products and services. These products and services include: drug regimen reviews, specialized packaging, emergency back-up systems, medication pass observation, 24-hour pharmacist availability, training and consulting services to patients and care teams, and medication delivery, records, disposal, and treatment carts.¹ In the most recent report on these services, which CMS commissioned in 2004 to help prepare for implementation of Part D, the estimated costs to provide these services to a 100-bed SNF were \$3,150–\$7,930.¹ Based on interviews with LTC pharmacies, the costs associated with these services have increased significantly since 2004. For example, interviewees estimate that the cost of providing emergency back-up systems alone has increased eight- to nine-fold.

STATE OF THE LTC PHARMACY SECTOR

The aging population is increasing the demand for geriatric care and geriatric and LTC pharmacy services, and these pharmacies serve higher acuity, sicker patient populations with more complex conditions. In 2015, 47.8 million adults are aged 65 and older in the U.S.; by 2035, that number is expected to rise to 79.2 million (an increase of 66 percent).¹⁸ Elderly patients are more likely to be in poor health and require more medications than younger patients.¹⁹ Nearly 92 percent of older adults have at least one chronic condition, and 77 percent have at least two.²⁰ Further, a 2015 study conducted by a GPO representing over 1,100 independent LTC pharmacies found that its LTC pharmacy members dispensed an average of 12 prescriptions per resident per month, or 144 prescriptions per resident annually.⁴ In contrast, a 2013 study found that retail

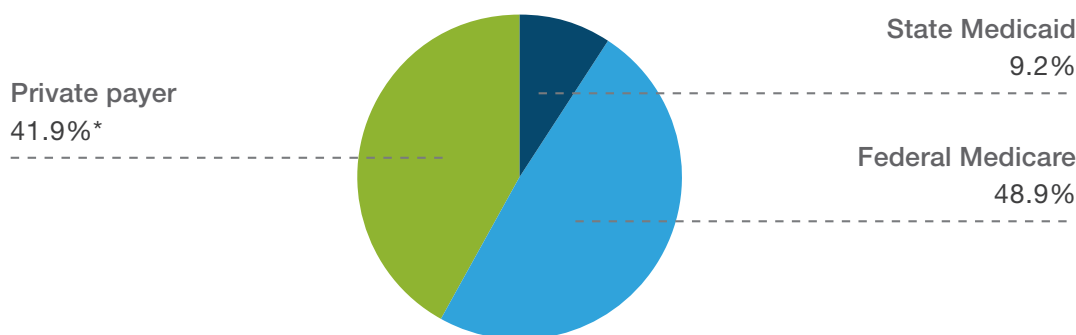
and mail order pharmacies dispensed an average of 28 prescriptions per consumer per year (or about 2.3 per month) among consumers 65 years and older.²¹ **Figure 7** illustrates the top 10 conditions for which LTC pharmacies dispense prescriptions and the relative distribution of prescriptions dispensed across these conditions.

Figure 7: Most Common Conditions for Which LTC Pharmacies Dispensed Prescriptions in 2013³



As the population ages and more individuals enroll in Medicare, the number of Medicare beneficiaries served by LTC facilities and their LTC pharmacies is increasing. Medicare represents the largest payer for LTC pharmacy, specifically Medicare Part D. As shown in **Figure 8**, in 2015, Medicare Parts B and D accounted for nearly half of all LTC pharmacy industry revenue, with a substantial majority from Medicare Part D and to a lesser extent Medicare Part B. Medicare Part A is also an important payer. Under a Part A stay, the nursing facility pays for LTC pharmacy services.² Based on interviews with LTC pharmacies, private payment is minimal compared to Medicaid and Medicare payments, whether direct (Part B and D) or indirect (Part A and patient copays).

Figure 8: LTC Pharmacy Sector Segmentation by Payer Type²



*The IBISWorld report defines “Federal Medicare” as Medicare Parts B and D. LTC pharmacies also receive payments from SNFs that are reimbursed by Medicare Part A (see **Figure 5**).

The reason for the discrepancy between interviewees and **Figure 8** is due to the classification of Medicare Parts A, B, and D payments. Since Medicare Parts B and D pay LTC pharmacies through non-provider intermediaries (e.g., PDPs), those payments comprise the federal Medicare percentage of 48.9%. However, since Medicare Part A provides a payment directly to SNFs, which then reimburse LTC pharmacies, IBISWorld classified these payments as “private payer.” Accordingly, employing a different methodology that summed Medicare Parts A, B, and D payments would demonstrate that LTC pharmacies rely overwhelmingly on Medicare for their revenues.

Potential Medicare payment reductions, PBM pricing practices, convenience access rules that favor large players in negotiations, and downward pressures on reimbursement under new payment and delivery models advanced by health reform increasingly threaten the viability of LTC pharmacies, particularly independent LTC pharmacies.² Despite the higher demand for LTC pharmacy products and services driven in part by the increase in Medicare beneficiaries, falling Medicare reimbursements in recent years (e.g., due to the growth of generic usage, the recent spike in the cost of generics, and various PBM practices including MAC pricing) have caused the industry to experience significant revenue loss in 2012 and 2013.² IBISWorld, an industry analysis and research firm, estimated an annual decline in revenue by one percent between 2010 and 2015.²

These reductions in Medicare reimbursement are compounded by the dual phenomena of increasing use of generics and significant lag between updating MAC pricing to reflect generic drug acquisition costs.^{22, 23} Between July 2013 and July 2014, the median increase in drug acquisition costs was 11.8 percent and almost 10 percent of generic drugs increased by more than 100 percent during this period.²³ The rising costs of generic drugs adds financial pressure to independent LTC pharmacies, especially when these pharmacies are unable to negotiate higher MAC reimbursement rates with PBMs and drug plans.²⁴

LTC Pharmacy Sector Consolidation

As policymakers and payers focus on managing drug spend, LTC pharmacies are consolidating to safeguard revenues and increase their market share.²⁵ Greater consolidation can be beneficial when creating efficiencies of scale (e.g., streamlined administrative processes) that lead to lower prices for payers and consumers. However, interviews with independent LTC pharmacies indicate they believe vertical and horizontal consolidation has decreased price competitiveness and transparency.

