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Medicare Part D and the Nursing Home Setting

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Abstract

Purpose—To explore how Medicare Part D's introduction is changing the operations of long-term care pharmacies (LTCPs) and nursing homes, as well as implications of those changes for nursing home residents.

Design and Methods—We reviewed existing sources of information and interviewed stakeholders across various perspectives. Thirty-one semi-structured, telephone interviews were conducted with key stakeholders between November 2006 and January 2007.

Results—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. Part D increased the variation around formularies and drug management processes for residents at the facility level, creating additional burden on clinical and pharmacy staff and introducing a tension between facilities' need to dispense medications quickly and assuring coverage for those drugs. Nursing home and LTCP stakeholders perceive wide variation across Part D plans in their ability to meet the needs of nursing home residents.

Implications—Although LTCPs, nursing homes and their clinicians, and Part D plans will gain experience with the benefit in the nursing home setting over time, stakeholders we interviewed identified a range of longer-term issues and questions that merit attention as the benefit proceeds.

Keywords

Medicare; Part D; nursing home; long-term care pharmacy

Introduction

The Medicare Modernization, Improvement, and Prescription Drug Act of 2003 (MMA) extended voluntary prescription drug coverage to all Medicare beneficiaries, including individuals residing in nursing homes. The program includes special protections for nursing

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home residents, but its core administrative reliance on private plans and emphasis on consumer choice is the same across settings.

Yet beneficiaries in nursing homes differ from their community-based counterparts in important ways. They suffer disproportionately from multiple chronic conditions, are predominantly low income, have higher levels of cognitive impairment, and typically take 6-10 different medications compared to 2-4 for those in the community.(Avorn & Gurwitz, 1995; Jones, 2002; Medicare Payment Advisory Comission, 2007; Stuart, Simoni-Wastila, Baysac, Shaffer, & Shea, 2006; The Lewin Group, 2004) Additionally, 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.(Gurwitz et al., 2000; Institute of Medicine (U.S.). Committee on Nursing Home Regulation., 1986; Mendelson, Rajeev, Abramson, & Tumlinson, 2002; The Lewin Group, 2004; U.S. Office of the Inspector General, 1997)

Part D represents a substantial departure from how prescription drugs were previously financed and administered in the nursing home setting. In this exploratory paper we discuss these changes and their implications for nursing home residents, nursing homes, and LTCPs. Initial media accounts identified significant transitional issues as well as some broader concerns (Appleby, 2005; Pear, 2006b); we were primarily interested in the longer term impact and fit of the benefit in the nursing home pharmacy environment. We were especially attuned to how well a competitive, multi-plan model could be integrated into the nursing home setting, clinically and administratively; and our work focused on Part D's impact for residents dually eligible for Medicare and Medicaid, for whom the program constituted the biggest change. Relying primarily on stakeholder interviews, we present an early snapshot of Part D's financial and clinical impacts and raise issues for further empirical study.

Background

Before Part D

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. Nursing homes have struggled to manage resident drug needs in the past,(Gurwitz et al., 2000; Institute of Medicine (U.S.). Committee on Nursing Home Regulation., 1986; U.S. Office of the Inspector General, 1997) and recent research suggests that adverse drug events still are a problem.(Gurwitz et al., 2005) Reducing medication errors and improving prescription practices have been a focus of previous 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.(The Lewin Group, 2004)

In part because of these regulations, LTCPs have come to dominate the nursing home pharmacy market, offering specialized supplies and services mandated by federal law – such as unit-dose packaging, 24-hour drug delivery, emergency drug supplies, and handling unused medications – and becoming 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. Although nursing homes can pay retail pharmacies for such specialized services, LTCPs serve more than 80% of all nursing home beds nationwide.(Long-Term Care Pharmacy Association) The LTCP industry itself is highly concentrated, with two companies accounting for around two-thirds of all nursing home beds.(D.G. Stevenson Newhouse, & Huskamp, 2007)

Historically, most nursing homes – at the facility and chain levels – relied on a single vendor for all pharmacy-related services.(U.S. Centers for Medicare and Medicaid Services, 2005a) Nursing homes reap several potential advantages by using a single pharmacy, including increased efficiency, predictability, and standardization. For instance, if LTCPs and their consultant pharmacists maintain compliance with a single LTCP formulary, nurses might be able to manage fewer medications across residents. Moreover, because of this compliance, LTCPs have traditionally secured manufacturer rebates in exchange for preferred placement of drugs on their formulary.(Mendelson et al., 2002) In the past, larger LTCPs reportedly have been particularly effective in leveraging their size to negotiate large rebates from manufacturers based on volume and market share targets.(Leavitt, 2005) Unlike community settings, consultant pharmacists in the nursing home can ensure a high degree of compliance with drugs on the LTCP formulary.

