Medicare Part D, Nursing Homes, and Long-Term Care Pharmacies

A study conducted by staff from Harvard Medical School for the Medicare Payment Advisory Commission

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FINAL REPORT

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Executive Summary

The Medicare Modernization, Improvement, and Prescription Drug Act of 2003 (MMA) extended voluntary prescription drug coverage to all Medicare beneficiaries, including individuals who reside in nursing homes. Although the program includes some special protections for nursing home residents, Part D's core reliance on private plans to administer the benefit and its emphasis on consumer choice is the same for institutionalized and community-based beneficiaries.

But because of their health needs and the setting in which they receive services, nursing home residents differ from community-dwelling beneficiaries in important ways. Nursing home residents suffer disproportionately from chronic conditions, have higher levels of cognitive impairment, and typically take a higher number of medications than beneficiaries in the community. The nursing home pharmacy market also differs from the community market in its regulatory environment, the important role of long-term care pharmacies (LTCPs), and the prominence of Medicaid financing.

The Medicare Payment Advisory Commission contracted with Harvard Medical School to explore how the introduction of Part D is changing the operations of LTCPs and nursing homes, as well as the implications of those changes for beneficiaries and the Medicare program. Based primarily on stakeholder interviews, the aims of the study were to obtain an early indication of how the Part D benefit is working for nursing home residents and to identify areas for further empirical study.

By some accounts, the transition to Medicare Part D has been a challenging one in the long-term care sector. Although LTCPs, nursing homes and their clinicians, and Part

D plans will gain experience with the benefit, its structure, and how it works in the nursing home setting over time, stakeholders whom we interviewed identified a range of longer-term issues and questions that merit attention as the benefit proceeds.

In sum:

- The overall fit between Part D and the nursing home pharmacy sector is a matter of contention among the stakeholders we interviewed. Many stakeholders characterized the Part D benefit as being a better fit for community-based beneficiaries who access medications in retail pharmacies than for institutionalized beneficiaries.
- Medicare beneficiaries in nursing homes have the same freedom to choose plans as community-based beneficiaries; however, stakeholder interviews highlighted a tension between balancing this freedom-of-choice and allowing nursing home providers to encourage enrollment into plans they perceive to be a better fit with residents' medication needs and that minimize facility and pharmacy administrative burden.
- Part D increased the variation around formularies and drug management processes for residents at the facility level. In general, stakeholder interviews highlighted the tension between cost-saving strategies used by PDPs such as utilization management and the burden these processes can place on clinical and pharmacy staff.
- Formulary coverage appears adequate for many medications used by nursing facility residents, and the special protections required for six medication classes plus Part D transition coverage requirements helped to shield residents from any coverage limitations. However, stakeholders noted what they consider to be important exceptions to overall formulary adequacy for the institutionalized population and

instances where the application of utilization management policies were particularly problematic.

- Empirical analyses are needed to assess the impact of Part D on utilization patterns, outcomes, and quality of care. Noting this important caveat, stakeholders pointed to within-class drug utilization shifts but did not report a change in gross drug utilization. To date, stakeholders have not perceived any adverse impact on resident outcomes or quality of care attributable to Part D.
- Stakeholders indicated that Part D's financial impact on nursing homes is still evolving. Part D altered the relationship between nursing homes and their LTCPs, introducing a tension between facilities' need to dispense medications quickly and LTCPs assuring coverage for those drugs. Nursing homes and LTCPs both have an incentive to minimize prescriptions for non-covered drugs, but how the financial impacts of these costs will be shared by these entities depends on nursing home-LTCP contracting, which will likely continue to vary across providers.
- The impact of Part D on the future competitiveness of the LTCP sector is also evolving. Although the LTCP sector is concentrated, financial analysts with whom we spoke characterized the sector as competitive, with few barriers to entry. The prominent role of Group Purchasing Organizations (GPOs) and LTCP network organizations in particular has helped smaller LTCPs access more favorable pricing from manufacturers and PDPs such that most small LTCPs have joined these organizations.
- Consensus among stakeholders was that LTCP rebates –which seem to have continued to date – would likely decline in future years. CMS has not disallowed

LTCP rebates under Part D, but it has expressed strong reservations about them, raising the possibility that they could constitute fraud and abuse.

- If LTCP rebates decline or disappear, these changes could lead to increased transparency of pricing and perhaps increased price competition. Although reduced rebates would likely have a greater negative impact on larger LTCPs, these entities would still likely maintain certain economies of scale that might be advantageous in terms of service pricing, dispensing costs, and negotiating power.
- A reduction or elimination of rebates also could result in LTCPs passing increased administrative costs or a greater share of costs for items like consultant pharmacist services onto the nursing homes with which they contract.
- PDPs generally did not express a reluctance to have institutionalized enrollees in their plans; however, there seemed to be a level of uncertainty among PDPs about the adequacy of payment and risk adjustment going forward as risk corridors widen. Reassessing the methodology of risk adjustment and possibly making future refinements could be important to ensure adequate availability of plans for dual eligible beneficiaries.

Medicare Part D, Nursing Homes, and Long-Term Care Pharmacies

The Medicare Modernization, Improvement, and Prescription Drug Act of 2003 (MMA) extended voluntary prescription drug coverage to all Medicare beneficiaries, including individuals who reside in nursing homes. Although the program includes some special protections for nursing home residents, Part D's core reliance on private plans to administer the benefit and its emphasis on consumer choice is the same for institutionalized and community-based beneficiaries.

But because of their health needs and the setting in which they receive services, nursing home residents differ from community-dwelling beneficiaries in important ways. Nursing home residents are one of the most vulnerable subgroups in the Medicare program. They are frail, suffer disproportionately from multiple chronic conditions, have higher levels of cognitive impairment, and typically take 6-10 different medications.[1-3] Most have low incomes, and the majority have their nursing home care financed by Medicaid.[4] In addition to these differences at the individual level, the nursing home pharmacy market differs from the community market in its regulatory environment, the important role of long-term care pharmacies (LTCPs), and the prominence of Medicaid financing.[2, 5-8]

Medicare Part D represents a substantial departure from how prescription drugs were previously financed and administered in the nursing home setting. The following report discusses these changes and their implications for nursing home residents, nursing homes and LTCPs. Based primarily on stakeholder interviews, the paper presents an

early snapshot of Part D's financial and clinical impacts and raises issues for further empirical study.

Project and Methods

The Medicare Payment Advisory Commission (MedPAC) contracted with Harvard Medical School to explore how the introduction of Part D is changing the operations of long-term care pharmacies (LTCPs) and nursing homes, as well as the implications of those changes for beneficiaries and the Medicare program. The aims of the study were to obtain an early indication of how the Part D benefit is working for nursing home residents and to identify areas for further empirical study. To achieve these aims, we interviewed stakeholders across a variety of relevant perspectives and reviewed existing sources of information. Unless otherwise noted, qualitative data collected from these interviews provide the basis for the information we present.

A total of 31 semi-structured, telephone interviews were conducted between November 2006 and January 2007. Stakeholder groups from which we collected information included nursing homes (n=6 interviews), LTCPs (n=6), group purchasing organizations/ LTCP networks (n=2), Part D plans (PDPs) (n=4), financial analysts covering the long-term care pharmacy sector (n=3), physicians working in nursing homes (n=4), consultant pharmacists (n=2), state and federal policymakers (n=2), and advocates for nursing home residents (n=2). In many instances, multiple stakeholders participated in the individual interviews. Separate protocols were developed for each of the stakeholder groups, and interviews were generally 30-60 minutes in length. Selection of stakeholders was systematic and, where relevant, sought to maximize representation among Medicare beneficiaries (e.g., efforts were made to interview the larger nursing home chains, long-

term care pharmacies, and PDPs). To examine whether and how perspectives and experience may differ for smaller providers and pharmacies, interviews were also conducted with these types of organizations; however, the findings may be less representative of the range of experience across these smaller entities. In a written consent form distributed prior to each interview and reviewed verbally at each interview's start, interviewees were assured the information provided would not be identified with them individually or organizationally. The study design, protocols, and consent form were all approved by the Committee on Human Subjects at Harvard Medical School.

The report begins with a brief background on the nursing home pharmacy environment and the changes instituted under the MMA. Although this section includes general information about the LTCP sector, the composition and profitability of this sector are covered in more depth in a companion report (see, Appendix, "*Overview of the Long Term Care Pharmacy Industry*"). Relying primarily on stakeholder interviews, this report goes on to describe the impact of Part D in the nursing home and long-term care pharmacy sectors, focusing on plan selection, pharmacy practice across multiple PDPs, and the clinical, administrative, and financial impacts of Part D thus far.

Background

The Nursing Home Pharmacy Market Pre-MMA. Over the last few decades, the nursing home pharmacy environment has been shaped by the extensive drug needs of residents and the complex regulatory environment in which nursing homes operate. Historically, nursing homes have struggled to manage resident drug needs effectively.[5-7]

Recent research suggests that preventable adverse drug events still constitute a substantial problem for nursing homes residents.[9] Reducing medication errors and improving prescription practices have been a focus of previous nursing home reforms, such as the Omnibus Budget Reconciliation Acts (OBRA) of 1987 and 1990. Among other provisions, these reforms established requirements for drug regimen review and the role of consultant pharmacists, documentation of medication errors and adverse drug events, and delivery of pharmacy services to nursing homes more generally.

In part because of these regulatory standards, LTCPs have come to dominate the nursing home pharmacy market. LTCPs not only offer specialized supplies and services mandated by federal law – such as unit-dose packaging, 24-hour drug delivery, emergency drug supplies, and handling unused medications – they have become integrally involved in nursing home pharmacy practice.

Through their consultant pharmacists, LTCPs offer comprehensive drug management services and often coordinate related quality assurance and improvement activities. These services include prospective review of resident drug orders and coordination of prior authorization and medical necessity documentation, in-service trainings for nursing home staff (e.g., on monitoring residents on complex drug regimens, using infusion pumps, and administering IVs), and drug regimen review (e.g., formulating and monitoring medication treatment plans and identifying potential contraindications). While nursing homes can pay retail pharmacies for such specialized services, LTCPs serve more than 80% of all nursing home beds nationwide.[10]

The LTCP market is highly concentrated. Three companies, Omnicare, PharMerica, and Kindred Pharmacy Services (KPS), account for around 60% of the

sector's revenues.[11] Of the three, Omnicare is by far the largest, covering around 850,000 of the nation's 1.7 million nursing home beds (compared to around 220,000 and 100,000 for PharMerica and Kindred, respectively). The remaining nursing home beds are served by smaller local or regional pharmacies (both LTCPs and retail pharmacies). (Exhibit 1)

Historically, most nursing homes – at the facility and chain levels – relied on a single vendor for all pharmacy-related services. Nursing home providers cited several advantages to using a single pharmacy, including increased efficiency, predictability, and standardization. For instance, since LTCPs and their consultant pharmacists typically maintained compliance with a single LTCP formulary, nurses managed fewer medications across residents. Because of this compliance, LTCPs have traditionally secured manufacturer rebates in exchange for preferred placement of drugs on their formulary.[8]

Prior to Part D, residents' drug coverage varied by their payer status. Not surprisingly, Medicaid played a substantial role, financing drugs for the almost two-thirds of residents eligible for Medicaid. State Medicaid programs typically paid LTCPs on a discounted fee-for-service (FFS) basis over and above the nursing home's daily rate.[12] By contrast, for Medicare-covered Skilled Nursing Facility (SNF) care financed by Part A, covered drugs were bundled into the prospective per-diem rate, and nursing homes typically paid LTCPs from this inclusive rate. Private paying residents paid LTCPs out-of-pocket or through existing coverage (e.g., retiree benefits).