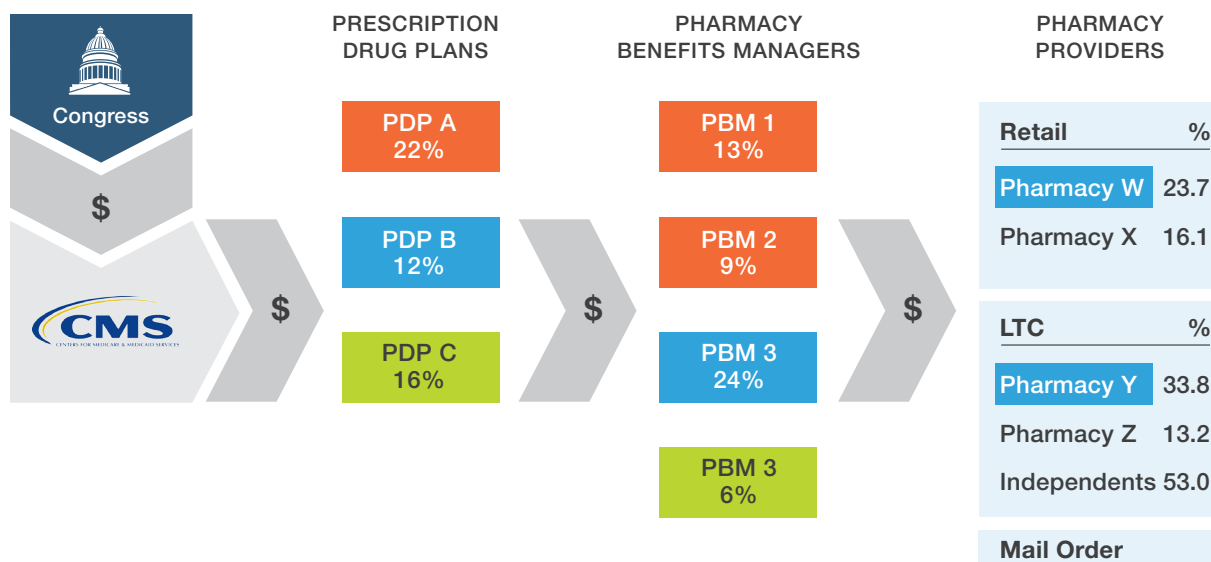
The LTC pharmacy sector includes two large, publicly traded companies that account for nearly half of the industry revenue (33.8 percent and 13.2 percent, respectively).² These two companies operate in nearly every state, while the third-largest industry player operates in 11 states and accounts for only about 2 percent of industry revenue.² More than 1,000 independent LTC pharmacies represent the remaining 53 percent of the market.

Over the last several years, the two largest publicly traded companies have expanded the scope and scale of their operations through acquisitions.² In 2011, the largest company attempted a hostile takeover of the second-largest LTC pharmacy company, but the Federal Trade Commission blocked the acquisition on antitrust grounds.² Independent LTC pharmacies are also consolidating, with increasing government regulation and declining reimbursement cited as the primary drivers.²⁶ More recently, CVS Health has acquired the largest LTC pharmacy company to increase its access to older, sicker Americans and to build on its specialty pharmacy services.²⁷ Along with its Medicare Part D plan (SilverScript), its PBM (Caremark), and its specialty pharmacy, CVS Health will expand its ability to provide prescriptions to patients in ALFs and SNFs.

Companies that consolidate, both horizontally and vertically, may increase their negotiating power with payers and providers. The Federal Trade Commission distinguishes between beneficial, neutral, and harmful horizontal integration, wherein integration that eliminates competition is harmful, because the larger company may command higher prices in particular geographic areas.²⁸ In the context of LTC, SNFs often contract with a single LTC pharmacy for the provision of drugs and consulting services.²⁹ As a result, horizontal integration may reduce the number of LTC pharmacy options in a market, potentially leading to higher prices for SNFs and/or PBMs.²⁹ Likewise, harmful vertical integration can increase barriers to entry in the market and also lead to greater pricing power.³⁰ In the LTC pharmacy sector, vertically integrated companies own subsidiaries at multiple levels of the revenue chain, from PDPs and PBMs to retail, specialty, and now LTC pharmacies (**Figure 9**). As a result, independent LTC pharmacies believe these vertically integrated companies may have incentives to provide more favorable

reimbursement, either in price or reimbursement methodology, to their subsidiaries versus other, unaffiliated companies. Vertically integrated companies have also received some public criticism outside of independent LTC pharmacies.³¹

Figure 9: PDP, PBM, and Pharmacy Relationships^{*2, 10, 32}



*Percentages indicate market shares within each respective industry segment. Colored boxes indicate subsidiary relationships across companies.