Prior to Part D, residents' drug coverage varied by payer status. Medicaid played a substantial role, financing drugs for the almost two-thirds of residents eligible for Medicaid and paying LTCPs on a discounted fee-for-service (FFS) basis over and above the nursing home's daily rate. By contrast, payments for drugs used during Medicare Part A Skilled Nursing Facility (SNF) stays were bundled into the prospective per-diem rate, with nursing homes typically paying LTCPs from this rate. Private paying residents paid LTCPs out-of-pocket or through existing coverage (e.g., retiree benefits).(The Lewin Group, 2004)

Part D Changes

The most significant changes Part D created for nursing homes center on the majority of nursing home residents who are dually eligible for Medicare and Medicaid (“duals”), with the new benefit shifting their drug coverage from Medicaid to Medicare on January 1, 2006 and requiring their enrollment in private plans. In contrast, medication coverage for Medicare SNF stays is unaffected, and the impact on private-pay residents depends on whether they enroll in PDPs. (Table)

At the clinical level, Part D introduced more variation into the nursing home pharmacy environment.(The California HealthCare Foundation, 2005) 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, 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). It would not be unusual for a 100-bed facility to have duals spread across a dozen different plans.

Part D's administrative reliance on private plans reflects an underlying expectation that informed consumers will choose the plan best suiting their needs and that price competition among plans will avoid the government's paying too much – or too little – for drugs. Within limits, plans have flexibility to structure formularies and cost-sharing. To ensure continuity of coverage and to mitigate the potential for adverse selection, 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. Non-dual nursing home residents were not autoenrolled, and they can switch to any plan up to once per month.

Under Part D, nursing homes and their LTCPs no longer function primarily under a single state's Medicaid policies, including its preferred drug list. Instead, they must negotiate prices and work across multiple plans, each of which generally has different coverage, cost-sharing, formulary design, and utilization management.(MedPAC, 2007) Because of CMS requirements that PDPs contract with any qualified pharmacy, nursing homes can keep their

current institutional pharmacy arrangement.(Leavitt, 2005) As a result, the program doesn't have a direct impact on nursing home-LTCP contracting; nonetheless, as we discuss below, the law could impact service and drug pricing that facilities receive from their pharmacies, including the transparency of such pricing.

According to the MMA legislation, PDPs – rather than LTCPs – have the authority to create and maintain Part D formularies, a change that could have implications for a revenue source of many LTCPs – rebates from drug manufacturers. LTCP rebates have not been disallowed under Part D, but they must be reported to the PDPs with which LTCPs contract and, in turn, to CMS for calculating allowable reinsurance and risk corridor costs for PDPs beginning in 2007. Finally, unlike Medicaid payment rates, Part D payments to LTCPs are not set administratively but instead are negotiated between LTCPs and plans.

Methods

To explore how Part D's introduction is changing the operations of LTCPs and nursing homes, as well as the implications of those changes for beneficiaries and the Medicare program, we interviewed stakeholders across various perspectives. To provide ourselves with a baseline understanding of the nursing home pharmacy sector and the changes made by the MMA, we also reviewed published articles, media accounts, and other government and research reports. The interviews were conducted under contract with the Medicare Payment Advisory Commission, and the findings are presented in more detail elsewhere.(D.G. Stevenson et al., 2007) Unless otherwise noted, qualitative data collected from these interviews provide the basis for the information we present.

Developed with input from MedPAC and guided, in part, by previous work by ourselves and others,(California HealthCare Foundation, 2005; Gottlich, 2004; D. G. Stevenson, Huskamp, Keating, & Newhouse, 2007), the interview protocols focused across several areas of interest, including 1) PDP selection and enrollment by nursing home residents; 2) working across PDPs and navigating variation in plan practices and formularies; 3) the clinical impact of Part D on residents; and 4) Part D's operational and financial impact on LTCPs and nursing homes.