As mentioned above, LTCPs provide services to nursing homes beyond dispensing drugs. Prior to Part D, LTCPs reportedly provided many of these services to nursing homes at little or no additional charge (i.e., were bundled with charges for other

goods and services). A 2004 report on the LTCP industry found that LTCPs usually charge nursing homes a small fee for consultant pharmacy services, occasionally charge for maintaining medication records, and provide a number of other services at no additional charge.[2] The report further noted that LTCP charges to facilities were often bundled such that assessing distinct service pricing (and costs) was difficult.

Part D Changes. Medicare's new drug benefit fundamentally altered the nursing home pharmacy market (Exhibit 2). The most significant changes center on the majority of residents who are dually eligible for Medicare and Medicaid ("duals"), because the new benefit shifts their drug coverage from Medicaid to Medicare and requires that they enroll in private prescription drug plans (PDPs). In contrast, those covered by Medicare for a post-acute SNF stay are unaffected, and the impact on private-pay residents depends on whether they enroll in PDPs.

The new benefit relies on private plans for its administration. The underlying expectation is that informed consumers will choose the plan that best suits their needs and that price competition among plans will avoid the government's paying too much – or too little – for drugs. Within limits, private plans have flexibility in structuring formularies and cost-sharing. Although policymakers had concerns about whether plans would enter, the number of stand-alone PDPs in the 34 regions ranged from 27 to 52 at the program's start. Duals initially were assigned randomly to PDPs with monthly premiums at or below regional benchmarks; however, they can switch to a different plan at or below the benchmark up to once per month. If the plan into which a dual enrolls is no longer offered or if its premium increases to more than the regional benchmark plus a *de minimis* amount ($2.00 for 2007), the dual is enrolled into another below-benchmark plan

offering from the same company or – if there is no such plan – is enrolled randomly in another below-benchmark plan. Non-dual nursing home residents were not auto-enrolled (like other Medicare beneficiaries, they initially had until May 15, 2006 to select a PDP), and they can switch to any plan up once per month.

In creating PDPs and removing Medicaid as the dominant payer, the MMA reconfigured the nursing home pharmacy market. Nursing homes and their LTCPs no longer function primarily under a single state's Medicaid policies, including its preferred drug list. Instead, they must work across multiple plans, each of which generally has different coverage, cost-sharing, formulary design, and utilization management. Under the new law, however, because of CMS requirements that PDPs contract with any qualified pharmacy, nursing homes can keep their current institutional pharmacy arrangement, and most have maintained a relationship with a single LTCP. The legislation does not have a direct impact on nursing home-LTCP contracting; however, as we discuss below, the law could impact service and drug pricing that facilities receive from their pharmacies, including the transparency of such pricing. PDPs contract with LTCPs – not nursing homes – and are required to offer standard contracts to any qualified pharmacy provider.

According to the MMA legislation, PDPs, rather than LTCPs, have the authority to create and maintain Part D formularies. Although LTCPs still maintain formularies, these Part D changes could have substantial implications for a revenue source of many LTCPs – rebates from drug manufacturers. Apart from the open question of whether manufacturers will continue to negotiate rebates with LTCPs, which we discuss below, CMS has emphasized that price concessions obtained by LTCPs must be reported to the

PDPs with which they contract and, in turn, to CMS beginning in 2007. Finally, unlike Medicaid payment rates, Part D payments to LTCPs (e.g., dispensing fees) are not set administratively but instead are negotiated between LTCPs and plans.[13]

Part D Enrollment and Plan Selection

Most of the nation's 1.6 million nursing home residents moved to the new drug benefit on January 1, 2006, a shift spurred by the necessary transition of dual eligibles to Medicare – rather than Medicaid – drug coverage. To ensure continuity of coverage and to mitigate the potential for adverse selection at the plan level, duals' initial plan assignment was required by the MMA to be automatic and random and occurred into plans with premiums at or below regional benchmark values, as described above. Some advocates, nursing home providers, and pharmacists with whom we spoke questioned the wisdom of randomly assigning nursing home residents to drug plans, reasoning that some individuals will inevitably be enrolled in less generous plans and/or plans that are less able to meet their medication needs than alternative below-benchmark plans. Indeed, our own analysis of CMS formulary data found that a minority of below-benchmark plans provide less generous coverage and have more stringent prior authorization requirements compared to the relatively broad coverage we found overall.[14] Some advocates have argued for an alternative assignment process that would consider medications that the beneficiary currently takes in making plan assignments, attempting to match a beneficiary to a plan with relatively generous coverage of those medications (e.g., see: http://waysandmeans.house.gov/hearings.asp?formmode=view&id=4930). Although such processes can vary considerably, a few states (e.g., New York, New Jersey, and

Maine) are currently either using or considering an approach allowed by CMS referred to as "intelligent random assignment" to assign state pharmacy assistance program enrollees to Part D plans.

Although duals may switch to a different plan at or below the benchmark once per month (and non-dual residents may switch to any participating plan), Part D's emphasis on consumer choice could be considered a poor fit with the characteristics of the nursing home population. In particular, the high prevalence of cognitive impairment in this setting undermines the potential for informed decision making. Even for cognitively intact residents, it could be difficult for them to access comparative plan information (e.g., via telephone or internet). Of course, many residents have actively engaged children, spouses, and legal guardians who help with medical decisions and who can help select plans. However, as a policy matter, it is a relatively safer assumption that few residents have the means and the ability to assess plan options on their own.

Importantly, MMA guidance includes restrictions on the ability of providers serving nursing home residents (including nursing homes, physicians, and pharmacies) to direct residents to particular plans. Providers are able to provide objective information to residents, including how well drug plans cover medications of interest, but they are restricted from directing residents more broadly to a smaller number of plans and from distributing information that could be construed as having this aim.[15] These restrictions are intended to minimize nursing home providers' ability to steer residents in financially beneficial ways (e.g., if LTCPs had favorable deals with specific PDPs), but they also could reduce the likelihood that some residents will enroll in plans that cover their current medications. Some nursing home and pharmacy providers expressed frustration at the

limits, positing that marketing restrictions undercut an advisory role that many residents and families want them to play and potentially jeopardized medication access for the subset that enrolled in plans that may be less appropriate for their medication needs. The CMS marketing guidelines are currently the subject of a first amendment lawsuit filed by the Washington Legal Foundation (http://www.wlf.org/upload/070706rotunda.pdf; (http://www.nasmd.org/WLF%20v.%20Leavitt%20lawsuit.pdf), and have been questioned by some members of Congress as well (e.g., Senator Schumer introduced S.2184 in the 109th Congress, facilitating nursing home-provided assistance in plan selection). Yet, at the same time, other nursing home providers supported the marketing restrictions, stating that such a role could pose a conflict of interest and open providers to the liability related to recommending particular plans. Other than emphasizing that random assignment did not seem ideal, the advocates with whom we spoke did not have a strong view on the matter, in part because they've heard little about Part D difficulties from residents and their families, a point to which we return below.

In practice, providers seem to take different approaches – and even seem to have somewhat differing views on what activities are allowed – around educating and communicating with residents about their Part D plan options. Although several LTCPs indicated their Part D role included providing nursing home clients with assessments of PDPs' coverage, utilization management, and overall flexibility, there seems to be variation in the extent and the manner in which nursing home clinical staff use this information based on our interviews with nursing homes, physicians, and LTCP providers. In particular, some LTCP respondents characterized clear differences across their nursing home clients in the extent to which they directed residents to particular

plans. While some nursing home providers viewed it as their responsibility to advise residents and their families on plan choice, others expressed greater concern about repercussions from survey agencies or the Office of the Inspector General. Importantly, at this point, it is unclear how and to what extent restrictions on steering will be enforced.

Provider level enrollment data are not yet available to assess plan switching at the nursing home or chain level; thus, it is difficult to describe whether and to what extent individuals have re-sorted from their originally-assigned plans (whether driven by steering on the part of nursing facilities or LTCPs or other factors). Most of the larger nursing home providers with whom we spoke stated that the majority of duals remained in their originally-assigned plans (according to some, this inertia exists in the face of efforts to provide objective information about plans). In contrast, however, one PDP with whom we spoke cited fluctuations in the plan's institutional enrollment over the course of 2006, attributing it, in part, to coordinated enrollment efforts on the part of nursing homes and their pharmacy providers. Similarly, one interviewee provided correspondence sent by one LTCP early in 2006 encouraging a client nursing home to consider changing residents from non-preferred PDPs in order to minimize charges to the facility that result from rejected claims.

Ultimately, discussion of plan selection, assignment, and steering turns on beneficiary freedom of choice. One LTCP provider with whom we spoke posed a fundamental question about the extent to which long-stay nursing home residents should be allowed/expected to choose among plans, pointing to Medicare Part A stays in hospitals and nursing homes. Unlike Part A, where providers deliver medications and other prospectively-reimbursed services at their discretion, long-stay nursing home

residents access medications through their PDP of choice. As established by the MMA, Medicare beneficiaries who are nursing home residents enjoy similar choices and flexibility under Part D as beneficiaries in the community (with the caveat that nursing homes typically choose the pharmacy with which they work). This freedom of choice is ensured by Section 1860D-1 of the Social Security Act and implementing regulations at 42 C.F.R. 423.32, and – unless changed – nursing homes and LTCPs are required to facilitate this choice in the Part D program (e.g., see following letter to state survey directors from CMS Survey and Certification Group: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06-16.pdf).

Working across PDPs

Part D introduced more variation into the nursing home pharmacy environment. Within a facility, residents may be enrolled in as many plans as are offered on the market, each with different formularies and utilization management policies. Although nursing homes worked across different coverage types prior to Part D, including Medicaid, Medicare Part A, and private coverage (e.g., managed care and retiree coverage), the number of plans is almost certainly greater under Part D and the enrollment of individuals will be more evenly distributed (i.e., the majority of individuals will not be enrolled in a single plan, as with Medicaid). With duals randomly assigned across below-benchmark plans, for example, it would not be unusual for a 100-bed facility to have duals spread across a dozen different plans. These changes have sparked concerns about quality of care problems resulting from potential gaps/restrictions in PDP formularies and the increased complexity and burden of working across multiple plans.