Interviews with independent LTC pharmacies suggest only the two largest LTC pharmacy companies have volume sufficient to negotiate directly and consistently with PDPs and PBMs.^d Although most independent LTC pharmacies participate in GPOs or pharmacy services administrative organizations to help with negotiations, these groups typically have less bargaining power than the larger companies. Some independent LTC pharmacies negotiate with PDPs and PBMs individually, with even weaker negotiating power than GPOs. Ultimately, disparities in negotiating power may affect the pricing methodologies or other terms of their contracts.

Independent LTC pharmacies maintain that disparities in negotiating power are due in significant part to the convenient access requirement in Medicare Part D, which CMS intended to ensure network adequacy among beneficiaries.³³ Under convenient access, PDPs must ensure their networks have a sufficient number of pharmacies to dispense drugs directly to patients (other than by mail order), including LTC pharmacies for

^d The largest LTC pharmacy company (accounting for 33.8 percent of the LTC pharmacy market) was acquired by one of the largest retail pharmacy companies, which also has a PDP and PBM.

Part D enrollees residing in LTC facilities.³³ For retail pharmacy access, CMS maintains specific and quantifiable standards that each Part D plan must satisfy, including precise geographic distances between beneficiaries and pharmacies. In contrast, the network adequacy standards for LTC pharmacies are subjective, which makes assessing a PDP's attestation of network adequacy harder to evaluate.³² As a result, advocates believe the lack of specificity in determining network adequacy means plans may assert that they satisfy the convenient access requirement while excluding independent LTC pharmacies from their networks.²

Larger LTC pharmacies may also secure more favorable reimbursement from Medicare Part D plans by negotiating directly with PBMs, manufacturers, and wholesalers. These pharmacies appear able to avoid certain reimbursement methods and instead utilize more consistent ones.^{34, 35} As a result, larger pharmacies command higher profit margins than the sector average, despite pressures to reduce costs from government agencies and healthcare providers.² Interviews with independent LTC pharmacies suggest that they do not have the same bargaining power but must still offer similar services to remain competitive, without commensurate reimbursement from PBMs. Less negotiating power and fragmented market shares amplify the negative effects of existing payment and regulatory policies on independent LTC pharmacies.

LTC PHARMACY POLICY ISSUES AND CHALLENGES

Despite the breadth of services and value provided by LTC pharmacies to LTC facility residents, they face a number of federal policy and related market challenges that threaten their sustainability. The most significant issues confronting LTC pharmacies (and, depending on the specific issue, all pharmacies) are:

1. Part D plan policies and practices, particularly MAC pricing for generic medications and changes in dispensing fees;
2. Subjective network adequacy standards under Part D;
3. Restrictions on prescribing and dispensing controlled substances in the LTC setting;
4. FDA repackaging guidance; and
5. The shift to value-based payment and delivery models.

1. Part D Plan Policies and Practices

A. Maximum Allowable Cost Pricing

The majority of drugs dispensed by LTC pharmacies are generics, and PBMs reimburse for these drugs using MAC pricing under Medicare Part D. MAC pricing establishes a total reimbursement limit that a plan will pay for particular dosages and strengths of drugs. Most often, payers use MAC pricing to reimburse for generics. The limit applies regardless of the manufacturer's version of the generic, and is intended to help contain the costs of these drugs. However, no standard definition of MAC prices exists and most MAC pricing lists are not publicly available, which limits transparency in the calculation and updating of MAC prices. As a result, MAC prices have little relationship to the acquisition cost of generic drugs.¹⁰

Individual PBMs establish MAC pricing lists, with variable processes for setting and updating them. Interviews with LTC pharmacies indicate that the lack of transparency increases the difficulty of tracking the drugs on each PBM's list, the timing of price updates relative to acquisition costs, and the market rationale for changes in pricing, including the degree of the change. Further, PBMs do not always promptly update MAC prices after a change, which can lead to pharmacies paying the manufacturer more for a drug than the reimbursement provided.³⁶

The lack of MAC pricing transparency and the low MAC pricing reimbursements for pharmacies is an issue across both the retail and LTC pharmacy sectors. However, due to higher dispensing costs, these issues may be more significant for LTC pharmacies than retail pharmacies. To mitigate this issue, the largest LTC pharmacy has converted a significant portion of its MAC-based reimbursement to AWP contracts to “soften the blow of the unpredictable timing of ‘MAC clauses’ by PBMs.”^{34, 35} In contrast to MAC pricing, AWP is a more transparent and predictable list-price benchmark that is used across many pharmaceutical transactions.¹⁰ While retail drug chains and other LTC pharmacies are attempting to follow the same strategy and migrate to AWP contracts, interviews suggest many of the independent LTC pharmacies, even those participating in GPOs, lack the market power to negotiate such contracts, and this leaves them vulnerable to variable and volatile MAC pricing.