A total of 31 semi-structured, telephone interviews were conducted between November 2006 and January 2007. Stakeholder groups from whom 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 LTCPs (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 representatives of a single organization participated in individual interviews. Separate protocols were developed for each of the stakeholder groups, and interviews generally lasted 30-60 minutes.

Stakeholder selection occurred in consultation with the MedPAC staff and, in the case of providers, sought to maximize the number of Medicare beneficiaries receiving services. In particular, efforts were made to interview the larger nursing home chains, long-term care pharmacies, and PDPs, a strategy guided by the fact that the nursing home population receives pharmacy services from a concentrated number of entities. To examine whether and how perspectives and experience may differ for smaller providers and pharmacies (e.g., independent nursing homes or pharmacies), some interviews were also conducted with these types of organizations; moreover, several interviews were conducted with representatives from associations and group purchasing organizations representing a wider range of independent providers. Still, our findings may be less representative of the range of experience across smaller entities, such as independent pharmacies or nursing homes. Interviewees were assured the information provided would not be identified with them individually or organizationally.

The study design, protocols, and consent form were approved by the Committee on Human Subjects at Harvard Medical School.

Detailed notes were taken during each telephone interview and reviewed by research team members who participated on the call. Where relevant, supporting documents were requested to verify assertions made during the interviews. Unless specified, however, subjective responses were not validated through other means. Analysis of the interview data identified key themes of interest across stakeholder groups. In areas where views across stakeholders were in conflict, we were not able to assess whether competing claims were contradictory or whether they simply reflected disparate experiences. In our presentation below, we note the perspectives from which views come; however, we sometimes are not precise in these characterizations (e.g., not detailing the size of a LTCP or nursing home chain) to avoid conveying identifiable information.

Results

PDP Selection and Enrollment

As mentioned above, duals initially were autoassigned to plans with premiums at or below regional benchmark values, although beneficiaries retained the right to change. 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 plans with more limited coverage of their current medications and not change to a more advantageous plan. In written testimony(Gottlich, 2006) and in our interviews, some advocates argued for an alternative assignment process that would consider medications the beneficiary currently takes, attempting to match a beneficiary to a plan with relatively generous coverage of those medications. Although such processes can vary considerably, some 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” that considers factors such as current medication use to assign state pharmacy assistance program enrollees to PDPs.(U.S. Government Accounting Office, 2007)

Although duals may switch to a different plan at or below the benchmark once per month, Part D's emphasis on consumer choice could be considered a poor fit with the characteristics of the nursing home population. In particular, stakeholders cited the high prevalence of cognitive impairment in this setting as potentially undermining individuals' capacity for informed decision making. Importantly, MMA guidance restricts the ability of providers serving nursing home residents (including nursing homes, physicians, and pharmacies) to direct residents to particular plans.[1] 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 who enrolled in plans less suited to their medication needs. Yet, at the same time, other nursing home providers have strongly 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.

In practice, providers seem to take different approaches – and seem to have differing views on what activities are allowed – around educating and communicating with residents about their Part D 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 manner in which nursing home clinical

[1]Providers are able to offer objective information to residents, including how well drug plans cover medications of interest, but they are restricted from directing residents to a smaller number of plans and from distributing information with this aim.

staff use this information. In particular, some LTCP respondents characterized clear differences across their nursing home clients in the extent to which they directed residents to particular plans. Some nursing home providers viewed it as their responsibility to advise residents and families on plan choice, and others expressed greater concern about repercussions from survey agencies and/or the Office of the Inspector General. 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 individuals have changed from their originally assigned plans (whether driven by steering 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. In contrast, however, one PDP with whom we spoke cited fluctuations in the plan's institutional enrollment during 2006, partly attributing it to coordinated efforts by nursing homes and their pharmacy providers to switch residents to a subset of plans preferred by the facility or pharmacy. Similarly, one interviewee forwarded correspondence sent by an LTCP early in 2006 encouraging a client nursing home to consider changing residents from non-preferred PDPs to minimize charges to the facility resulting from rejected claims.

Working across PDPs

Prescribing in nursing homes depends on a series of communications between four parties – the prescribing physician, nursing home, LTCP, and PDP. 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. As noted above, Part D increased the clinical variation in nursing home prescribing, sparking some quality of care concerns among stakeholders who work in this setting. Clinical staff noted potential difficulty in determining individuals' Part D coverage at the point of prescribing. In cases where medications aren't covered or prior authorization or other requirements must be met, physicians often must be re-engaged in the prescribing process, either with the PDP directly or through the nursing home or pharmacy. 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.

