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Impact of Therapeutic Switching in Long-Term Care

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As growth in the senior population booms toward 40.2 million by 2010, the long-term care (LTC) market is emerging as a more important business line for managed care. Pharmacy and medical spending in the LTC population represents one of the fastest growing categories for Medicare Part D prescription drug plans. For example, of the 150,000 Humana LTC Part D members, approximately 148,000 are enrolled in the company's stand-alone drug plan (as of August 2007), and costs for this population are 2 to 3 times higher than they are in the retail setting—highest in skilled nursing facilities.[1]

Given the potential clinical and cost implications of designing and managing a benefit for the LTC population, HCPro, a publisher of regulatory resources for nursing homes, undertook research to understand provider perceptions of and experiences with Part D plan policies. (HCPro publications primarily reach directors of nursing, consultant pharmacists, medical directors, nurse practitioners, and administrators who use the publisher for its regulatory resources and Medicare training.) The goal of this research was threefold:

1. Identify major challenges and Part D policies, and their effects on providers and patients in skilled nursing facilities.
2. Collect individual facility accounts through a qualitative survey that could be used as an impetus for more robust research and policy discussions.
3. Aid Medicare Part D plans in understanding the potential implications of their policies for the LTC population.

METHODS

Initial Questionnaire and Phone Interviews

Using its database demographic profiles for each subscriber, HCPro selected a sample of 1200 clinicians who work in nursing homes representing all 50 states. In April 2007, HCPro disseminated an e-mail questionnaire to these subscribers, who had clinical credentials in nursing (RN, Director of Nursing), pharmacy (RPh, Consultant Geriatric Pharmacist), and medicine (MD, DO). The survey asked the recipients an open-ended question: What are your top 3 challenges in dealing with the new Medicare Part D prescription drug benefit?

A total of 884 clinicians representing 804 unique facilities responded (628 nurses and directors of nursing, 136 medical directors, 120 pharmacists). It should be noted that these 804 facilities are only a small portion (~5%) of the 16,000 nursing homes in the United States.[2]

Unsure how each respondent defined "switching" and the patient health impact of switching, the researchers conducted phone interviews with 10 randomly selected respondents. These interviews, which took place on September 18, 20, and 21, 2007, were with the following individuals: Teresita Orlina, RN, Director of Nursing, Potomac Valley Nursing Center, Rockville, Maryland; Matthew Murawski, RPh, PhD, Associate Professor of Pharmacy, Purdue University, West Lafayette, Indiana; Wendy Jobe, RN, Staff Nurse, Springfield, Illinois; Lesha Yerka, RN, Director of Nursing, Eden Park Nursing Home, Brattleboro, Vermont; Jannette Buchanan, RN, Director of Nursing, Ocean View Convalescent Center, Long Beach, Washington; Bonnie Hageman, RN, Nurse

Manager, Mercy Living Plus, Oelwein, Iowa; Ellen Kelly, RN, BC, Certified Director of Nursing Administration, Colonial Hills Nursing Center, Maryville, Tennessee; Leigh Davis, RN, Director of Nursing, Town & Country Health & Rehab, Minden, Louisiana; Cathy Leone, RN, staff nurse, Mt. Ascutney Health Center, Windsor, Vermont; Leah Westover, RN, Director of Nursing, Infinia of Show Low, Show Low, Arizona; Malcolm Fraser, MD, President, Bay Geriatrics, St. Petersburg, Florida.

Follow-up Survey

To uncover more case histories and facility accounts as to whether outcomes for nursing home patients and day-to-day quality of life could be adversely affected when a Part D plan switches medications for nonmedical reasons, we developed a follow-up electronic survey. Our hope was to gather individual facility profiles and then analyze them to see whether there were any noteworthy trends. At the time of the research in September 2007, little information existed to show whether switching for nonmedical reasons in the LTC population led to any negative outcomes (eg, an increase in hospitalizations).

Three online surveys—one each for nurses, physicians, and pharmacists—were created to identify the prevalence of nonmedical switching and to learn what each provider group's experience has been. Surveys contained the same questions generally. (See the **eAppendix Table** at **www.ajmc.com** for a list of the questions disseminated to the participants.) In each survey, we defined switching as therapeutic substitution; we further alerted each clinician filling out the survey that switching did not refer to substituting generic versions of the same molecule.