Prescribing in nursing homes depends on a series of communications between four parties – the prescribing physician, the nursing home, the LTCP, and the PDP. First, the attending physician or, in some cases, the facility's medical director writes an order for a medication, notifying the resident or responsible party of the order. Typically, a licensed nurse from the facility then faxes the order to the pharmacy, at which point the pharmacy reviews the order for coverage against the PDP formulary. If covered, the medication order is processed and sent to the facility by the pharmacy. If covered with prior authorization or step therapy requirements, the pharmacy or facility contacts the physician to initiate this process. If a medication is not covered, the pharmacy or facility contacts the physician to inquire about the possibility of an alternate medication. If there isn't an appropriate substitute for a non-covered drug, the pharmacy or facility will contact the physician to begin the appeals process. To address appeals and PDP utilization management, the physician typically shepherds the process from off-site, possibly with input or assistance from the LTCP and facility. When a resolution is achieved, PDPs communicate this back to physicians, who in turn contact facilities or the pharmacy. Throughout these processes, consultant pharmacists – typically employed by the LTCP – review drug regimens, oversee dispensing, and potentially suggest therapeutic substitutions.

When asked to describe the communication behind these processes, some clinicians characterized it as tenuous, with multiple points where the flow of information could break down. Clinical staff noted potential difficulty in determining particular individuals' coverage at the point of prescribing. Communicating PDP-physician interactions (e.g., PDP decisions on prior authorization or appeals) back to nursing

homes, LTCPs, and consultant pharmacists was described as especially challenging and important in relation to the timely delivery of medications. A related point is that our conversations identified variation across PDPs in the parties able to call on residents' behalf, with some allowing nurses and pharmacies to play this role and others limiting these interactions to physicians. One stakeholder mentioned the use of collaborative practice agreements as a model for allowing non-physicians to participate in utilization management processes or to make therapeutically equivalent substitutions within a drug class. Under a collaborative practice agreement, allowed in various forms in the majority of states, a physician agrees to allow a pharmacist to make particular types of changes (as specified in the agreement) to medication orders without seeking approval on a case by case basis. Although the physicians with whom we spoke characterized themselves as particularly aggressive and diligent in working through PDP requirements, they wondered whether doctors who have less direct involvement with particular nursing homes – such as many attending physicians – would do the same.

In speaking with nursing homes, physicians, and LTCPs, it was clear that they perceived PDPs as widely variable in how "friendly" they were to long-term care. Several elements contributed to these perceptions, the first of which was coverage of drugs important to the nursing home population. Although several stakeholders pointed to particular drugs where coverage was perceived to be problematic, the general – though not universal – view seemed to be that coverage *per se* was not the most problematic issue. To this end, CMS requirements such as establishing protected classes of medications[16] and guaranteeing transition coverage of medications during an enrollee's first 90 days of enrollment were cited as important safeguards for residents. (There do

not appear to be any plans to discontinue these protections; however, it is not certain that these safeguards will remain in place indefinitely.) Importantly, as we discuss below, medication access depends on factors beyond coverage, including prior authorization and step therapy requirements. Other elements that contributed to LTCP perceptions of PDP friendliness toward long term care included the proportion of drugs that require prior authorization and step therapy edits, the speed in paying claims, and rules regarding the emergency supply of medications (e.g., number of days supplied during the appeals process, number of days supplied upfront for a new order).

Compared to coverage issues, pharmacy and clinical providers in the nursing home setting were more vocal about the variation in utilization management requirements across PDPs (prior authorization especially) and the variation in PDPs' flexibility in addressing what were perceived to be nursing home-specific needs. Among nursing home-based clinicians, dealing with the burden of prior authorization and, to a lesser extent, appeals or exceptions processes was universally raised as an important and problematic issue. In particular, nursing home physicians described the challenges of completing numerous and different prior authorization forms, providing medical records and lab results from off-site (i.e., without access to residents' medical records), navigating help desks not attuned to the nursing home setting, and struggling with what were perceived to be relatively unfriendly processes that had variable results. Nursing homes and pharmacies noted that prior authorizations typically were approved in the end, but – for some plans – this outcome only came after considerable effort. Although some noted that nursing homes and physicians dealt with prior authorization in the past under Medicaid, physicians and nursing homes characterized these processes as much more

challenging under Part D, something detailed by the American Medical Director's Association in a recent survey of members.[17]

CMS has instituted steps to ease the burden of prior authorization, exceptions (to formulary coverage or tier), and appeals, developing a standard coverage determination request form that can be used to request approval for non-formulary drugs, for exceptions to a formulary tier, and for giving information to meet prior authorization requirements (http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf). CMS regulations require PDPs to accept these forms, but most nursing home and pharmacy providers stated that PDPs generally require completion of the PDP-specific forms as well. CMS indicated that it has begun the process of developing more detailed, class-specific forms for prior authorization, something representatives characterized as a much more involved process. Although standardization of utilization management forms could help to reduce the administrative burden associated with working across multiple PDPs, enforcement of standardization requirements may be needed to achieve this goal.

With few exceptions, PDP carriers had little experience working with LTCPs and nursing home residents prior to Part D (and vice versa). Even under Part D, only a small minority of PDP enrollees are nursing home residents. To put PDPs' nursing home business into context, most plans with whom we spoke indicated that nursing home residents accounted for 3-5% of total enrollees. Since the advent of Part D, some PDPs have made strides to become more knowledgeable and attuned to the long-term care setting, both to manage their own risk and to work effectively in meeting the needs of their nursing home members. For instance, one large PDP hired high-level staff familiar with the LTCP industry, engaged in a dialogue with its LTCP contractors, and made

changes in the way it administers claims to account for those originating from the nursing home setting (e.g., instituting prior authorization codes specific to the long-term care setting and waiving prior authorization requirements to ensure expedient delivery of drugs). Other PDPs have initiated practices such as 24-hour/7-day-a-week availability for prior authorization calls, coverage of injectables and other alternate routes of medication administration for nursing home residents, and flexible coverage of emergency medicines required to be onsite in nursing homes.

Over time, nursing homes and their pharmacies will gain more experience working across PDPs, lessening the initial level of uncertainty. Similarly, PDPs will become more familiar with LTCPs and the nursing home pharmacy environment generally. At this point, most PDPs we interviewed did not express a desire to avoid these beneficiaries as enrollees, although one PDP representative noted that the PDP was offering fewer below-benchmark plans for 2007 than they did for 2006. The availability of below-benchmark plan options will need to be monitored as risk corridors widen and as plans gain more experience in the sector. Importantly, stakeholder interactions will be shaped by the financial, administrative, and clinical implications of Part D, topics to which we now turn.

Clinical Impact of Part D

Assessing the clinical impact of Part D in the nursing home sector is one of the more difficult areas to evaluate without quantitative data describing drug utilization and other related processes and outcomes for nursing home residents. As the benefit progresses, additional empirical work will be needed to illuminate these issues further.

With this caveat, our conversations with stakeholders in this area centered on three broad topics – Part D's impact on clinical and prescribing processes, its impact on drug utilization, and its overall impact on resident outcomes and quality of care.

As described above, nursing homes and their LTCPs must now work across multiple PDPs to deliver medications. In addition to the administrative, clinical, and operational burden detailed elsewhere in this report, we heard about related changes in how drugs are dispensed by LTCPs. In particular, a tension seems to have emerged between timely provision of medications from LTCPs and obtaining determinations of coverage from the PDP (or guarantees of payment from the nursing home). Although CMS's "transition fill" policy should help alleviate this tension (plans are directed to fill a transition supply of prescriptions within the first 90 days of enrollment, and nursing home residents may receive multiple refills if necessary, see http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07TransitionGuidance.pdf), some physicians still expressed concern about potential delays in medication access if LTCPs and/or nursing homes wish to verify coverage or prior approval before dispensing a drug. We heard about varying approaches to this issue from nursing homes and LTCPs, with some dispensing medications in advance of determining payment, and others being more hesitant to do so. One large nursing home provider indicated that pharmacies have gotten more aggressive over time and as non-covered medications have grown in magnitude about verifying coverage before dispensing. Another strategy we heard about from LTCPs in response to this challenge is to dispense shorter supplies of medications in anticipation of resolving PDP-specific administrative issues before the prescription is refilled.

As raised above, medication access depends on several factors, including coverage and utilization management requirements. Based on data from one large LTCP, Exhibit 3 conveys information about 20 drugs with the most claims in rejected status at the end of the 2006 calendar year. For each of the drugs listed, the distribution of claims rejections across various categories is given, including the drug not being covered; no (medical) history record on file (e.g., to fulfill step therapy or diagnostic requirements); the refill being requested too soon (e.g., if the plan doesn't think the prescription should be depleted yet); and prior authorization requirements. At the bottom of the Exhibit, this information is also given for all the LTCP's Part D claims in rejected status at this time. Importantly, the data are not adjusted for prescribing volume, meaning that one should not make inferences about relative probabilities of submitted claims being rejected across listed (or unlisted) medications.

Although these data are not necessarily representative of other LTCPs' experience, they generally seem consistent with information obtained in stakeholder interviews. In particular, nursing home and LTCP stakeholders highlighted access challenges under Part D for Alzheimer's drugs, selected antibiotics, erythropoetin (EPO) drugs, and some alternate formulations of medications (e.g., injectable, inhalation, topical, and infusion solutions) relative to coverage under Medicaid and LTCP formularies before Part D implementation. The Exhibit highlights how access challenges may stem from different limitations. Some claims rejections (e.g., Lexapro and Prevacid) primarily stem from lack of coverage; others (e.g., Namenda and Procrit) primarily from prior authorization requirements not being met; and still others (e.g., warfarin sodium and Seroquel) primarily from having no (medical) history records on file.

Importantly, the clinical impact of limited coverage or extensive prior authorization requirements depends on a number of factors, including prevalence of use, available alternatives, and the efficacy of specific medications. For instance, if a drug is seldom used because there are clinically superior alternatives, low coverage levels may be appropriate and cause minimal burden clinically. Similarly, high levels of prior authorization might add valuable safeguards in cases where prescribing could be questionable or inappropriate, either due to controversy about efficacy or concerns about risks or side effects.

With the caveat that empirical data are not yet available to assess the impact of Part D on utilization, nursing home and LTCP providers have noticed a shift in drug utilization within classes (e.g., from an uncovered to a covered statin), but almost none of the stakeholders whom we interviewed reported a change in the overall utilization of drugs by nursing home residents. [The one exception to this sentiment was a consultant pharmacist in a state where the Medicaid program has opted to drop its coverage for benzodiazepines, which are excluded from Part D coverage. It was noted that the use of benzodiazepines has plummeted, a change the pharmacist described as positive overall.] This is a relevant point not only in terms of ensuring adequate access to medications for residents but also because some policymakers characterized drug utilization prior to Part D as excessive and expected it to decline as manufacturer rebates – and incentives for LTCPs to move market share – diminished. In detailing concerns in this area, CMS emphasized the importance of reducing incentives to over-prescribe,[18] something it argues could not only lead to higher drug costs but also to increased health costs and

burden (e.g., through adverse drug events). It clearly will be important to monitor drug utilization and resident health outcomes with empirical data as the benefit proceeds.