Recently, federal and state lawmakers have started to address the need for MAC pricing transparency. In the Contract Year 2015 Final Rule for Medicare Advantage and the Medicare Prescription Drug Benefit Programs, CMS finalized its proposal to add MAC prices to the list of prescription drug pricing standards that may be used by PBMs to reimburse network pharmacies starting on January 1, 2016.³⁶ CMS also finalized a requirement for PBMs to disclose any updates to MAC prices to network pharmacies in advance of their use for the reimbursement of claims.³⁶ However, in providing further

guidance to the PDPs/PBMs for calendar year 2016, CMS did not require plans to send this enhanced information to network pharmacies in electronic formats, which would have enabled pharmacies to incorporate the data into information management systems in a timely fashion. As a result, the disclosure requirement may have limited utility. In addition to federal action, over 15 states, including most recently Ohio, have enacted similar MAC transparency laws, which require PBMs to disclose the sources used to determine the MAC pricing, to update MAC lists every seven business days, and to exclude dispensing fees from the MAC pricing calculations.^{10, 37, 38}

A pending federal effort is H.R. 244, the MAC Transparency Act, introduced by Rep. Doug Collins (R-GA) and Rep. Dave Loebsack (D-IA) in January 2015. H.R. 244 aims to expand MAC pricing transparency but also transparency for all pricing models by requiring PBMs to disclose “the sources used for making any update of the prescription drug pricing standard, and if the source for such a standard is not publicly available, disclose to such pharmacies all individual drug prices to be updated in advance of their use for the reimbursement of claims.”³⁹ Further, H.R. 244 would establish an appeals process to investigate and resolve disputes regarding individual drug prices that are less than the pharmacy’s acquisition price for the drug.³⁹

The retail and LTC pharmacy sectors are advocating for initiatives such as H.R. 244 for increased MAC pricing transparency. Interviews suggest that reducing the volatility of MAC prices is of greater urgency to retail and LTC pharmacies alike. Advocates for regulating MAC pricing argue that PBMs should be held accountable for releasing their updated MAC pricing lists in a timely manner as well as sharing their calculations with payers and pharmacies. Increasingly, they also are arguing for greater oversight and structure to payments for generic medications under Part D, such that prices more accurately reflect actual acquisition costs of medications and the costs of professional services necessary to comply with state legal and regulatory requirements.

B. Dispensing Fees and Short-Cycle Dispensing

As part of the Affordable Care Act, CMS expanded the use of short-cycle dispensing—defined as dispensing less than a 30-day supply of medications at a time—for solid oral, brand-name drugs dispensed by LTC pharmacies for Medicare Part D beneficiaries residing in SNFs.⁴⁰ The goal of short-cycle dispensing is to reduce medication waste and overutilization compared with the prior standard of dispensing all drugs in 30-day supplies. Notably, short-cycle dispensing only applies to pharmacies that dispense medications to beneficiaries in LTC facilities. Retail pharmacies do not have a similar requirement.

In response to this short-cycle dispensing policy, CMS acknowledged that “some of the largest PBMs” adjusted the dispensing fees paid to LTC pharmacies.⁴¹ The plans and CMS both assumed that dispensing a smaller amount of medication would decrease the total dispensing costs as compared to the costs for dispensing the normal 30-day amount.⁴² However, LTC pharmacies have not realized this proportional reduction in dispensing costs as reflected in the adjusted dispensing fee they receive. A 2012 briefing on short-cycle dispensing argues that short-cycle dispensing actually imposes greater operating inefficiencies on LTC pharmacies and doubles the effort and cost to dispense.⁴³

A 2013 study on the costs to dispense prescriptions among 64 independently owned LTC pharmacies found that the median cost to dispense a prescription in a 30-day cycle was \$13.54. Researchers also found that converting to 14-day cycles reduced the median cost to dispense to \$11.63 (a decrease of \$1.91 per prescription).⁸ While this is not an insignificant decrease in the cost to dispense a prescription, this decrease is outweighed by the additional 14-day prescription that pharmacies need to fill to cover a comparable number of days as a single 30-day dispensing cycle. Thus, the median cost to dispense about 30 days of medication in two 14-day cycles was \$23.26, while dispensing a single 30-day cycle cost only \$13.54.⁸ The shorter dispensing cycle results in a slight reduction in dispensing costs mainly because of the difference in packaging materials. However, interviews with various LTC pharmacies indicate that the labor cost of LTC pharmacy staff reviewing and delivering the prescription is the same as a 30-day supply. Under short-cycle dispensing, the LTC pharmacy must dispense and deliver multiple prescription packs to cover the same number of days, compounding already inadequate dispensing fees to account for the actual costs to dispense.

The short-cycle dispensing provision in the Affordable Care Act created incentives for PBMs to prorate dispensing fees to LTC pharmacies.⁴⁴ This change created further financial strain on LTC pharmacies, and the industry advocated for banning proration. In February 2015, CMS finalized its Medicare Part D rule, which prohibits the use of prorated dispensing fees to ensure LTC pharmacies receive appropriate reimbursement for the costs of filling prescriptions (i.e., the full dispensing fee associated with a 14-day supply even if the patient only received the prescription for less than 14 days). This final regulation is scheduled to take effect in January 2016. While this regulation will reduce the financial strain caused by proration of dispensing fees, interviewees say it does not overcome the added costs borne by LTC pharmacies under short-cycle dispensing. In addition, it is unclear as of this writing whether PBMs that had used prorated dispensing fees will attempt to use differing dispensing fees in a manner designed to be consistent with the new regulation or if CMS will deem the attempts compliant with the new regulation. In interviews, LTC pharmacies express concern that they will still be negatively affected by short-cycle dispensing reimbursement amounts even after the modified Medicare Part D final regulation takes effect in 2016.