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 being coverage of drugs important to nursing home residents. Although several stakeholders pointed to particular drugs where coverage was perceived to be problematic, the general 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 and guaranteeing transition coverage of medications during an enrollee's first 90 days of enrollment were cited as important safeguards. Importantly, medication access depends on factors beyond coverage, including prior authorization and step therapy requirements.

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 were raised as important and problematic issues. 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 often 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 more challenging under Part D, something detailed by the American Medical Director's Association in a recent survey of members.(American Medical Director's Association, 2006)

To ease the burden of prior authorization, exceptions, and appeals, CMS developed 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 that PDPs accept these forms, but most nursing home and pharmacy providers stated that PDPs generally require completion of PDP-specific forms as well. 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 noted that they 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. Most plans with whom we spoke indicated that nursing home residents accounted for 3-5% of total enrollees. 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 nursing home-specific prior authorization codes and waiving prior authorization requirements). 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.

Clinical Impact of Part D

Assessing the clinical impact of Part D in the nursing home sector is difficult without quantitative data describing drug utilization and other related processes and outcomes. 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 LTCPs must now work across multiple PDPs to deliver medications. In interviews, we heard about changes in drug dispensing by LTCPs and a tension that has emerged between timely provision of medications from LTCPs and obtaining coverage determinations from the PDP (or guarantees of payment from the nursing home). Although CMS's “transition fill” policy has reportedly helped 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), 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 LTCPs dispensing medications in advance of determining payment, and others being more hesitant to do so. One large nursing home provider indicated that pharmacies have become more aggressive in verifying coverage

before dispensing as non-covered medications have grown in magnitude. We also heard of some LTCPs dispensing shorter medication supplies in anticipation of resolving PDP-specific administrative issues before the prescription is refilled.

Nursing home and LTCP providers reported 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. 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 has emphasized the importance of reducing incentives to over-prescribe,(Leavitt, 2005) with the associated higher drug costs and potentially increased health costs and burden (e.g., through adverse drug events).

Finally, we asked stakeholders whether they felt Part D has had any impact on resident outcomes or quality of care. 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. Consistent with this response, 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 centered primarily on 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.

LTCPs

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, which we discuss in detail elsewhere.(Huskamp, Stevenson, Keating, & Newhouse, 2007) 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 (Pear, 2006a)) but they could also imply a loss if the drug has already been dispensed by the LTCP.

Like other aspects of Part D, LTCPs and PDPs have struggled with numerous administrative complexities associated with the transition, ranging from the logistical (e.g., reliably identifying full benefit duals to assess cost sharing properly) to the structural (e.g., meshing the distinct approaches LTCPs and PDPs have traditionally 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 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 is 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, but some noted 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.

An evolving area of Part D's impact on LTCPs is revenue from drug manufacturer rebates. Based on our interviews, it appears that manufacturers continued to pay rebates to LTCPs in the first year of the program but also that those rebates were anticipated to diminish in the coming years. Although some financial analysts questioned why federal policymakers singled out LTCP rebates and not those in other parts of the drug supply chain (e.g., PDPs), policymakers responded that rebates to LTCPs represent 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 highlyrebated medications before Part D, having the potential to impact residents negatively (e.g., through overutilization and adverse drug events) and to increase program expenditures.

Neither PDPs nor LTCPs have a direct financial incentive to ensure that nursing home residents receive the most beneficial medications under Part D, but some stakeholders noted that PDPs do have direct financial incentives to control drug expenditures because they share financial risk for drug costs with the Medicare program. PDPs reported that payments for institutionalized enrollees currently seem adequate; yet, plan representatives acknowledged that this could change in future years as risk corridors widen for plan payments. At the same time, if rebates paid to LTCPs diminish or disappear, LTCPs and analysts stated that LTCPs would likely attempt to recoup lost revenue through increasing dispensing fees to PDPs and service costs to nursing homes.

Nursing homes

Beyond the initial transition costs, 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. 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.

The long-term administrative and financial burden of the MMA on nursing homes depends largely on their contractual relationships with LTCPs. Most nursing homes 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 on the core LTCP 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.