Finally, we asked stakeholders whether they felt Part D has had any impact on resident outcomes or quality of care. Despite a great deal of concern among some stakeholders, we did not hear about instances where quality of care was perceived to be suffering. One state representative indicated that the survey agency had not noticed any problematic trends or outcomes subsequent to Part D's introduction. Advocates with whom we spoke indicated that – somewhat to their disbelief – they have heard little from residents and families about problems with the benefit. Despite the lack of specific concerns, however, advocates still expressed a general concern about whether nursing homes could absorb the added burden that Part D places on staff. When asked about whether residents have been impacted by Part D (negatively or positively), nursing homes, LTCPs, and physicians concurred that residents and their families have been largely shielded from Part D's changes thus far and likely have noticed little or no difference between the pre- and post-Part D clinical environment.

Financial and Administrative Impact of Part D

Our discussions of the financial and administrative impacts of Part D in the nursing home pharmacy sector centered primarily on the experiences of LTCPs and nursing homes. As noted above, PDPs must contract broadly with LTCPs, while nursing homes typically contract with a single LTCP. Importantly, nursing homes are the entities held responsible by regulators for ensuring residents' freedom of choice under Part D and, more broadly, as defined by the Nursing Home Reform Act, for meeting residents'

prescription drug needs. The LTCP-PDP interaction is the locus of Part D claims administration and payment issues; as we describe below, however, these interactions affect and are often mediated by LTCP-nursing home interactions. We first discuss the operational impact of Part D on LTCPs and nursing homes, before moving to a broader discussion about the impact of Part D on the competitiveness of the LTCP sector.

LTCPs. Part D represented a fundamental shift in how LTCPs get paid for the majority of their business. Under the new benefit, a LTCP receives negotiated dispensing fees from multiple PDPs and functions, at least for its Part D business, under the formularies of these plans. Not only do these changes have implications at the level of pharmacy-PDP interactions, such as claims processing and systems compatibility issues, but the structure of Part D also has broader financial implications for a traditionally important revenue source for LTCPs, rebates (discussed below).

LTCPs perceive PDPs to vary widely in the ease or difficulty of working with them under Part D. Many of the relevant considerations of this assessment relate directly to issues with financial consequences for LTCPs. The first and perhaps most visible issue discussed by LTCPs was that of rejected claims. Although pharmacies were reluctant to describe the magnitude of the problem in detail, one large LTCP estimated that 4% of all submitted Part D claims were rejected in a recent time period and that it had hundreds of thousands of claims in a "rejected status" at the end of 2006. Rejected claims not only can imply delayed payments for LTCPs (which may be particularly problematic for smaller pharmacies[19]) but they could also imply a loss if the drug in question has already been dispensed by the LTCP, pushing the issue of payment to be between the pharmacy and its client nursing home.

Showing data from one LTCP, Exhibit 4 details rejected claims across 16 PDPs in 2006. The Exhibit shows that claims can be rejected by PDPs for a variety of reasons, including non-coverage of a drug (identified by a particular National Drug Code (NDC)) in question (20% of rejected claims, on average across the 16 PDPs); no history record on file (16%); and refill too soon (14%). According to LTCPs, some rejected claims result from the fact that individuals transition in and out of nursing homes and that coverage and institutional status may not be reflected in eligibility data immediately. Importantly, the data on which the table is based only include claims that were in a rejected status as of the end of 2006; in other words, claims that were initially rejected and then resolved do not appear in the data. This feature might explain why prior authorization seems relatively low (6% of rejected claims) compared to what had been communicated to us about its relative burden.

Exhibit 4 also details "reject ratios" across PDPs, providing a sense of the variation in claims rejection rates across plans. The reject ratios convey the relative portion of claims rejections by each plan. For example, the reject ratio of Plan A implies that, relative to its claims volume, its share of rejected claims is 0.39 times the average rate. This share varies substantially across the listed plans (from 0.23 to 3.54). If a LTCP has an average Part D claims rejection rate of around 4% (an estimate consistent with LTCP interviews), the corresponding rejection rates would vary between 1-14% across plans.

Even in the context of empirical data such as those detailed above, stakeholders have differing views on the factors driving claims rejections. For instance, on documenting previously administered therapies, LTCPs pointed to instances where

residents had tried and failed medications before admission to the nursing home, but with no documented medical history on the patient, plans wanted such residents to try inappropriate medications first. In contrast, some PDP representatives questioned whether LTCPs could focus more energy moving individuals to alternate therapies within what they perceived to be relatively generous formularies.

Like other aspects of the Part D benefit, LTCPs and PDPs have struggled with numerous administrative complexities associated with transitioning to the new benefit. Many of these issues have improved over the course of the program, but others have remained. One matter LTCPs claim still to be hampered by is questionably withheld co-payments and other difficulties emanating from PDPs' inability to identify reliably when individuals are (a) full benefit duals and (b) nursing home residents. In addition, CMS guidance requires that medication copayments be charged for dually-eligible nursing home residents in the first calendar month of institutionalization (http://questions.cms.hhs.gov, Answers 7907 and 7042). Not all LTCPs pointed to this as a major financial liability, although several raised the issue as a persistent and growing financial burden. Both LTCPs and PDPs pointed to lag times between state and CMS reporting and the speed with which CMS's information system is updated as a major contributing factor to the problem.

Finally, meshing LTCP and PDP administrative practices has been challenging simply because of the distinct approaches each entity traditionally has used for billing and dispensing. A common refrain from almost every nursing home, LTCP, and nursing home clinician with whom we spoke was that PDPs (and, indeed, Part D more broadly) were oriented to the retail community setting. In response, some PDPs expressed

frustration about LTCPs' willingness and preparedness to deal with basic traits of the commercial insurance world. A typical example of such a disjuncture pertains to the practice of post-consumption or retrospective billing (i.e., billing that occurs after a drug is dispensed, usually at the end of the month or at the first of the next month), common among LTCPs under retrospective Medicaid payment. PDPs, used to real-time billing practices in the commercial setting, are required to accommodate post-consumption billing under Part D guidelines, but some noted that the practice increases the possibility for safety issues (e.g., if prior authorization is not received prior to dispensing) and disputes over rejected claims for drugs already dispensed. Many interviewees described Part D as a poor fit for the nursing home setting. A physician suggested having a few PDPs that served only the LTC market as one option; alternatively, the nursing home sector could be "carved out" from the rest of Part D, with PDPs competing to serve institutional beneficiaries in a given area. A nursing home representative suggested requiring a single formulary for nursing home patients.

Nursing homes. The initial transition to Part D was likely the most difficult period for nursing homes, with the majority of residents-and all duals-switching within a short time period. Beyond the initial transition costs of moving to Part D (e.g., educating staff about how the new benefit worked, educating residents and families about plans, and identifying the plans into which residents were enrolled), the financial impact of Part D on nursing homes seems to center in two areas, the indirect costs of coordinating drug provision across multiple PDPs and the direct costs of non-covered medications. Our focus is primarily on the latter of these concerns.

Similar to LTCPs, nursing home providers complained about the increased administrative burden of Part D that has fallen primarily on nursing home physicians and nurses who help coordinate paperwork on prior authorizations, exceptions processes, and appeals. Providers were unable to estimate the cost of the additional burden on staff financially, and most stated that they dealt with the challenge through existing personnel (e.g., claiming that Medicaid reimbursement levels were insufficient to pay for additional staff). Not surprisingly, nursing home chain providers pointed to variation across member facilities in the ability to absorb and perform these additional responsibilities.

The long-term administrative and financial burden of the MMA on nursing homes depends largely on their contractual relationships with LTCPs. Most nursing homes will rely on LTCPs for assistance in working across PDP formularies, prior authorization, and appeals processes. In characterizing LTCPs role under Part D, nursing homes expressed a general expectation that LTCPs would help ensure that residents' prescription drug needs are met, that facilities' prescription practices and documentation were in compliance with state and federal requirements, and that exposure to non-covered drugs was minimized. Most nursing homes expressed satisfaction with their LTCPs on their core responsibility of dispensing medications and ensuring compliance with survey regulations; however, some expressed frustration in how well their LTCPs anticipated challenges under Part D and how well they have navigated PDP requirements and coverage variations. Peripheral to Part D but relating to the matter of survey compliance, nursing home representatives pointed to the likely need for LTCPs and consultant pharmacists to play an expanded role in meeting newly revised survey guidelines on unnecessary drugs, pharmacy services,

and drug regimen review (commonly referred to as "the new pharmacy F-tags") that were effective December 18, 2006.

As discussed above, non-covered drugs have been a concern for LTCPs in the first year of Part D. Nursing homes are also attuned to this issue, in part because of their clinical responsibilities under existing statute, which were raised by multiple stakeholders. In particular, the Nursing Home Reform Law, passed under the Omnibus Budget Reconciliation Act of 1987, established standards of care for nursing home residents and stated that the nonavailability of program funding did not relieve facilities of this obligation.[20] Importantly, these requirements are driven by residents' clinical care plans, meaning that if physicians choose not to switch residents' medication orders, facilities are required to adhere to the written treatment plan. Beyond regulatory requirements, however, the cost of non-covered drugs are an issue for LTCPs and nursing homes to assign financially. In addition, the challenge of minimizing these costs is a shared challenge, requiring nursing homes and LTCPs to partner in ways that they haven't before.

It should be noted that non-coverage of medications may be Part D program-wide or PDP-specific. It is important to distinguish between the two, as they raise distinct policy issues. For instance, Medicare Part D excludes coverage for benzodiazepines, barbiturates, over-the-counter medications, prescription vitamins, and cough and cold remedies. States can provide coverage for these drugs, many of which were previously covered by state Medicaid programs (http://www.cms.hhs.gov/States/EDC/list.asp); however, the extent to which this coverage is sufficient and the extent to which nursing homes have to pay LTCPs for these medications are currently unclear. In contrast, when

a prescribed, Part D-allowable drug is not on a plan formulary, three options (apart from going without the drug) seem available to the nursing home – switch the individual to a therapeutically-equivalent drug that is covered; appeal to the plan for coverage of the medication; or encourage the individual to enroll in another plan. As mentioned above, non-covered medications may be dispensed in advance of pursuing one of these alternate routes for coverage.

How nursing homes and their LTCPs are dealing with the non-covered drug issue seems to vary across providers. With the caveat that some providers were reluctant to characterize financial arrangements with their pharmacies, some LTCPs seem to be shouldering the costs of non-covered medications at this point (e.g., focusing most efforts to recoup these costs on PDPs), while others have passed these costs to nursing homes earlier in the process. In any case, one would expect the costs of unpaid medications and increased LTCP administrative costs to be passed down to nursing homes eventually, either directly in payments for non-covered drugs or indirectly in higher service and drug prices for residents whose drugs are covered under Medicare Part A.