2. Subjective Network Adequacy Standards Under Part D

As required by the Medicare Prescription Drug Improvement and Modernization Act of 2003, PDPs must demonstrate network adequacy by providing residents of LTC facilities convenient access to any willing LTC pharmacy.⁴⁵ Willing pharmacies need to agree on standard contract terms and conditions, including payment rates, with the PDP.³³ In guidance, CMS defines convenient access as requiring PDPs to attest that residents of LTC facilities “routinely receive their Part D benefits through the plan’s network of pharmacies... not rely[ing] on the out-of-network benefit.”⁴⁶ These requirements are far less stringent than those established for retail pharmacies, which specify the percentage of beneficiaries who must live within a certain number of miles from a pharmacy in urban, suburban, and rural areas. For example, at least 90 percent of beneficiaries must live within two miles of a network pharmacy in urban areas.³³ No similar quantifiable standard exists for LTC pharmacies.

Advocates for independent LTC pharmacies suggest that the absence of explicit standards for LTC pharmacies means that PDPs can exclude independent pharmacies from their networks and still claim that they satisfy the network adequacy requirements. The risk of exclusion increases downward pressure on reimbursement during negotiations, with interviewees stating that they need to decide between potentially unsustainable reimbursement levels and no reimbursement at all. This outcome appears contrary to the objective of CMS when establishing network adequacy requirements for LTC pharmacies. Specifically, the requirements are to ensure “all long-term care pharmacies in a region will have to negotiate with as many Part D plans as possible or risk losing this business to another more competitive long-term care pharmacy.”⁴⁷ However, instead of driving competition between LTC pharmacies, advocates for independent LTC pharmacies argue that the subjective network adequacy requirements have given substantial leverage to PDPs to offer take-it-or-leave-it prices and terms. When prices are unsustainable, beneficiaries and SNFs may have fewer options when selecting LTC pharmacies in the long run.

3. Restrictions on Prescribing and Dispensing Controlled Substances in the LTC Setting

In some instances, physicians prescribe nursing facility patients controlled substances, which are regulated under the Controlled Substances Act (the Act) under the authority of the Drug Enforcement Agency (DEA).¹ However, Schedule II Controlled Substances, which include narcotics and stimulants such as oxycodone and amphetamines, have a high potential for abuse. Under the Act, only those practitioners who are registered with the DEA may dispense drugs that are on the DEA’s list of controlled substances. Those drugs may only be dispensed with a written prescription, unless the situation is

an emergency or the drug is being dispensed directly by the practitioner.⁴⁸ CMS has also implemented other initiatives to address the overutilization and off-label use of other types of medications, such as antipsychotics.^e

For LTC residents, the Act has become a barrier to accessing both routine and emergency prescriptions in a timely manner because it restricts the prescribing and dispensing of controlled substances to a select subset of LTC facility staff.^{49, 50} Both LTC providers and pharmacies have advocated for amending the Act to recognize nurses working in LTC facilities as agents of the prescriber and to be able to prescribe and dispense controlled substances.⁴⁹ Further, allowing chart orders to be used as prescription orders would remove an additional barrier to timely dispensing and administration for LTC patients.⁴⁹ LTC pharmacies must have a physician's prescription before dispensing these drugs, but physicians do not always send the prescription at the same time as the order provided to the SNF. This lag can create delays in treatment. The Nursing Home Resident Pain Relief Act of 2011 was intended to amend the Controlled Substances Act to overcome these barriers.⁵¹ If enacted, advocates believe the Act would have enabled LTC facilities to comply with important drug abuse prevention policies without impeding their ability to deliver high-quality care to their residents.⁵¹ The Act was introduced to the Senate Judiciary Committee by Sen. Herb Kohl (D-WI) but did not advance out of committee. No further legislation has addressed this problem.

4. FDA Repackaging Guidance

The FDA's Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities, issued in February 2015, proposed limiting the ability for pharmacies to repackage and deliver drugs in advance of a specific patient's prescription.⁵² Repackaging prescriptions includes taking a finished product from the manufacturer's container and placing it in a different one or combining the contents of multiple containers of the same drug into a single container.⁵² Although this draft guidance resulted from issues surrounding compounding pharmacies and responsive legislation enacted in 2013, it nonetheless appears to apply to all pharmacies, including LTC pharmacies.⁵³ However, application to LTC pharmacies would create significant patient safety issues for LTC facility residents, and may create compliance issues for SNFs.⁵⁴

LTC pharmacies often put medications obtained from wholesalers in special packaging to cater to the specific needs of their residents, to reduce medication errors, to allow the resident to obtain their medications through their own pharmacy benefit plan, and to

e Initiatives include a goal to decrease the off-label use of antipsychotics by 15 percent in SNFs by December 2012 and the National Partnership to Improve Dementia Care. Together these initiatives have decreased antipsychotic medication use nationally for the treatment of dementia by 15 percent.⁴²

maintain emergency and remote dispensing supplies of prescription drugs.^{52, 55, 56} For example, LTC facilities often require LTC pharmacies to make available “unit of use packaging, bingo cards, cassettes, or unit doses” of prescription drugs for timely delivery to their residents and to comply with state requirements for emergency supplies of medications in the facilities.⁵⁵ In addition, LTC pharmacies often alter drug delivery formulations to allow patients who cannot swallow large pills to intake them as split or crushed pills.⁵⁵ Current repackaging practices enable LTC pharmacies to meet these state and facility packaging requirements in a timely manner, and to use methods and practices that substantially reduce the risk of medication errors.