As discussed above, non-covered drugs have been a concern for LTCPs in the first year of Part D.[2] Nursing homes are also attuned to this issue, in part because of their responsibilities under existing statute, raised by multiple stakeholders. In particular, the Nursing Home Reform Law, passed under OBRA '87, established standards of care for nursing home residents and stated that the nonavailability of program funding did not relieve facilities of this obligation. 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 is an issue for LTCPs and nursing homes to assign financially. Moreover, the challenge of minimizing these costs is joint, with stakeholders noting that nursing homes and LTCPs have to partner in ways stakeholders indicated they haven't before.

How nursing homes and their LTCPs are dealing with the non-covered drug issue seems to vary across providers. With the caveat that some nursing home 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. 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, the financial implications of Part D for nursing homes and LTCPs are intertwined. This realignment is still evolving, but it has already spurred changes in the way facilities and pharmacies interact and approach contracting. For instance, several stakeholders mentioned the importance of better integrating information systems to ensure consistent communication between the nursing home and pharmacy with PDPs.

Limitations

As noted above, there are several limitations to our study. Although we interviewed stakeholders across a variety of perspectives, we interviewed a limited number of individuals in each of the categories. We maximized coverage of Medicare beneficiaries by interviewing larger providers (e.g., large nursing home chains and LTCPs) and association representatives where possible; however, our findings are not necessarily comprehensive or representative, particularly of smaller providers. Second, our study presents a snapshot of Part D's impact in the nursing home sector to date and are largely unconfirmed by empirical data. This caveat is especially important to note relative to the clinical impact of Part D. We are also generally unable to evaluate competing viewpoints across stakeholders. Finally, although we do note the perspectives from which findings come, we sometimes are not able to provide further context for specific viewpoints to avoid conveying identifiable information.

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.

[2]Non-coverage of medications may be program-wide (e.g., for benzodiazepines) or PDP-specific.

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. For instance, Medicare beneficiaries in nursing homes have the same freedom to choose plans as community-based beneficiaries; yet, 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 burdens. 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.(D. Stevenson, Huskamp, Newhouse, & Keating, 2007)

Part D has increased the variation around formularies and drug management processes for residents at the facility level. At this point, medication coverage seems generally adequate, helped in part by CMS safeguards. Yet, stakeholder interviews also highlighted a tension between cost-saving strategies used by PDPs such as utilization management and the burden these processes can place on clinical and pharmacy staff. To date, stakeholders have not perceived adverse impacts on resident outcomes or quality of care attributable to Part D; however, further empirical work will be needed to verify and monitor these aspects. Importantly, plan features are not static; plan offerings (including below-benchmark plans) and coverage and utilization management across plans will change over time. Part D enrollment patterns for nursing home residents and the adequacy of below benchmark plans in meeting their medication needs should be monitored.

Stakeholders indicated that Part D's financial impact on nursing homes and LTCPs 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. Importantly, PDPs generally did not express a reluctance for having institutionalized enrollees in their plans; still, there seemed to be a level of uncertainty among PDPs about the adequacy of payment and risk adjustment going forward as risk corridors widen. The adequacy of Part D payments for institutionalized beneficiaries should be monitored closely as the benefit proceeds.

At this point, there are many uncertainties about the long-term impact of Part D in the nursing home setting. The benefit implies substantial change for institutional and financial arrangements in the LTCP sector, and it introduces new tensions in administering drugs to nursing home residents. These new tensions have the potential to produce positive and negative impacts clinically and financially. Although it seems premature to consider dramatic changes to the structure of the Part D benefit for nursing home residents, researchers and policymakers will need to be vigilant in monitoring utilization patterns and health outcomes for nursing home residents and in assessing the broader impact of Part D on nursing home quality of care. Should the current benefit structure prove too ill-suited to the nursing home environment, a different structure may need to be considered for institutionalized Medicare beneficiaries.

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References

American Medical Director's Association. Long Term Care Physicians Still Experience Difficulties in Prescribing Selected Drugs for Patients in Medicare Part D. Columbia, MD: AMDA; 2006. (Available at: http://www.amda.com/news/releases/2006/101206.cfm).

Appleby J. Nursing homes uneasy about Medicare plan; switch from Medicaid, random enrollment could be confusing. USA Today 2005 December 20;:3B.