These changes signify a shift in LTCP-nursing home contractual relations. Prior to Part D, LTCPs viewed nursing homes primarily as clients to whom they were delivering a service. With Part D, nursing homes are still clients of the LTCPs, but they are also partners. In particular, the financial implications of Part D for nursing homes and LTCPs are intertwined, with each depending on the other's performance under the benefit. This realignment is still evolving, but it has already spurred changes in the way facilities and pharmacies interact. For instance, several stakeholders mentioned the importance of better integrating information systems to ensure consistent communication

between the nursing home and the pharmacy with PDPs. It has also spurred some changes in the way medications are dispensed vis-à-vis coverage determinations, which we will discuss below in the clinical impact section. At this point, it is unclear whether and how these changes will affect nursing home-LTCP contracting. Although nursing home providers were reluctant to discuss the topic in detail, they did note that LTCP contracts were trending toward shorter time periods (e.g., a few large providers cited contract periods of a few years, while some smaller providers noted annual contracts with 30-day cancellation policies), a change they considered to be positive.

Competitive Impact of Part D in the LTCP Sector

Prior to Part D's implementation, CMS predicted that the Medicare Part D program would "improve competition in the LTC pharmacy market while preserving the pharmacy relationships and levels of service that LTC facilities now enjoy."[21] CMS anticipated that the MMA's changes would help level the playing field between large and small LTCPs.[22] Specifically, CMS expected that LTCP rebates would disappear over time, resulting in the unbundling of LTCP dispensing and service fees and greater transparency in LTCP pricing. As a result of these changes, CMS predicted there would be entry into the LTCP market by smaller organizations, resulting in increased price and quality competition.

Current Level of Competition in the Market. A variety of stakeholders, including LTCP representatives, nursing home providers, and analysts, expressed the view that the LTCP market continues to be very competitive after Part D's implementation despite the fact that almost half of all nursing home beds are served by a single LTCP (Omnicare)

and almost two-thirds by the three largest LTCPs. As evidence of competition in the market, stakeholders pointed to the lack of barriers to entry in the market and the high rate of "bed churning" (i.e., nursing home beds that switch from one LTCP to another).

Importance of Economies of Scale. A number of stakeholders, including several analysts, agreed that economies of scale remain an important feature of the LTCP industry after Part D's implementation. Economies of scale enjoyed by the larger LTCPs include those related to the ability to buy in greater volume (and thus negotiate lower drug prices and/or larger rebates from pharmaceutical manufacturers), the lower costs associated with performing their own repackaging of medications for LTC settings, greater bargaining power in negotiations with PDPs over dispensing fees, and the ability to absorb the receivables that have accrued as a result of Part D implementation (e.g., copayments charged for institutionalized dual eligibles).

In the past, larger LTCPs had an important competitive advantage because they were able to leverage their size to negotiate large rebates from manufacturers. These rebates reportedly were shaped additionally by market share targets (e.g., ensuring that a certain percentage of prescriptions in a class were for a particular drug). Importantly, in the nursing home environment, consultant pharmacists could help ensure a high degree of compliance with drugs on the LTCP formulary. Bank of America Securities analyst Robert Willoughby was quoted in a December 2006 *Wall Street Journal* article that Omnicare's size helped it to negotiate "fantastic rebates" from drug manufacturers.[23]

However, several stakeholders noted that the use of group purchasing organizations, or "GPOs," (e.g., GeriMed, Innovatix, and MHA) by smaller LTCPs has increased the negotiating power of smaller LTCPs, allowing them to negotiate lower drug

prices and helping to level the playing field between small and large LTCPs with respect to pricing. As noted above, the member pharmacies of the largest GPO (MHA) together serve close to 1 million beds (including assisted living beds, which account for an estimated 20-25% of its beds served), which substantially increases the bargaining power of smaller local and regional pharmacies in price negotiations with manufacturers.[24] The other two LTCPs (GeriMed and Innovatix) together account for approximately 1/3 of the privately-held independent pharmacies.[24]

LTCP rebates have not been disallowed under Part D, but they must be reported to the PDPs with which LTCPs contract, which, in turn, must report the rebates to CMS. These price concessions should be deducted when calculating allowable reinsurance and risk corridor costs for PDPs. Furthermore, as noted above, it is the PDPs and not LTCPs that have legislative authority to design formularies and negotiate with manufacturers under Part D. In fact, CMS has hinted that rebates received by LTCPs could "raise significant fraud and abuse concerns" under Federal anti-kickback statutes.[25] Yet, in practice, LTCP formularies and consultant pharmacists still likely influence nursing home prescribing practices on the ground. In the context of PDP formularies and Part D requirements (e.g., the six protected drug classes), this influence likely varies across drugs and classes (http://www.healthstrategies.com/download/document.cfm?d=2145&download=1).

Based on our stakeholder conversations, it appears that manufacturers continued to pay rebates in the first year of the program but also that rebates were anticipated to diminish somewhat in the coming years. Due to the sensitivity of the topic, it was difficult to get a sense of the magnitude of rebates' importance toward the profitability of

LTCPs. One small regional LTCP estimated that rebates represent approximately 25% of the LTCP's bottom line; no other LTCPs (including the large LTCPs with potentially greater negotiating power with drug manufacturers) provided an estimate.

LTCPs and some analysts who cover the sector questioned why federal policymakers singled-out rebates to LTCPs and not those in other parts of the drug supply chain (e.g., PDPs). Federal policymakers have viewed rebates to LTCPs as representing a conflict of interest that may be particularly problematic given the institutional arrangements in long term care and the vulnerability of the institutionalized population. According to this view, LTCPs had considerable power to move market share to medications for which they negotiated higher rebates before Part D, even if lower-cost alternatives were more beneficial for patients clinically. According to some federal policymakers, these incentives had the potential to trigger overutilization, adverse drug events, and increased Medicare expenditures. While neither PDPs nor LTCPs have a direct financial incentive to ensure that patients receive the most beneficial medications under Part D, PDPs (unlike LTCPs) do have direct financial incentives to control drug expenditures because PDPs share financial risk for drug costs with the Medicare program. If rebates paid to LTCPs diminish or disappear, LTCPs questioned whether these rebates would actually accrue to the benefit of PDPs, beneficiaries, or the Medicare program more generally as opposed to the benefit of pharmaceutical manufacturers. LTCPs and analysts mentioned that LTCPs would likely attempt to recoup lost revenue through increased dispensing fees to PDPs and increased service costs to nursing homes if rebates decline. It is unclear whether the considerable market power of the larger

LTCPs would allow them to maintain their margins in this manner even without the rebates.

In addition to helping level the playing field between large and small LTCPs in price negotiations with drug manufacturers, GPOs have also done so with respect to PDP negotiations over dispensing fees. In anticipation of Part D, GPOs began offering what they refer to as "network" services (provided through a separate business entity) that involve negotiating contracts with PDPs. For example, MHA created its Long-Term Care Network in 2004 to contract with PDPs under Part D. The Network currently has over 650 member pharmacies, or approximately 2/3 of all privately-held, independent LTCPs.[24] Because MHA has the legal authority to act on behalf of its members in matters related to contracts with PDPs, the large number of beds represented by MHA has given the GPO considerable negotiating power with PDPs. The emphasis placed on adequacy of a PDP's LTCP network in the Part D negotiations may also have increased GPOs' negotiating power with PDPs due to the presence of GPO pharmacy members in rural areas.

According to one GPO representative, limited negotiating power with PDPs over LTCP dispensing fees, which are generally lower for smaller pharmacies than larger pharmacies for some PDPs, was the major competitive disadvantage that its members still faced. Most PDPs we interviewed felt that dispensing fee levels represented proprietary information but stated that the dispensing fees they negotiated were similar across LTCPs. One PDP representative stated that the PDP's dispensing fees varied based on negotiations with each LTCP, with a differential of approximately 10-20 cents per prescription. It is unclear the extent to which the size of the GPO affects its negotiating

power over dispensing fees (i.e., whether members of larger GPOs face a smaller dispensing fee differential relative to large LTCPs).

Although stakeholders felt that economies of scale remained important in the LTCP industry after Part D's implementation, two regional LTCPs felt that an advantage of smaller LTCPs over larger LTCPs was the ability to better personalize their services and communicate directly with patients, physicians, and administrators. They noted the importance of local relationships between pharmacists, physicians, and nursing home administrators in this business as being particularly helpful in the context of Part D implementation. Several interviewees also noted that the decentralized billing systems of some of the larger LTCPs (especially Omnicare, whose repeated acquisitions have resulted in decentralized billing) have created billing problems not experienced by smaller pharmacies.

New Market Exit or Entry after Part D. Several stakeholders speculated that smaller pharmacies may have had greater difficulty than larger pharmacies (which are likely to have larger reserves and greater cash flow) in holding receivables resulting from Part D copay charges for institutionalized duals (who face no copayments after the first 30 days of institutionalization) and rejected claims while these issues were being resolved with PDPs. However, there were mixed accounts of whether there has actually been either additional entry or exit in the LTCP industry since Part D was implemented. For example, one nursing facility representative noted that four small LTCPs with which the organization had contracted in the past had dropped out of the market this year (unclear whether the exits were due to acquisition by a competitor or closure). A representative of the LTCP stakeholder group and an analyst also thought there had been a low level of

drop out by smaller LTCPs, although neither could provide documentation. A GPO representative noted that none of its members had exited the market due to issues related to Part D. Another stakeholder noted that although he/she was aware of little drop out thus far, smaller LTCPs were ripe for acquisition and further consolidation was likely. An analyst with whom we spoke saw no evidence of entry in 2006 but noted that some regional LTCPs were trying to position themselves to increase market share under Part D. Another stakeholder predicted future entry by private equity-based firms in the near future, particularly on the assisted living side of the market.

In theory, there could be entry into the LTCP market by PDPs, retail pharmacies, or nursing homes looking to diversify (vertical integration). No stakeholders were aware of other types of organizations besides institutional pharmacies entering the market to assume the functions of a LTCP. One PDP representative stated that a PDP was unlikely to try to assume the LTCP role on its own because of the importance of local delivery and relationships within nursing facilities, although a partnership with an institutional pharmacy might make sense for the assisted living population. Another PDP representative said his/her organization had no interest in pursuing this line of business. A third PDP representative also noted no current interest on the part of his organization, although the individual thought that PDPs with specialty pharmacy distribution capacity might consider using this type of model for entering the LTCP market in the future, given that the specialty pharmacy and LTCP lines of business are somewhat similar (unlike the highly-automated mail order pharmacy business). Nursing home representatives also expressed no interest in performing LTCP functions internally. An analyst noted that a large retail chain could choose to enter the market in the future, either by starting its own

division or by acquiring Omnicare. Although Omnicare is very large in the LTCP space, it is a relatively small company and could be acquired easily by a larger retailer, the analyst noted.

Price Competition for Part D Now and in the Future. As noted in the Appendix, nursing home providers and analysts both pointed out that the two most important factors influencing the choice of a LTCP by a nursing facility or chain before Part D were: 1) performance of core LTCP functions, e.g., whether pharmacy services and medications are delivered in a timely fashion, and 2) the pricing of drugs for residents covered by Medicare Part A (for whom the nursing facility is paid a per diem that covers all care including prescription drugs). These same stakeholders reported that performance of core LTCP functions and price of drugs for Part A covered stays remained the most important factors in 2006, while Part D pricing and coverage issues were a secondary concern.

