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Medicare Part D and Quality of Prescription Medication Use

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Abstract

In 2006, the United States Centers for Medicare and Medicaid Services implemented Medicare Part D to provide outpatient prescription drug insurance to disabled and older adults. In creating Part D, a key provision to address quality included medication therapy management (MTM) programs designed to increase proper and safe use of medications among targeted Part D beneficiaries. A preponderance of evidence shows that Part D has increased medication affordability and accessibility; however, what remains less clear is whether it has improved the quality of medication use and optimized health outcomes. Now in its sixth year, Part D is undergoing its first major revision with the gradual elimination of the coverage gap by 2020. Therefore, now is a good time to review the accumulated evidence on the impact of Part D and MTM programs on quality of medication use to help inform future policy decisions and research directions. In this review, we find that Part D's net effect on quality of medication use mainly has been positive. Cost-related medication nonadherence improves moderately and treatment interruptions happen less than expected. However, vulnerable subgroups, such as sicker and dual-eligible beneficiaries, experienced lags in improvement. Beneficiaries who entered the coverage gap consistently experienced interruptions and displayed worsening medication adherence after entering the gap, with generic-only gap drug coverage offering only suggested limited benefit. Such findings can serve as baseline information as the coverage gap phases out. Limited availability of data is the biggest barrier to research in Part D. Part D's overall effect on health outcomes and adverse medical events, such as hospitalizations, is inconclusive because of inadequate evidence to date. Similarly, no evaluation of quality of medication use is available on

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utilization management strategies and MTM programs delivered under Part D. Future research will need to further examine the added value of Part D and address whether it optimizes health outcomes in the Medicare population. As the current economic recession increases the pressure to cut costs, the effect of future spending restrictions, such as restrictions on coverage subsidies, will also be of special concern.

Introduction

In 2006, the United States Medicare system of health insurance for disabled and older adults began offering an outpatient prescription drug insurance program, called Medicare Part D. This program is coordinated by private health insurance plans and subsidized by the federal government to encourage enrollment. Drug coverage is close to universal as nearly 60% of all Medicare beneficiaries are enrolled in Part D and another 30% have creditable drug coverage from other sources including retiree drug plans or Veterans Affairs.^[1] Nationally, over 1,000 Part D plans are offered as either stand-alone prescription drug plans or Medicare Advantage managed care plans that include prescription drug coverage.^[2]

Now in its sixth year, the Medicare Part D legislation is about to undergo its first major revision. As part of the Patient Protection and Affordable Care Act (2010), the coverage gap (known as the doughnut hole) of Part D coverage will be gradually phased out by 2020.^[3] Out-of-pocket costs for Part D brand-name drugs will drop by 50% in 2011. Given these impending changes, now is a good time to review what is known about the performance of Medicare Part D and to identify the gaps in the evidence.

To date, nearly 60 studies have been published on the impact of Part D.^[4] Due to the delayed availability of nationally-representative Part D utilization data, published research has primarily used self-reported beneficiary surveys, examined claims data from single pharmacy chains, and restricted their analysis largely to the transitional year, 2006. Nonetheless, almost studies all have concluded that due to Part D, out-of-pocket drug spending decreased by about \$150 per year and overall medication use increased by 1 to 3 more prescriptions per year.^[5–8] Some vulnerable groups, such as the disabled and sicker beneficiaries, experienced a lag in these benefits and their medication use and out-of-pocket costs did not improved until the second year of the program, in 2007.^[9, 10]

Besides increasing medication accessibility, what remains less clear is whether Part D has improved the quality of medication use and optimized treatment outcomes.^[11] By making medications more affordable for beneficiaries, Part D conceivably can have implications for improved quality by increasing access to needed medications, reducing cost-related medication non-adherence, and ultimately avoiding medication-related adverse medical events.

To address quality, a key provision in the creation of Part D is the requirement of health plans to offer medication therapy management (MTM) programs for the purpose of increasing proper and safe use of medications in targeted Medicare beneficiaries with expected high medicine needs.^[12, 13] Initial federal regulations have purposefully been vague in defining the required services and eligibility criteria of MTM programs in order to promote innovation through competition among plans. As information on program costs and effectiveness emerges, policy changes will be made to set new requirements^[14] and MTM programs will develop eventual quality measures to establish practice standards.^[13] As a result, there is a continuing need to review accrued evidence on MTM's performance to inform policymakers in their efforts to optimize program design to promote quality within Medicare.

In this paper, we will review accumulated evidence on the impact of Part D and MTM programs on different quality indicators of medication use, including medication nonadherence, treatment interruptions, use of medications potentially inappropriate for older patients, and adverse medical events. With impending elimination of Part D's coverage gap and potential federal restrictions on MTM targeting criteria,^[14] reviewing accrued evidence on the accomplishments of Part D and MTM programs would help inform future policy decisions and research directions concerning quality and safety of medication use.