The FDA's draft guidance fails to recognize the unique operations of LTC pharmacies surrounding drug dispensing and repackaging to support LTC facilities and their residents. Via a comment letter, various trade associations and LTC pharmacies recommended that the FDA revise its draft guidance to accommodate LTC pharmacies serving institutional healthcare providers. Specifically, LTC pharmacies asked FDA to allow them to create emergency supplies of medications, to be exempted for remote dispensing equipment, and to repackage drugs that are not distributed to the public.⁵⁵

5. The Shift to Value-Based Payment and Delivery Models

CMS is in the process of transitioning much of fee-for-service Medicare to new payment and delivery models, including ACOs and bundled payments; and tying traditional fee-for-service to value-based care under a series of mandatory programs for hospitals, physicians, and post-acute care/LTC (e.g., the Hospital Readmissions Reduction Program). The Secretary of Health and Human Services intends for these models and programs to achieve the explicit goals for Medicare fee-for-service payments that the Department announced in January 2015. Specifically, the Secretary set goals to have 50 percent of all payments made through alternative payment models and 90 percent of traditional Medicare payments linked to quality and value in 2018.⁵⁷

This transition to value-based care is transforming relationships between acute and post-acute providers, including SNFs. Hospitals have higher expectations around quality and efficiency, including shorter length of stay, discharging to less costly settings, fewer readmissions, and greater interest in five-star ratings. These expectations will translate to post-acute and LTC providers, as they aim to demonstrate high-quality, efficient care to be part of hospital preferred provider networks. In addition, CMS is creating direct incentives for SNFs to improve. As mandated by the Protecting Access to Medicare Act of 2014, CMS must establish a mandatory SNF Value-Based Purchasing program that will affect payments beginning in FY 2019.⁵⁸ CMS has only started to detail the parameters of the program, but has finalized inclusion of a 30-day all-cause readmission measure.⁵⁹

Voluntary initiatives also have the potential to affect the interaction between post-acute/LTC providers and LTC pharmacies. For example, Models 2 and 3 of the Bundled Payments for Care Improvement initiative, which encompass episodes in post-acute care settings, include over 1,700 participating providers.⁶⁰ As these providers enter into the risk-bearing phase of the program, they will seek opportunities to decrease Medicare Part A and B spending for their chosen episodes of care. In addition, among the first two rounds of Medicare Shared Savings Program ACOs, researchers found that “the most significant decrease in total spending... occurred in skilled nursing facility expenditures.”⁶¹

As a result of this new dynamic, SNFs are focused on developing and refining key capabilities to succeed in the changing healthcare environment, including:

- Managing clinical care based on evidence;
- Demonstrating quality and value;
- Developing capabilities to manage risk;
- Cultivating health plan relationships; and
- Fostering provider relationships and integration.

LTC pharmacies serve a critical role in facilitating efficient, high-quality outcomes in the SNF. Some of these services include patient counseling and engagement, medication management, drug regimen review, generic substitution, provider education, and regulatory compliance. As SNFs face increasing pressures from hospitals and payers, they will evaluate LTC pharmacies in their market, preferring those that help them meet their cost and quality objectives.

CONCLUSION

LTC pharmacists are an essential provider for the aging population residing in LTC facilities. Their clinical skills in concert with regulatory and operational knowledge provide them with a unique set of capabilities to serve this vulnerable patient population. As baby boomers age, the population over 85 will grow by nearly 90 percent over the next 20 years. Past trends indicate that these seniors' needs for medications and related services will grow.

LTC pharmacies have demonstrated the expertise to meet these needs and ensure that elderly patients receive the right medications at the right time. However, independent pharmacies are struggling under new policies and the prevailing reimbursement method. Policymakers and researchers should ensure that LTC pharmacies receive appropriate reimbursement for the medications and services they provide. Without that support, payers and providers will have fewer options when seeking LTC pharmacy partners.

Policymakers should consider these questions when evaluating avenues to improve the LTC pharmacy sector:

1. How can the federal government best regulate MAC pricing to ensure maximum transparency, with useful data available in real time for LTC pharmacies?
2. What other pricing models might be better suited for LTC pharmacies?
3. What reimbursement changes are required to sustain the host of services provided by LTC pharmacies within the payments they receive?
4. What are the implications of greater horizontal and vertical consolidation on patient outcomes and Medicare expenditures?
5. How can LTC pharmacists be properly compensated for the clinical and regulatory activities they perform in the LTC-only setting?
6. What role can LTC pharmacies play in the new and emerging payment and delivery models for post-acute/LTC?

METHODOLOGY

The Senior Care Pharmacy Coalition retained Avalere Health to prepare an overview of the LTC pharmacy sector. Avalere undertook a structured literature review as well as a series of interviews. To conduct the literature review, Avalere completed a comprehensive scan of:

- Reports and issue briefs from trade associations and research firms;
- Centers for Medicare & Medicaid Services reports, briefs, and rules;
- Publicly available industry reports;
- Academic literature; and
- Federal regulations.

The research brief includes data and information from 61 sources. Avalere also conducted five structured interviews with representatives from independent LTC pharmacies.