Although pricing for Part D business has not been a primary factor for nursing homes selecting a long-term care pharmacy to date, pricing strategies of LTCPs and the level of price competition in the Part D market may change over time, depending on a number of factors. A substantial decrease or elimination of rebates paid to LTCPs in the future may, as some predict, lead to the unbundling of fees charged to both nursing homes and PDPs. The greater transparency of LTCP fees charged to these parties could serve to increase price competition in the market, as some federal policymakers expect, or could serve to disadvantage smaller LTCPs to some extent. For example, larger LTCPs might have an efficiency advantage in terms warehousing, packaging, and dispensing capabilities.. Alternatively, smaller LTCPs might be able to run more specialized programs targeted at particular nursing homes for a lower cost, just as some

local pharmacies can do now. Although large LTCPs will clearly lose a major component of their competitive advantage if their rebates shrink or disappear, the extent to which scale economies will leave them advantaged is unknown.

Finally, the reduction or elimination of rebates may also result in LTCPs passing increased administrative costs or a greater share of costs for items like consultant pharmacist services (which are generally not reimburseable through Part D[26]) onto the nursing homes with which they contract. If they occur, these changes would likely accompany higher LTCP and consultant pharmacist costs that result from the revised pharmacy F-tags mentioned above. Diminished rebates could also lead to higher drug prices for Part A residents from LTCPs, something only one nursing home provider claims to have experienced just prior to Part D's start. Similarly, as risk corridors widen for PDP payments, PDPs may have greater incentive to press LTCPs for lower costs, which could lead LTCPs to charge higher prices to their nursing home customers.[27] Although PDPs reported that payments for institutionalized enrollees currently seem adequate, plan representatives did not have views about the anticipated adequacy of payments in future years (e.g., as risk corridors widen).

Conclusions

Part D represents a substantial departure from how prescription drugs were previously financed and administered in nursing homes, and nursing home providers and LTCPs have struggled in adapting to some of these changes. At the same time, meeting the needs of nursing home residents and working with LTCPs are new challenges for most PDP carriers as well. Although LTCPs, nursing homes and their clinicians, and Part

D plans will gain experience with the benefit, its structure, and how it works in the nursing home setting over time, stakeholders whom we interviewed identified a range of longer-term issues and questions that merit attention as the benefit proceeds. Nursing home residents are a particularly vulnerable population, and vigilance is needed to ensure the benefit works well in meeting their needs.

In sum:

- The overall fit between Part D and the nursing home pharmacy sector is a matter of contention among the stakeholders we interviewed. Many stakeholders characterized the Part D benefit as being a better fit for community-based beneficiaries who access medications in retail pharmacies than for institutionalized beneficiaries.
- Medicare beneficiaries in nursing homes have the same freedom to choose plans as community-based beneficiaries; however, stakeholder interviews highlighted a tension between balancing this freedom-of-choice and allowing nursing home providers to encourage enrollment into plans they perceive to be a better fit with residents' medication needs and that minimize facility and pharmacy administrative burden.
- Part D increased the variation around formularies and drug management processes for residents at the facility level. In general, stakeholder interviews highlighted the tension between cost-saving strategies used by PDPs such as utilization management and the burden these processes can place on clinical and pharmacy staff.
- Formulary coverage appears adequate for many medications used by nursing facility residents, and the special protections required for six medication classes plus Part D transition coverage requirements helped to shield residents from any coverage

limitations. However, stakeholders noted what they consider to be important exceptions to overall formulary adequacy for the institutionalized population and instances where the application of utilization management policies were particularly problematic.

- Empirical analyses are needed to assess the impact of Part D on utilization patterns, outcomes, and quality of care. Noting this important caveat, stakeholders pointed to within-class drug utilization shifts but did not report a change in gross drug utilization. To date, stakeholders have not perceived any adverse impact on resident outcomes or quality of care attributable to Part D.
- Stakeholders indicated that Part D's financial impact on nursing homes is still evolving. Part D altered the relationship between nursing homes and their LTCPs, introducing a tension between facilities' need to dispense medications quickly and LTCPs assuring coverage for those drugs. Nursing homes and LTCPs both have an incentive to minimize prescriptions for non-covered drugs, but how the financial impacts of these costs will be shared by these entities depends on nursing home-LTCP contracting, which will likely continue to vary across providers.
- The impact of Part D on the future competitiveness of the LTCP sector is also evolving. Although the LTCP sector is concentrated, financial analysts with whom we spoke characterized the sector as competitive, with few barriers to entry. The prominent role of Group Purchasing Organizations (GPOs) and LTCP network organizations in particular has helped smaller LTCPs access more favorable pricing from manufacturers and PDPs such that most small LTCPs have joined these organizations.

- Consensus among stakeholders was that LTCP rebates –which seem to have continued to date – would likely decline in future years. CMS has not disallowed LTCP rebates under Part D, but it has expressed strong reservations about them, raising the possibility that they could constitute fraud and abuse.
- If LTCP rebates decline or disappear, these changes could lead to increased transparency of pricing and perhaps increased price competition. Although reduced rebates would likely have a greater negative impact on larger LTCPs, these entities would still likely maintain certain economies of scale that might be advantageous in terms of service pricing, dispensing costs, and negotiating power.
- A reduction or elimination of rebates also could result in LTCPs passing increased administrative costs or a greater share of costs for items like consultant pharmacist services onto the nursing homes with which they contract.
- PDPs generally did not express a reluctance to have institutionalized enrollees in their plans; however, there seemed to be a level of uncertainty among PDPs about the adequacy of payment and risk adjustment going forward as risk corridors widen. Reassessing the methodology of risk adjustment and possibly making future refinements could be important to ensure adequate availability of plans for dual eligible beneficiaries.

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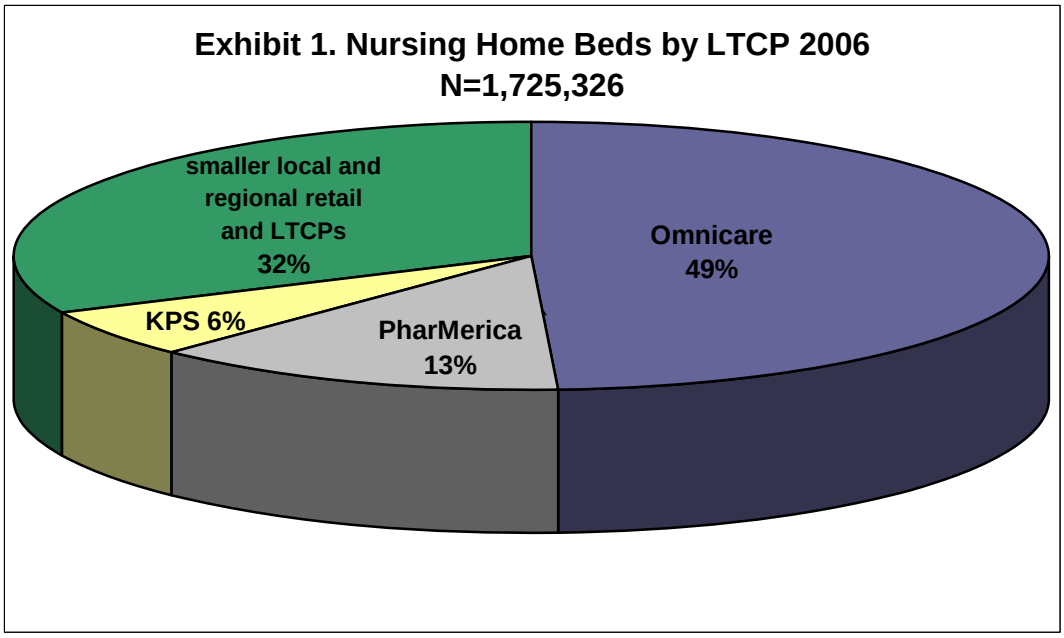

Sources: Total nursing home beds obtained from AHCA's June 2006 estimate at http://www.ahca.org/research/oscar/rpt_certified_beds_200606.pdf, accessed 01/11/2007. *Omnicare, PharMerica, and KPS estimates obtained through January 2007 communications with representatives and are estimated.*

Exhibit 2: The Long-Term Care Pharmacy Market before and after Medicare Part D

		----------Before Medicare Part D----------					----------After Medicare Part D----------			
Resident Payer Type	**% of Total[a]**	**Rx Drug Coverage**	**Payment[b]**	**Formulary/ Utilization Management**	**Contracting[b]**		**Rx Drug Coverage**	**Payment[b]**	**Formulary**	**Contracting[b]**
Medicaid	62%	Medicaid	Medicaid paid LTCP on discounted FFS basis outside of daily rate	LTCP/NH formulary and Medicaid prior authorization and preferred drug list	NH typically contracted with single LTCP; LTCP contracted with drug manufacturers, often securing rebates; LTCP contracted with state Medicaid program for payment		All duals automatically enrolled in Medicare Part D	Part D plans pay LTCPs on negotiated basis	Multiple Part D formularies and utilization management tools	NH expected to continue contracting with single LTCP; LTCP still contracts with drug manufacturers, but future role of rebates unclear; LTCP contracts with multiple Part D plans for payment
Medicare	15%	Medicare Part A (SNF)	Medicare bundled Rx drugs into prospective per-diem rate; NH paid LTCP from bundled rate	LTCP/NH formulary	NH typically contracted with single LTCP; LTCP contracted with drug manufacturers, often securing rebates; LTCP contracted with NH for payment		Unchanged	Unchanged	Unchanged	Unchanged
Private Pay	23%	private funds	Residents without supplemental coverage paid OOP; for residents with supplemental coverage, third-party coverage paid LTCP on FFS basis	LTCP/NH formulary	NH typically contracted with single LTCP; LTCP contracted with drug manufacturers, often securing rebates; LTCP contracted with third-party payer or accepted OOP payments from resident	*If private pay resident doesn't enroll in Part D:*	Unchanged	Unchanged	Unchanged	Unchanged
						If private pay resident enrolls in Part D:	Medicare Part D	Part D plans pay LTCPs on negotiated basis	Multiple Part D formularies and utilization management tools	NH expected to continue contracting with single LTCP; LTCP still contracts with drug manufacturers, but future role of rebates unclear; LTCP contracts with multiple Part D plans for payment

Notes:

a. Authors' calculations using 2004 On-Line Survey Certification and Reporting (OSCAR) Data

b. Payment and contracting arrangements described are typical in the LTCP market but are not universal. See paper text for more detail.