Overall Effect

Medication Nonadherence

Cost-related medication nonadherence (CRN) is an important quality indicator because of its significant association with poor health outcomes and adverse medical events, including hospitalizations and nursing home admissions. Among studies using beneficiary surveys to examine Part D's net effect on lowering self-reported CRN, most findings have been positive but moderate in magnitude, and varied by beneficiaries' morbidity, prior prescription insurance status, and income level. For example, using 2003–2006 longitudinal administrative and survey data, one study of a national sample of Medicare beneficiaries found that after Part D enrollment, beneficiaries had a small but statistically significant reduction in self-reported CRN (e.g., reporting not filling prescriptions and skipping or reducing doses due to costs).^[6] The improve in CRN was greatest among beneficiaries who lacked prior prescription coverage or had Medigap before transitioning to Part D. In a 2004–2006 national survey of Medicare beneficiaries, self-reported CRN decreased modestly but significantly for all beneficiaries after Part D implementation.^[15] However, significant declines in CRN did not occur among low-income, chronically-ill beneficiaries until the second year of the program, in 2007. This suggests that more vulnerable patients might have needed more time to adapt to new enrollment and administrative procedures before reaping the benefits of the new program.^[10] Similarly, the net effect of Part D on self-reported CRN was not detectable among beneficiaries with mental illness in the first year of the program. Using a 2005–2006 national survey of Medicare beneficiaries, another study found that self-reported CRN did not decline among post-Part D beneficiaries with depressive symptoms compared to beneficiaries without depressive symptoms.^[16]

Studies using pharmacy claims data have found more consistent and immediate effects of Part D on improving adherence, even across various clinical subgroups. For example, one study examining 2003–2007 claims data of beneficiaries with heart failure in a large Medicare managed care organization found that after Part D enrollment, beneficiaries were more likely to adhere to their heart failure therapies than before enrolling in Part D.^[17] Higher adherence to heart failure therapies was also observed among beneficiaries with Part D coverage as compared to those without any drug coverage. Another study found that beneficiaries with hyperlipidemia, hypertension, and/or diabetes had statistically significant improvements in medication possession ratios (MPRs) for cardiovascular and diabetes medications after 2 years of enrollment in Medicare Advantage Part D plans.^[18] However, the clinical significance of the increase has yet to be determined. Over 22%–59% of the beneficiaries still did not achieve good adherence as defined by MPRs < 80% after Part D.

Inappropriate Medication Use

The literature is still accumulating on the impact of Part D on potentially inappropriate medications (PIRx) that should generally be avoided among older patients. The one study on this topic found no significant difference in the likelihood of using PIRx between Part D enrollees and non-Part D enrollees.^[19] However there was some indication that the risk of PIRx use was increasing for Part D enrollees. One possible explanation is that many Part D

drug formularies cover PIRx medications in the lowest cost tiers thereby creating financial incentives to use these inappropriate medications.^[20] Additional research is needed to confirm these results.

Treatment Interruptions

Treatment interruptions may be especially concerning for beneficiaries whose previous drug plans were more generous than their new Part D plans in terms of coverage policies and formulary restrictions. Most studies examining treatment interruptions have focused on the transition period in 2006 among dual-eligible beneficiaries with both Medicare and Medicaid assistance. Almost all of the literature found small or no treatment interruptions that were attributable to the transition to Part D.

Dual Eligibles—Medicare beneficiaries with previous drug coverage through Medicaid had to either choose a Part D plan or be automatically enrolled in a plan based on a random assignment.^[21] Many states instituted wrap-around policies to supplement coverage gaps in Part D plans; however, if the wrap-around policies are less generous than their previous Medicaid plan, patients were likely to experience treatment interruptions due to insufficient supplemental coverage. Medicare allowed dual eligibles to switch prescription drug plans at any time during the year in order to address issues related to coverage or convenience in this special population. Using 2005–2006 claims data from a multi-state pharmacy chain, one study found that assignments of dual eligibles to Part D plans had moderate but no significant impact on the discontinuation of four essential drugs/drug classes covered by Part D (clopidogrel, proton pump inhibitors (PPIs), warfarin, and statins).^[22] In contrast, statistically significant and clinically large decreases occurred in the use of benzodiazepines after Part D, which was a group of drugs explicitly excluded from Part D coverage due to safety concerns (although some states offered wrap-around policies for these drugs). In addition, no significant increases in drug switching were observed after Part D transition except PPIs, a class in which all medications have similar efficacy and safety profiles. Similar observations were found in a small telephone survey of 325 dual-eligible beneficiaries in Kansas, where only 8% reported treatment discontinuations during the transition to Part D. These findings suggest that assigning dual eligible beneficiaries to Part D plans with different formularies did not significantly interrupt medication continuity to the extent originally expected, perhaps due to continued supplemental drug coverage by state wrap-around policies or the year-round opportunity for dual eligible beneficiaries to switch to the best plan for them.