Avorn J, Gurwitz JH. Drug use in the nursing home. Ann Intern Med 1995;123(3):195–204. [PubMed: 7598302]

California HealthCare Foundation. The Medicare Drug Benefit: Impact on Nursing Facilities. Oakland, CA: CHCF; 2005.

Gottlich, V. Issues for Medicare Beneficiaries in Long-Term Care Facilities: An Analysis of the MMA and Proposed Regulations. Washington, DC: Kaiser Family Foundation; 2004.

Gottlich V. Testimony Before the Subcommittee on Health of the House Committee on Ways and Means. May 4, 2006. 2006

Gurwitz JH, Field TS, Avorn J, McCormick D, Jain S, Eckler M, et al. Incidence and preventability of adverse drug events in nursing homes. Am J Med 2000;109(2):87–94. [PubMed: 10967148]

Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. Am J Med 2005;118(3):251–258. [PubMed: 15745723]

Huskamp, HA.; Stevenson, DG.; Keating, NL.; Newhouse, JP. Prescription Drug Claim Rejections for Nursing Home Residents under Medicare Part D. Draft working paper. Department of Health Care Policy, Harvard Medical School; 2007.

Institute of Medicine (U.S.). Committee on Nursing Home Regulation. Improving the quality of care in nursing homes. Washington, D.C: National Academy Press; 1986.

Jones A. The National Nursing Home Survey: 1999 summary. Vital Health Stat 2002;13(152):1–116.

Leavitt, M. Report to Congress: Review and Report on Current Standards of Practice for Pharmacy Services Provided to Patients in Nursing Facilities. Washington, D.C.: US Department of Health and Human Services; 2005.

Long-Term Care Pharmacy Association. Retrieved February 7, 2007, from http://www.ltcpa.org/

Medicare Payment Advisory Comission. Issues in Medicare Coverage of Drugs in June Report to the Congress: Promoting Greater Efficiency in Medicare. Washington, D.C.: MedPAC; 2007.

MedPAC. Report to Congress: Promoting Greater Efficiency in Medicare. Washington, D.C.: MedPAC; 2007. Issues in Medicare Coverage of Drugs; p. 155-184.

Mendelson, D.; Rajeev, R.; Abramson, R.; Tumlinson, A. Prescription Drugs in Nursing Homes: Managing Costs in a Complex Environment. Washington, D.C.: George Washington University; 2002.

Pear R. Pharmacists say drug plans threatens their livelihood. New York Times 2006a March 13;:A 12.2006

Pear R. Rules of Medicare Drug Plan Slow Access to Benefits. New York Times 2006b February 14;:A 17.

Stevenson D, Huskamp H, Newhouse J, Keating N. Medicare Part D and Nursing Home Residents. Under revision at the Journal of the American Geriatrics Society. 2007

Stevenson DG, Huskamp HA, Keating NL, Newhouse JP. Medicare Part D and nursing home residents. J Am Geriatr Soc 2007;55(7):1115–1125. [PubMed: 17608889]

Stevenson, DG.; Newhouse, JP.; Huskamp, HA. Medicare Part D, Nursing Homes, and Long-Term Care Pharmacies. Washington, DC: Medicare Payment Advisory Commission; 2007. (,http://www.medpac.gov/documents/Jun07_Part_D_contractor.pdf).

Stuart B, Simoni-Wastila L, Baysac F, Shaffer T, Shea D. Coverage and use of prescription drugs in nursing homes: implications for the medicare modernization act. Med Care 2006;44(3):243–249. [PubMed: 16501395]

The California HealthCare Foundation. The Medicare Drug Benefit: Impact on Nursing Facilities. Oakland, CA: CHCF; 2005.

The Lewin Group. Review of Current Standards of Practice for Long-Term Care Pharmacy Services: Long-Term Care Pharmacy Primer. Baltimore, MD: US Centers for Medicare and Medicaid Services; 2004.

U.S. Centers for Medicare and Medicaid Services. High Quality Access to Long-Term Care Pharmacies. Baltimore, MD: CMS; 2005a.

U.S. Centers for Medicare and Medicaid Services. Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plans, and 1876 Cost Plan. Baltimore, MD: CMS; 2005b.

U.S. Government Accounting Office. Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries. Washington, DC: GAO; 2007. (No. GAO-07-272)

U.S. Office of the Inspector General. Prescription Drug Use in Nursing Homes. Washington, D.C.: U.S. Department of Health and Human Services; 1997. No. OEI-06-96-00080