FFS=fee-for-service; LTCP=long-term care pharmacy; NH=nursing home; OOP=out-of-pocket; SNF=skilled nursing facility

Exhibit 3: Top 20 Drugs Rejected by Part D Plans, 2006. Data from One LTCP.*

	REJECT CODE GIVEN - % OF TOTAL REJECTS FOR LINE ITEM										
BRAND NAME	NDC NOT COVERED(2)	NO HISTORY RECORD ON FILE(2)	REFILL TOO SOON(2)	PRIOR AUTHORIZATION REQUIRED(2)	CLAIM HAS BEEN PAID(2)	PLAN LIMITATIONS EXCEEDED(2)	CLAIM NOT PROCESSED(2)	CLAIM TOO OLD(2)	CARDHOLDER LOCKED-IN TO ANOTHER PROVIDER(2)	NON-MATCHED CARDHOLDER ID(2)	ALL OTHER REJECTS(2)
LEXAPRO	49.1%	20.0%	6.6%	3.2%	2.3%	2.3%	0.0%	3.4%	2.6%	1.9%	8.5%
FUROSEMIDE	4.0%	30.3%	18.2%	0.0%	10.2%	0.0%	0.0%	8.3%	8.3%	5.7%	14.9%
WARFARIN SODIUM	4.4%	40.0%	23.8%	0.0%	8.8%	0.2%	0.0%	5.9%	2.9%	1.0%	12.8%
OMEPRAZOLE	10.9%	17.6%	15.3%	13.2%	7.1%	15.0%	0.0%	1.3%	2.5%	4.8%	12.2%
HYDROCODONE W/ACETAMINOPHEN	8.5%	34.2%	10.3%	0.0%	8.0%	4.3%	0.0%	6.6%	7.1%	6.0%	15.1%
ARICEPT	7.2%	13.3%	7.2%	33.6%	2.6%	7.8%	0.0%	10.1%	4.1%	2.3%	11.6%
FENTANYL	66.5%	10.2%	4.7%	0.0%	1.6%	6.5%	0.3%	0.9%	0.9%	0.0%	8.4%
SEROQUEL	1.9%	40.3%	14.0%	3.2%	9.7%	5.5%	0.0%	7.5%	3.2%	3.9%	10.7%
LEVAQUIN	37.7%	13.1%	5.1%	0.0%	10.8%	1.3%	17.8%	1.3%	1.3%	1.7%	9.8%
LISINOPRIL	7.7%	22.1%	15.9%	0.0%	13.3%	5.9%	0.0%	4.1%	4.4%	6.6%	19.9%
LEVOTHYROXINE SODIUM	5.7%	26.4%	18.8%	0.0%	12.3%	0.8%	0.4%	6.1%	3.8%	9.6%	16.1%
NAMENDA	3.1%	11.2%	10.4%	32.3%	6.5%	10.4%	1.5%	8.1%	4.6%	2.7%	9.2%
PROCRIT	7.1%	1.6%	0.0%	82.1%	0.0%	2.4%	1.6%	4.0%	0.4%	0.4%	0.4%
NORVASC	10.0%	19.2%	10.8%	0.0%	5.2%	6.8%	28.4%	2.4%	4.0%	4.0%	9.2%
PREVACID	49.4%	5.3%	3.3%	2.5%	0.8%	6.2%	15.6%	0.8%	2.1%	4.5%	9.5%
K-TAB	86.6%	2.1%	1.7%	0.0%	2.5%	0.4%	0.0%	1.3%	0.4%	0.0%	5.0%
XENADERM	81.0%	1.3%	0.8%	0.0%	1.7%	0.4%	0.0%	3.0%	0.4%	1.7%	9.7%
RISPERDAL	4.7%	28.9%	20.3%	0.0%	9.1%	9.5%	0.0%	3.9%	2.6%	1.7%	19.4%
LIPITOR	6.3%	14.0%	10.8%	0.0%	4.1%	15.8%	18.5%	5.4%	3.6%	2.3%	19.4%
RANITIDINE HCL	40.8%	22.9%	5.0%	1.4%	6.9%	0.0%	1.8%	5.0%	1.4%	2.3%	12.4%
TOP 20	23.6%	19.9%	10.7%	8.2%	6.3%	5.0%	3.6%	4.6%	3.2%	3.2%	11.7%
TOTAL	27.4%	18.4%	9.1%	6.5%	5.4%	5.0%	5.0%	4.3%	2.9%	2.8%	13.2%

**Data on claims in rejected status as of December 2006 provided by one LTCP in January 2007.*

(1) Number of times line item is rejected divided by the total number of rejected claims.
(2) Represents the percentage of rejects attributable to a particular reject code for each line item, i.e.. 49.1% of Lexapro rejects were for NDC not covered.

NDC = National Drug Code

Exhibit 4: Part D Claims Rejections for One LTCP, 2006*

Part D Plan	Plan Rejection Rate Relative to the Average Plan[1]	NDC not covered[2]	No History Record on File[2]	Refill too soon[2]	Claim too old[2]	Plan limitations exceeded[2]	Prior authorization required[2]	Claim has been paid[2]	No Reject Code[2]	Claim not processed[2]	Non-matched Cardholder ID[2]	All other rejects[2]
Plan A	0.23	15.8%	19.2%	12.8%	26.8%	4.8%	0.0%	0.6%	8.0%	0.0%	1.1%	10.9%
Plan B	0.39	9.6%	38.8%	0.0%	8.6%	5.7%	3.9%	5.1%	5.2%	0.0%	6.5%	16.5%
Plan C	0.53	25.1%	27.7%	12.0%	0.0%	8.5%	4.5%	1.1%	2.6%	0.1%	1.2%	17.1%
Plan D	0.79	4.8%	5.1%	34.1%	0.5%	10.3%	2.9%	17.4%	5.5%	0.0%	0.4%	18.9%
Plan E	0.98	19.9%	19.7%	13.7%	19.7%	7.1%	2.4%	1.0%	4.6%	0.3%	0.1%	11.5%
Plan F	1.06	30.2%	23.8%	10.8%	1.0%	5.7%	5.3%	0.8%	4.3%	0.5%	4.6%	13.0%
Plan G	1.09	31.3%	4.0%	28.4%	0.0%	0.3%	0.9%	6.6%	2.3%	0.3%	0.5%	25.5%
Plan H	1.25	2.0%	10.3%	24.7%	12.8%	1.5%	20.7%	9.3%	2.9%	0.0%	2.9%	12.9%
Plan I	1.36	40.3%	40.2%	0.0%	0.3%	2.0%	4.7%	0.7%	4.4%	0.0%	1.0%	6.2%
Plan J	1.45	22.7%	3.9%	22.8%	7.2%	8.3%	8.8%	6.8%	4.7%	0.0%	2.8%	12.1%
Plan K	1.92	19.2%	0.5%	21.3%	0.0%	3.1%	23.1%	1.4%	1.6%	0.0%	2.8%	26.8%
Plan L	1.98	17.3%	5.9%	9.4%	37.4%	6.0%	8.9%	1.2%	1.3%	0.2%	0.8%	11.6%
Plan M	2.06	20.4%	9.9%	31.7%	0.0%	6.6%	14.6%	0.5%	1.7%	0.0%	4.0%	10.6%
Plan N	2.50	15.6%	16.2%	6.2%	32.8%	7.1%	10.6%	0.7%	3.3%	0.6%	0.4%	6.5%
Plan O	2.99	18.8%	0.0%	12.6%	7.4%	5.0%	0.0%	0.1%	4.0%	39.8%	0.2%	12.1%
Plan P	3.54	15.1%	7.4%	9.5%	33.3%	20.4%	1.3%	0.6%	0.2%	0.0%	0.7%	11.7%
TOTAL		20.3%	16.4%	13.9%	11.1%	6.0%	5.9%	3.6%	3.4%	3.0%	2.0%	14.2%

**Data on claims in rejected status as of December 2006 provided by one LTCP in January 2007.*

(1) Percentage of LTCP rejects attributable to a PDP divided by the percentage of the LTCP's Part D claims filled by that same PDP. Ratio over 1 is above average.
(2) Represents the percentage of rejects attributable to a particular reject code for each line item, i.e. 15.8% of Plan A's rejects were for NDC not covered.

NDC=National Drug Code

Appendix: Overview of the Long Term Care Pharmacy (LTCP) Industry

Structure of LTCP Industry

According to the Sanofi-Aventis Managed Care Digest, there were approximately 1,079 LTCP providers in the U.S. in 2005, down from 1,148 in 2004.[1] The industry is heavily concentrated, with three large LTCPs (Omnicare, PharMerica, and Kindred Pharmacy Services (KPS)) providing pharmacy services to approximately two-thirds of nursing home beds in the U.S. (Exhibit A-1).

With respect to firm-size, the LTCP industry could be described as having four tiers: 1) Omnicare, 2) PharMerica and KPS; 3) smaller regional pharmacy chains; and 4) small local pharmacies. Omnicare, the largest LTCP, serves an estimated 850,000 nursing home beds and provides pharmacy services to approximately 1.4 million nursing home, assisted living facility, and other institutional beds in the U.S. and Canada.[2] In addition to its LTCP business, Omnicare's divisions include a contract research entity that provides clinical trials management and data analysis, infusion therapy services, specialty drug distribution services, and pharmacy benefit management services.[3]

The second tier includes the #2 and #3 firms in the industry. PharMerica, a division of the drug distributor AmerisourceBergen Corporation, is the second largest LTCP, serving approximately 234,600 beds.[4] The third largest LTCP is Kindred Pharmacy Services (KPS), a division of Kindred Healthcare, which operates hospitals, nursing homes and rehabilitation services throughout the U.S. KPS currently serves an estimated 105,000 beds, approximately 100,800 of which are nursing home beds. During the first quarter of 2007, AmerisourceBergen and Kindred Healthcare are expected to spin off PharMerica and KPS, respectively, to create a single, publicly-traded firm.

The third tier of LTCP providers includes substantially smaller regional pharmacies, which tend to serve from a few thousand to 50,000 beds in either a single state or small number of states. Finally, the fourth tier of LTCP providers consists of small local institutional pharmacy providers[a] that serve only a few hundred or thousand beds in a defined geographic area. Because both regional and smaller local LTCPs (tiers 3 and 4) are not publicly-traded, it is difficult to obtain data on the number of beds served and financial performance for these providers. As noted below, most pharmacies in the third and fourth tiers are members of group purchasing organizations (GPOs), increasing their negotiating power with pharmaceutical manufacturers over drug prices and with PDPs over dispensing fees. The largest GPO (MHA) negotiates on behalf of an estimated 2/3 of pharmacies in these tiers, which together represent close to 1 million beds (including both nursing home beds, assisted living beds and other institutional beds).[5] As a result, the combined market power of member pharmacies rivals that of Omnicare.

There has been considerable consolidation in the LTCP industry over the past decade. One analyst who studies the LTCP industry said that increased concentration in this industry mirrors that found in its customer base or other parts of the drug supply chain. In addition to consolidation by the larger LTCPs (e.g., Omnicare's 2005 acquisition of NeighborCare, Inc., and its acquisition of other smaller LTCPs in recent years; the upcoming PharMerica/KPS merger), there has been an increased level of acquisitions by smaller regional LTCPs.

Margins of LTCPs

[a] Particularly in rural areas, some retail pharmacies also provide institutional pharmacy services.