REFERENCES

1. *CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services: Long-Term Care Pharmacy Primer*. (The Lewin Group, 2004). <<http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/LewinGroup.pdf>>
2. *Institutional Pharmacies in the US: Market Research Report*. (IBISWorld Inc., 2015). <<http://www.ibisworld.com/industry/institutional-pharmacies.html>>
3. *Public Payer Digest 2014*. (SANOFI, 2014). <<https://www.managedcaredigest.com/pdf/PublicPayer.pdf>>
4. *Group Purchasing Organization's LTC Pharmacy Member Study*. (2015).
5. *Long Term Care Guidance*. (Centers for Medicare & Medicaid Services, 2005). <<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf>>
6. *Becoming a Long-Term Care Pharmacy: Opportunities and Important Considerations*. (McKesson, 2015).
7. 42 CFR §423.100 Definitions. <<http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol3/CFR-2011-title42-vol3-sec423-100>>
8. Carroll, N.V., Rupp, M.T. & Holdford, D.A. Analysis of costs to dispense prescriptions in independently owned, closed-door long-term care pharmacies. *J Manag Care Spec Pharm* 20: 291-320, (2014).
9. Anthony, L. *Grappling with the Long-Term Care Market*. (Pharmaceutical Commerce, 2012). <http://www.pharmaceuticalcommerce.com/index.php?pg=brand_communications&articleid=26622&keyword=LTC-long-term%20care-healthcare>
10. Fein, A. *2014-15 Economic Report on Retail, Mail, and Specialty Pharmacies*. (Pembroke Consulting, Inc., 2015).
11. 42 CFR §483.60 Pharmacy Services. <http://www.ecfr.gov/cgi-bin/text-idx?SID=2eba3a0a15212180f771ef34f7f3813e&mc=true&node=se42.5.483_160&rgn=div8>
12. *ASCP Fact Sheet*. (The American Society of Consultant Pharmacists, 2015). <<https://www.ascp.com/articles/about-ascp/ascp-fact-sheet>>
13. 42 CFR §483.20 Resident Assessment, §483.25 Quality of Care, and §483.60 Pharmacy Services.
14. *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*. (Centers for Medicare & Medicaid Services, proposed rule, 2015). <<http://www.gpo.gov/fdsys/pkg/FR-2015-07-16/pdf/2015-17207.pdf>>
15. *Study Finds Long-Term Care Pharmacies Face Higher Dispensing Costs; Must Meet Specialized Needs*. (National Community Pharmacists Association, 2013). <<http://www.ncpanet.org/newsroom/news-releases/news-releases---2013/2013/02/22/study-finds-long-term-care-pharmacies-face-higher-dispensing-costs-must-meet-specialized-patient-needs>>
16. Stevenson, D., Huskamp, H. & Newhouse, J. *Medicare Part D, Nursing Homes, and Long-Term Care Pharmacies*. (Harvard Medical School, 2007). <<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=11160>>
17. Bradbury, S. *Independent pharmacies focus on local ties to battle competitors, benefit manager cost cutting*. (Chattanooga Times Free Press, 2014). <<http://www.timesfreepress.com/news/business/aroundregion/story/2014/mar/02/independent-pharmacies/132965/>>
18. Table 3. Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060. *2014 National Population Projections: Summary Tables*. (United States Census Bureau, 2015). <<https://www.census.gov/population/projections/data/national/2014/summarytables.html>>
19. Fu, A.Z., et al. Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly. *Med Care* 45: 472-476 (2007).
20. *Chronic Disease Self-Management Fact Sheet*. (National Council on Aging, 2014). <<http://www.ncoa.org/improve-health/center-for-healthy-aging/content-library/CDSMP-Fact-Sheet.pdf>>
21. *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*. (IMS Institute for Healthcare Informatics, 2014).
22. *Why Are Reimbursement Rates Such a Trouble For Walgreen And Other Drugstore Chains?* (Trefis, 2015). <<http://www.trefis.com/stock/wag/articles/281443/why-are-reimbursement-rates-such-a-trouble-for-walgreen-and-other-drugstore-chains/2015-02-24>>
23. Fein, A. Retail Generic Drug Inflation Reaches New Heights. *Drug Channels* (2014). <<http://www.drugchannels.net/2014/08/retail-generic-drug-inflation-reaches.html>>
24. Hoey, B.D. *Generic drug costs rise - Congress asks why*. (2014). <<http://thehill.com/blogs/congress-blog/healthcare/224420-generic-drug-costs-rise-congress-asks-why>>
25. Lachapelle, T. *Omnicare at Almost \$10 Billion Still Worth It for CVS: Real M&A*. (2015). <<http://www.bloomberg.com/news/articles/2015-04-23/omnicare-at-almost-10-billion-still-worth-it-for-cvs-real-m-a>>
26. Oliver, G. *Vancouver specialty pharmacy sold*. (The Columbian, 2015). <<http://www.columbian.com/news/2015/mar/19/vancouver-specialty-chs-pharmacy-sold/>>