The initial survey respondents (n = 884) were invited to take the follow-up survey during the week of September 5, 2007. To ensure that they were qualified professionals and had the relevant experience beyond the minimum 10 years in LTC, HCPro asked each to fill out a pre-survey screening checklist to help identify their background in LTC. The checklist included these items:

- Minimum of 10 years' experience in LTC setting.
- Membership in the major LTC associations (American Medical Directors Association, Association Directors of Nursing Administration/Long Term Care, American Society of Consultant Pharmacists).
- Attendance at 5 or more association meetings in the last 5 years.
- High understanding of F-Tag guidelines for nursing homes (based on rating scale).
- Working in facility with 90 beds or more.
- Experience with 3 Part D plans.
- Having switched or observed someone switch a medication for a nonmedical reason (required).
- At least 2 years working at or consulting for current facility (required).

The researchers only reviewed responses from individuals meeting 6 of the 8 criteria. Other information also was collected prior to the qualitative questions (ie, respondent's title, location of facility).

The HCPro researchers acknowledged several limitations in collecting perceptions and individual case histories. For example, it was difficult to ask clinicians to recall their experiences from 2005 (before the Part D drug benefit took effect). To address this recall limitation, the research questionnaires asked respondents to provide general insights on the prevalence and implications of switching in this population in 2007 compared with before implementation of Part D.

RESULTS

Approximately 75% (N = 804) of the initial survey respondents commented that they had been experiencing various problems with medication switching or therapeutic substitution. Based on the 10 telephone interviews and other internal discussions, we defined switching as the practice of dispensing a chemical entity (within the same therapeutic class) different from the drug a physician originally prescribes, one that may require physician consent. More than 150 respondents to the initial survey were experiencing a greater number of requests by Medicare Part D plans and pharmacy benefit managers to "please switch patients to the formulary medication," but at times "without regard to how they worked" in the institutional elderly population, according to commenters.

The follow-up survey resulted in 768 anecdotal case accounts. (For demographic information on survey respondents, see **Table 1**.) In all, 569 responses were included in the research analysis, representing 555 skilled nursing facilities. A total of 199 responses were not included because the clinicians either (1) had not worked at their current facility consecutively since before the inception of Medicare Part D (42 respondents) or (2) did not meet the screening minimum (157 respondents).

Switching resident medications due to a nonmedical/Part D formulary requirement was very common at the time of the survey in September 2007, according to the 569 cases reviewed. It was the most common reason for switching in LTC (**Figure 1**). Among the clinicians who responded, 71% said Part D switches occurred typically at the initiation of therapy, whereas 29% wrote in a comments box that they recalled instances in which medication switches had occurred after prescriptions had been in place. At the time of the survey, lack of efficacy was the most common clinical reason that a resident in LTC was switched from one drug to another. As Figure 2 shows, switches for nonmedical reasons appeared to be most common for patients with hypertension (68%), high cholesterol (66%), gastrointestinal/stomach conditions (62%), diabetes (51%), and depression (44%)—the 5 diseases cited most among all respondents.

Outcomes

More than three-quarters of the respondents (76.6%) said it was common for a resident's new drug to be less effective after a switch for formulary reasons. In a nursing home, this is relevant for Medicare compliance reasons. For example, a portion of the clinicians noted circumstances in which a Part D plan's formulary preference (the therapeutic switched drug) was tried and proven ineffective. As a result, these facilities were forced to dispense a drug ineffective for the patient, and by doing so risked a violation of Medicare's F-Tag #329 unnecessary drug guidelines (see Discussion section).

Side Effects

Almost half of the respondents (45%) said side effects typically increased after a nonmedical switch in this population, and 37% said there were situations under Part D when patients needed a completely new medication to treat a side effect respondents believed was caused by the nonmedical switch. According to one nursing director, "What impacts the facility most with these switches is that we're seeing more side effects and as a result we've noticed a spike in using certain pain medications and antinausea medications in some cases. It takes longer, more staff time and causes more pain for the residents with switching to another formulary" (Teresita Orlina, RN, Director of Nursing, Potomac Valley Nursing Center, phone interview on September 20, 2007).