Among the three (soon to be two, after the PharMerica/KPS merger) largest LTCP providers, margins are highest for Omnicare, with an estimated margin of 11.3% in 2005.[b] The margin for Kindred was 10.9%.[c] PharMerica has lower reported margins, 5.0%, although this may be because it calculates segment operating income net of corporate office expense and certain other allocations.[d] If one allocates corporate overhead for Kindred to its lines of business in proportion to revenues in an effort to obtain a number more comparable to the PharMerica value, the Kindred number would be 7.7%.[e]

Margins for Omnicare and Kindred thus appear to be higher than firms in some other related industries (e.g., 4-6% for PBMs, 3-7% for retail pharmacies, and 1-6% for distributors) during the same period (Exhibit A-2). One analyst we interviewed believes that Omnicare has had greater efficiency due to its scale, but these efficiencies have not fully materialized in Omnicare's margins thus far. A number of operational problems (e.g., billing issues, a fire and quality control problems at the company's main drug repackaging facility), a pending lawsuit with United HealthGroup, and investigations and legal settlements with state and federal governments reportedly lowered Omnicare margins for '06.[6] Another analyst predicted that Omnicare should be able to improve its profitability and increase its margins this year by addressing these and other operational problems through planned reengineering efforts such as centralizing billing and collections functions. Expectations for 2007 margins for the merged PharMerica/KPS firm differ. Last summer, AmerisourceBergen CEO David Yost stated that a sizeable margin expansion (over previous levels for PharMerica) was expected for the combined

[b] This figure was calculated from Omnicare's 10-K filing dated March 16, 2006. It uses the operating income figure for pharmacy services (page 135) less the restructuring charge divided by net sales (0.113 = (583,954-5,245)/5,110,414.
[c] This figure was calculated from Kindred's 10-K filing dated Maarch 8, 2006. It uses the revenues of the pharmacy division (page F-21) divided by revenues (0.109=56,837/522,225).
[d] Calculated from AmerisourceBergen's 10-K filed December 8, 2006, pages 84 and 85 (0.050=83,745/1,668,308).
[e] This would net out (522,225/4,252,616)(134,514)=16,518 from the operating income of 56,837 in the previous calculation.

firm because of economics of scale.[4] In January 2007, Amerisource Bergen reported strong revenues and market share growth for PharMerica, according to a Stifel Nicolaus analyst report on the LTCP industry.[7] A September 2006 Lehman Brothers analyst report notes that previous relative underperformance of PharMerica despite a management change in the past few years suggests that "fixing the business may take some time."[8]

Competition in the Industry

Despite the fact that the majority of beds are served by just three LTCPs (and most by the largest LTCP in the market, Omnicare), a variety of stakeholders, including LTCP representatives, nursing home providers, and analysts, expressed the view that the LTCP market is competitive. In fact, analysts with whom we spoke described the industry as "extremely" or "very" competitive. Nursing home providers and analysts both pointed out that the two most important factors that have traditionally influenced the choice of a LTCP by a nursing facility or chain are: 1) performance of core LTCP functions (e.g., whether pharmacy services are delivered in a timely fashion), and 2) the pricing of drugs for residents covered by Medicare Part A (for whom the nursing facility is paid a per diem that covers all care including prescription drugs).

Lack of Barriers to Entry. Several stakeholders pointed to the lack of barriers to entry in the market. The Federal Trade Commission (FTC) concluded in its 2005 ruling on the potential merger of Omnicare and NeighborCare (two of the four largest LTCPs at the time) that there had been several recent examples of competitive entry in the industry and that "relatively easy entry conditions in the current marketplace further reduce the likelihood that incumbents, under current market conditions, could profitably sustain a course of coordinated interaction over a

significant time period."[9] The FTC based this conclusion on the fact that there were multiple rivals, including several independent LTCPs, serving a high percentage of the service areas where Omnicare and NeighborCare compete, and that independent LTCPs "generally are effective rivals to the chain LTCPs in these areas."[9] The FTC also investigated whether Omnicare (after acquiring NeighborCare) would be able to leverage its position in the market to "extract above-market rates from PDPs as a condition of joining their networks" after Part D was implemented, and concluded that the available facts did not support this theory at the time the ruling was made.[9] Several stakeholders we interviewed also pointed to the high rate of "bed churning" (i.e., nursing home beds that switch from one LTCP to another), as evidence of competition in the market.

Importance of Economies of Scale. A number of stakeholders, including several analysts, agreed that there were important economies of scale enjoyed by the larger LTCPs, particularly related to the ability to buy in greater volume (and thus negotiate lower drug prices and/or larger rebates from pharmaceutical manufacturers) and the lower costs associated with performing their own repackaging of medications for LTC settings. Regarding price negotiations, Bank of America Securities analyst Robert Willoughby was quoted in a recent Wall Street Journal article that Omnicare's size helped it to negotiate "fantastic rebates" from drug manufacturers.[10]

However, several stakeholders noted that the use of group purchasing organizations, or "GPOs," (e.g., GeriMed, Innovatix, and MHA) by smaller LTCPs has increased the negotiating power of smaller LTCPs, allowing them to negotiate lower drug prices. One GPO representative noted that they passed all rebates negotiated on behalf of their member LTCPs on to the LTCP, and these rebates have allowed them to effectively level the playing field between large and small LTCPs on this issue.

The member pharmacies of the largest GPO (MHA) together serve close to 1 million beds (including assisted living beds, which account for an estimated 20-25% of its beds served) and almost two-thirds of all privately-held, independent LTCPs.[5] Interestingly, Omnicare, PharMerica, and KPS are also GPO members, which allows them to take advantage of group purchasing for items for which it would not be cost-effective for them to contract directly. The other two LTCPs (GeriMed and Innovatix) together account for approximately 1/3 of the privately-held independent pharmacies.[5]

Although stakeholders felt that economies of scale were important in the LTCP industry, two regional LTCPs felt that an advantage of smaller LTCPs over larger LTCPs was the ability to better personalize their services and communicate directly with patients, physicians, and administrators. They noted the importance of local relationships between pharmacists, physicians, and nursing home administrators in this business. Several interviewees also noted that the decentralized billing systems of some of the larger LTCPs (especially Omnicare, whose repeated acquisitions have resulted in decentralized billing) have created billing problems not experienced by smaller pharmacies.

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Exhibit A-1. Profiles of the 3 Largest Long-Term Care Pharmacies (LTCPs)

LTCP Rank Annual Revenue	LTCP	Corporate Headquarters	Geographic Area Served	Types of Institutions Served	# Nursing Home Beds Served	Total Beds Served
1 **$5,293M**	**Omnicare Inc.**	Covington, Kentucky (incorporated in Delaware)	47 states, D.C. and Canada	-skilled nursing -assisted living -other healthcare facilities	**850,000**	**1,400,000**
2 **$1,668M**	**PharMerica**[†] Parent company: Amerisource Bergen Corp.	Chesterbrook, Pennsylvania (incorporated in Delaware)	36 states	-long-term care and alternate care patient populations	**222,870**	**234,600**
3 **$635M**	**Kindred Pharmacy Services**[†] Parent company: Kindred Healthcare	Louisville, Kentucky (incorporated in Delaware)	29 states	-nursing centers -assisted living facilities -other specialized care centers -includes nearly all Kindred facilities	**100,800**	**105,000**

[†]PharMerica and Kindred Pharmacy Services have spun off from their parent companies and are merging in 2007 into one publicly traded company. The merged company is projected to have 119 pharmacies in 41 states and will serve approximately 330,000 beds.

Sources:
Omnicare data were obtained from the corporate website accessed 01/11/07 at http://www.omnicare.com/home.asp and http://ir.omnicare.com/phoenix.zhtml?c=65516&p=irol-homeProfile&t=&id=&
PharMerica/AmerisourceBergen data were obtained from the corporate websites accessed 01/11/07 at http://www.pharmerica.com/about_pm.aspx and http://www.amerisourcebergen.com/cp/1/; the number of beds was obtained from Lehman Brothers Equity Research, "AmerisourceBergen: Perspectives on Proposed Pharmerica Spin" August 8 2006; and the estimated number of nursing home beds obtained through PharMerica correspondence.
Kindred Pharmacy Services/Kindred Health Care data were obtained from Kindred Healthcare website accessed 01/11/07 at http://www.kindredhealthcare.com/InvestorInfo/profile/kps.asp; http://www.kindredhealthcare.com/; the geographic area served and bed estimates were obtained through correspondence.
PharMerica-Kindred merger data were obtained in the ABC Annual Report/SEC Form Filed 12/08/06 and Kindred Investor Presentation, November 2006 accessed 01/11/07 http://www.kindredhealthcare.com/documents/January%202007%20Presentation.pdf

Table A-2. EBITDA and Revenue Measures: Selected LTCPs, PBMs, and Distributors, 2005-2007E
(US$ in millions)

	EBITDA			Total Revenue			EBITDA Margin		
Company	**2005**	**2006**	**2007E***	**2005**	**2006**	**2007E***	**2005**	**2006**	**2007E***
Long Term Care Pharmacies									
Omnicare	$630	$797	$870	$5,264	$6,441	$6,666	12%	12%	13%
Pharmacy Benefit Managers									
Caremark Rx	$1,628	$1,891	$2,155	$32,991	$36,769	$38,955	5%	5%	6%
Express Scripts	$728	$948	$1,058	$16,266	$17,686	$18,141	4%	5%	6%
Medco Health Solutions	$1,350	$1,673	$1,893	$37,871	$42,788	$46,620	4%	4%	4%
HealthExtras	$40	$53	$71	$695	$1,268	$1,733	6%	4%	4%
Distributors									
AmeriSourceBergen†	$754	$856	$868	$55,594	$62,794	$67,088	1%	1%	1%
Cardinal Health	$2,758	$2,702	$2,838	$77,416	$84,998	$92,375	4%	3%	3%
McKesson	$1,465	$1,539	$1,822	$85,330	$92,625	$98,881	2%	2%	2%
PSS World Medical	$92	$110	$128	$1,598	$1,727	$1,850	6%	6%	7%
Retail Pharmacies‡									
Walgreen Co. (WAG)	$2,938	$3,326	-	$42,202	$47,409	-	7%	7%	-
CVS Corp (CVS)	$2,609	not avail. yet	-	$37,006	not avail. yet	-	7%	-	-
Rite Aid Corporation (RAD)	$676	$570	-	$16,816	$17,271	-	4%	3%	-

Sources: Willoughby, RM and Wood, JD. "Pharmaceutical Services Valuation Update." 12/14/06, Bank of America Equity Research: Exhibit 2: Enterprise Value to EBITDA (2007E) Multiple Analysis and Exhibit 3: Price to Revenue (2007E) Multiple Analysis. Data on retail pharmacies calculated based on EBIT and revenue values from http://finance.yahoo.com and D,A values from recent annual reports/SEC form 10-K filings.

*2007 data are Bank of America estimates

†Includes PharMerica

‡EBITDA measures for retail pharmacies were calculated by authors