27. Cyran, R. *CVS to expand pharmacy business with \$10.1 billion Omnicare buy*. (2015). <<http://www.reuters.com/article/2015/05/21/us-omnicare-m-a-cvs-health-idUSKBN00619T20150521>>
28. *Horizontal Merger Guidelines*. (U.S. Department of Justice and the Federal Trade Commission, 2010). <<https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf>>
29. Leibowitz, J., et al. *In the Matter of Omnicare, Inc. a corporation*. (Federal Trade Commission, 2012). <<https://www.ftc.gov/sites/default/files/documents/cases/2012/01/120127omnicareadmincmpt.pdf>>
30. *Non-Horizontal Merger Guidelines*. (U.S. Department of Justice and the Federal Trade Commission, 2015). <<http://www.justice.gov/atr/non-horizontal-merger-guidelines>>
31. Pearlstein, S. Stop the pharmacy consolidation train. *Washington Post* (2011). <http://www.washingtonpost.com/business/economy/steven-pearlstein-stop-the-pharmacy-consolidation-train/2011/12/06/gIQA7POIO_story.html>
32. Hoadley, J., Summer, L., Hargrave, E., Cubanski, J. & Neuman, T. *Medicare Part D in Its Ninth Year: The 2014 Marketplace and Key Trends, 2006-2014*. (Kaiser Family Foundation, 2014). <<http://kff.org/medicare/report/medicare-part-d-in-its-ninth-year-the-2014-marketplace-and-key-trends-2006-2014/>>
33. 42 CFR §423.120.
34. Valiquette, S. *Heightened Risk Factors Seem Baked In Guidance*. (UBS, 2014).
35. *Omnicare, Inc. Form 10-K*. (United States Securities and Exchange Commission, 2015). <<http://www.sec.gov/Archives/edgar/data/353230/000035323015000010/0000353230-15-000010-index.htm>>
36. 79 FR 100 (May 23, 2014), 29882-5.
37. *States With Maximum Allowable Cost (MAC) Transparency Enacted*. (National Community Pharmacists Association). <<http://www.ncpa.co/pdf/mac-states-map.pdf>>
38. Brown, T. *MAC Transparency Legislation*. 3901 (2015). <<https://www.legislature.ohio.gov/legislation/legislation-summary?id=GA131-HB-127>>
39. Collins, D. *MAC Transparency Act*. (2015). <<https://www.congress.gov/bill/114th-congress/house-bill/244>>
40. *Patient Protection and Affordable Care Act, Section 3310*. (2010).
41. *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs*. (Centers for Medicare & Medicaid Services proposed rule, 2014). <<https://www.federalregister.gov/articles/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the>>
42. *Overview of Short-Cycle Dispensing for Long-Term Care*. (National Community Pharmacists Association, 2012). <<http://www.ncpaltc.org/pdfs/Overview-of-Short-Cycle-Dispensing-for-LTC-June2012.pdf>>
43. *Short Cycle Dispensing - Contracting Policy and Guidelines*. (PharMerica, 2012).
44. Jeffery, S. & Delafuente, J. Re: Docket No. CMS-4159-P - January 10, 2014 Federal Register Notice: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. (American Society of Consultant Pharmacists, 2014). <https://www.ascp.com/sites/default/files/FINAL_ASCP%20Comments%20CY2015%20Part%20D%20Rule_030714.pdf>
45. *H.R. 1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. <<https://www.congress.gov/bill/108th-congress/house-bill/1>>
46. *Long Term Care Guidance*. (Centers for Medicare & Medicaid Services, 2005). <<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf>>
47. *Medicare Program; Medicare Prescription Drug Benefit*. (Centers for Medicare & Medicaid Services final rule, 2005). <<http://www.gpo.gov/fdsys/pkg/FR-2005-01-28/pdf/05-1321.pdf>>
48. *Title 21 United States Code (USC) Controlled Substances Act*.
49. *Prescribing and Dispensing Controlled Drugs in the Long-Term Care Setting*. (American Society of Consultant Pharmacists). <<https://www.ascp.com/sites/default/files/barriers-controlled-meds-leave-behind.pdf>>
50. Sollins, H. *DEA Restates Position on Authorized Prescriber Use of Agents in Long Term Care Facilities*. (Ober Kaler Attorneys at Law, 2010). <<http://www.ober.com/publications/1099-dea-restates-position-authorized-prescriber-use-agents-long-term-care-facilities>>
51. *Nursing Home Residents Pain Relief Act of 2011*. (2011). <<https://www.govtrack.us/congress/bills/112/s1560/text>>
52. *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities: Guidance for Industry*. (Food and Drug Administration, 2015). <<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434174.pdf>>
53. Upton, F. *Drug Quality and Security Act of 2013*. (2013). <<https://www.congress.gov/bill/113th-congress/house-bill/3204>>
54. Rosenbloom, A. Re: Docket No. FDA-2014-D-1524. (Senior Care Pharmacy Coalition, 2015). <<http://seniorcarepharmacies.org/wp-content/uploads/2015/05/FDA-Repackaging-Comment-Letter-May-20-2015.pdf>>

55. Comments on Draft Repackaging Guidance Document. (2015). <<http://www.ncpa.co/pdf/joint-ltc-repackaging-guidance.pdf>>
56. *Repackaging of Medications from Other Pharmacies*. (American Society of Consultant Pharmacists, 2015). <<https://www.ascp.com/articles/repackaging-medications-other-pharmacies>>
57. *Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value*. (U.S. Department of Health and Human Services, 2015). <<http://www.hhs.gov/news/press/2015pres/01/20150126a.html>>
58. *H.R. 4032 Protecting Access to Medicare Act of 2014*. <<https://www.congress.gov/bill/113th-congress/house-bill/4302>>
59. *Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection*. (Centers for Medicare & Medicaid Services final rule, 2015). <<http://www.regulations.gov/#!documentDetail;D=CMS-2015-0047-0056>>
60. *BPCI Initiative Episodes: Details on the Participating Health Care Facilities*. (Center for Medicare & Medicaid Innovation, 2015). <<http://innovation.cms.gov/initiatives/Bundled-Payments/Participating-Health-Care-Facilities/index.html>>
61. Tu, T., Bennion I., and Templin, M. *The Right Care for the Right Cost: Post-Acute Care and the Triple Aim*. (MHA ACO Network and Leavitt Partners, 2014). < http://www.mhainc.com/uploadedFiles/MHAinc/UPLOADED_DOCUMENTS/MHA_LeavittPartnersWhitePaper091814.pdf>

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