Common Negative Outcomes

Table 2 shows the differences between what nurses, pharmacists, and physicians "perceive and recall" as the most common negative outcomes after a nonmedical switch at the time they took the survey in 2007. Although

there are limitations in asking for opinions without backup claims data, these findings suggest that potential quality of care and possibly cost implications are associated with these policies. More than half of the physicians said they are at least occasionally called on to prescribe new medications for symptoms or side effects that arise as a result of nonmedical switches, though only about one-fifth of pharmacists thought so. Sixty-two percent of physicians said nonmedical switching resulted in increased side effects, compared with 49% of pharmacists and 24% of nurses. It's difficult to understand why the majority of nurses surveyed did not believe that side effects increased after a nonmedical switch, when most said that the new medication was less effective. This disconnect may be due in part to a lack of education on recognizing various signs and symptoms of diseases.

Switchbacks: Plan and Patient Health Impact

The **eAppendix Figure** (**www.ajmc.com**) illustrates that 44% of the 569 respondents who provided case accounts (63% of pharmacists) saw a Part D resident switched back to an original medication at least once after a nonmedical switch. Given the cost of switching for both the plan and the provider, this finding may indicate a need for additional research on the prevalence of switchbacks in the 2 years since Part D's implementation. According to the 354 nurse accounts, failure of the resident to respond to the drug was the most common reason for switchbacks (33%), followed by failure to tolerate the new drug (26.1%). One nurse director commented, "RxAmerica has a continual problem with switching patients back and forth between medications. This adds administrative costs to us and a number of side effect challenges for the nursing staff to deal with" (Lesha Yerka, RN, Director of Nursing, Eden Park Nursing Home, phone interview on September 21, 2007).

Medical Risk

Nurses thought that hypertension was the most medically risky disease in which to make a switch for nonmedical reasons. Physicians said depression was most risky, and pharmacists said depression and bipolar disorder were the most risky. Highlights from the clinician case experiences include:

- 88% of LTC residents with a gastrointestinal/stomach disorder were somewhat likely to highly likely to experience reduced efficacy if their medication was switched for nonmedical reasons.
- 95% of LTC residents with dementia were somewhat likely to highly likely to experience reduced efficacy if their medication was switched for nonmedical reasons.
- 100% of residents with Parkinson's disease were somewhat likely to highly likely to experience reduced efficacy if their medication was switched for nonmedical reasons.

Staff Time

Providers appeared to be spending more time in 2007 communicating formulary changes to payers, families, and peers. The time increase was relevant because some respondents said that some facilities had to hire administrative staff to support them with Part D–related communication. These assessments had limitations, given that respondents had to gauge the time they spent on specific tasks in 2006; however, about half of nurses said they were spending more time in 2007 than in 2006 on follow-up care because of formulary switching. As staff nurse, Wendy Jobe, RN, noted in her follow-up phone interview on September 21, 2007:

> Medicare Part D has created a greater demand on nurses and physicians to deal with issues that do not really impact quality of care. Physicians are contacted to switch from one [proton pump inhibitor] to another and then switch back again as the formulary changes, and the resident and family are caught in the

middle. Of course, the facilities and pharmacies cannot afford to take on the additional cost if the switch is not made, so there is a lot of time spent changing orders for medications that have no added benefit to the resident and sometimes may even cause adverse drug events or less efficacy.

In a phone interview on September 20, 2007, Matthew Murawski, RPh, PhD, an Associate Professor of Pharmacy at Purdue University, stated that switching for nonmedical reasons in nursing homes can produce unintended costs that far outweigh the potential savings generated from a highly managed formulary.

In long-term care, some patients will experience difficulties such as adverse reactions if a plan moves patients from a drug they are stabilized on to another medication. Some of those difficulties may lead to more medical charges, such as hospitalizations that far outweigh any savings the plan may have gained from switching. Many patients may experience minor problems only. However, these will require additional nursing care time but not generate any billable services.

DISCUSSION

Although the individual facility accounts suggest that nursing homes could be experiencing some increases in medical, pharmacy, and administrative costs—and ultimately costing Part D plans—how widespread and important these increases are could not be extrapolated from these anecdotal findings. However, according to one respondent, the findings serve as a cautionary tale: “Some Medicare Part D plans don’t understand anticholinergic side effects in the elderly, and their formularies illustrate their lack of education on this issue” (Malcolm Fraser, MD, President, Bay Geriatrics, phone interview of September 18, 2007). The possibility of adverse events and other negative outcomes increases as patients age, so what might be appropriate for a 65-year-old might cause an unwanted consequence in an 85-year-old.

Part D: Before and After

Assessing provider experiences with patient care before Part D took effect was difficult given the high probability that respondents would not be able to recall accurately their decisions and experiences. This was a significant limitation for gathering perceptions retrospectively. Overall, the majority of respondents (82%) said that they “believed” that nonmedical switches had increased, and of that number 58% thought that nonmedical switches were at least twice as common in 2007 than they were before Part D was implemented. These findings were difficult to evaluate given recall bias, but could serve as impetus for discussion about more data-driven research in this area.

Implications of Part D Policies for Long-Term Care

The survey and interview responses suggest that more exploratory research is needed on the effects of therapeutic switching in nursing home patients receiving the Medicare Part D benefit. Given the number of comorbid conditions for many patients and the higher risk of drug–drug interactions and safety accidents related to side effects, the responses from the 569 survey participants serve as cautionary guidance for plans. The Part D payer community or individual Part D plans may need to address their policies further as their LTC membership increases. According to comments from several of the physician survey respondents, switches within classes are not a major issue. However, if a Part D plan requires a resident to switch medications out of a chemical class, doing so brings inherent risks and potential downstream costs.1 For example, anticonvulsants have a narrow therapeutic index, and switching usually will require drug-level monitoring.[1]

On another level, medication-switching policies in this population have created an educational disconnect. Here

is an obvious example cited by Lesha Yerka, RN, Director of Nursing, Eden Park Nursing Home, in a phone interview on September 21, 2007:

> We have doctor's secretary/nurse refuse to assist with nursing home prior authorizations that are needed when switching is required by the plan. They think the nursing home can do it. We need to communicate with the MD, but are not given a chance to do so. We also have a problem with the MD who receives 2 prior authorizations, since a resident needs 2 pills with different doses to make up the ordered dose. The MD signs one, but not the other so we have to repeat the process. Also, the state is not accepting the date the drug was ordered and filled. They are paying from the day they receive the PA signed by the MD. So the nursing home gets stuck with the bills for meds that are ordered because we have to give them, but the MD feels too overworked to do the paperwork for the orders. We had this happen recently over a sleep medication; the MD got the PA and he changed the name of the drug and the PA was denied. We got stuck with paying for 50 pills to the tune of $224.00. This whole process takes up a lot of my time in a week, but doesn't help to decrease cost especially if you include my salary time.

At the same time as LTC providers have been managing Part D, nursing homes have had to comply with stricter Medicare medication monitoring guidelines that took effect in January 2007. Respondents complained that Part D switching policies conflicted with a Medicare regulatory mandate called F-Tag #329, which requires LTC facilities to ensure that any prescription medication is helping a patient to reduce side effects and meet the goals of their therapy—not produce the opposite effect. For example, if a drug causes side effects (eg, pain that prevents a patient from taking part in occupational therapy), nursing homes have a regulatory mandate under this F-Tag #329 to respond by adjusting the drug's dose or making a change in therapy or intervention. Complying with the F-Tag #329 mandate was becoming difficult for some facilities in the face of Part D therapeutic substitution policies. The fact that some nursing directors report conflicts between Part D switching policies and the FTag requirements is cause for discussion among stakeholders and perhaps greater education across the LTC continuum—payers, providers, and patients. The timing of F-Tag #329 and Part D presents an opportunity for managed care to conduct true medication therapy management for LTC.[1]

CONCLUSION

Nurses, physicians, and pharmacists clearly differ in their experiences and opinions about which diseases are most medically risky for nonmedical switches in LTC, but agree overall that this practice increases administrative time and raises the overall risk of more costly outcomes. Part D organizations may want to carefully consider adding clinicians with LTC experience to their clinical and various pharmacy and therapeutics committees, or consider taking a closer look at switching policies for Medicare Part D beneficiaries in LTC.