Nursing Home Residents—The evidence is still growing on the effects of Part D in the institutional setting, although preliminary findings are somewhat negative. A study of 800,000 nursing homes residents detected disruptions in overall use of medications immediately following the first months of Part D. Initiation of the new program coincided with a statistically significant decrease of about half a prescription in the average monthly prescription use per resident and this decrease persisted throughout the end of the year.^[23] Another study of over 1 million nursing home residents found an abrupt and large discontinuation of benzodiazepine use in nursing homes immediately after implementation of Medicare Part D if state wrap-around coverage was not available.^[24] Furthermore, significant increases occurred in the use of potential substitute agents for the benzodiazepines, although the increases were temporary and not a complete offset. Given the frailty of this patient population, large changes in medication use raise concerns.

Disease Cohorts—Several small disease-specific surveys provide additional but limited evidence on low proportion of beneficiaries having treatment interruptions during transition. In a study of 125 homeless and marginally housed beneficiaries living with HIV, only 9

(7%) reported HIV treatment interruptions and cited their transition to a Part D plan with different coverage restrictions as a cause.^[25] In a small national survey of 908 psychiatrists, about 15% reported that their dual-eligible patients with mental illness had difficulties accessing refills or new psychiatric prescriptions and 8% had to switch psychiatric medications due to coverage restrictions during the transitional period.^[26]

Adverse Medical Events

Evidence has just started to accumulate on Part D's net effect on adverse medical events as quality indicators of medication use. For example, one study using 2005–2006 claims data from a large Colorado health plan found that changes in nonadherence to chronic medications did not result in an immediate apparent reduction of subsequent healthcare utilization, including medical office visits and emergency room visits, during the transition year 2006.^[27] However, in another study that used 2005–2007 multi-state data to examine hospitalization rates for eight chronic conditions hypothesized to be sensitive to medication adherence, Part D was associated with reduced hospitalization rates by 4%, representing approximately 42,000 admissions, among beneficiaries.^[28] More research is needed to confirm these results.

Benefit Design: Coverage Gap

One possible reason why the net effect of Part D on quality varies may be that the benefit design changes based on the level of spending – namely a flat deductible for the lowest level of spending, 25% coinsurance for the second level, a coverage gap in the third level, and a catastrophic coverage of 5% for the highest level of spending. The result is that Part D beneficiaries face different cost-sharing burdens throughout the year, which may influence medication use. In practice, Part D plans can modify the benefit design as long as it is “actuarially equivalent” to the standard drug benefit as defined by Part D.^[29] All plans must offer one actuarially equivalent design and then may offer additional enhanced designs. For example, beneficiaries may pay higher premiums for enhanced benefits for coverage of generic drugs while in the coverage gap.^[30]

Although the coverage gap is expected to phase out by 2020, it has been one of the most controversial features of Part D and has been most researched separately in the literature.^[3] Almost 15% of all beneficiaries reach the coverage gap and they tend to have high morbidity and medication use.^[31] Compared to the pre-gap period, the average monthly out-of-pocket spending for beneficiaries nearly doubles during the gap period.^[32] The coverage gap has been associated with a 9% to 16% decrease in the total number of prescriptions, potentially indicating a rise in CRN or treatment interruptions during that period.^[33, 34] Studies on quality include those examining no coverage in the doughnut hole and those examining gaps with only generic drug coverage.

No Coverage in Gap

Accumulated evidence consistently shows that the coverage gap (also called the doughnut hole) is associated with overall increase in nonadherence and interruptions in the use of chronic medications once beneficiaries reach the coverage gap. For example, one study using 2005–2006 dispensing data from multi-state pharmacy chains found that beneficiaries who reached the coverage gap had a significant decrease in the number of prescriptions filled for essential medications, including clopidogrel, warfarin, PPIs, and statins, that they had been using prior to entering the gap period, indicating interruptions across multiple drug classes.^[7] Similarly, another study examining 2005–2006 claims data from a large Colorado health plan found that nonadherence to multiple chronic medications increased significantly among beneficiaries after reaching the coverage gap.^[27] Furthermore, in a multi-state study

that used 2007 pharmacy claims data, 20% of the beneficiaries who reached the coverage gap reported stopping their medications, reducing/skipping doses, or switching to an alternative often a generic drug.^[32] Beneficiaries with the highest proportions who stopped, switched, or reduced their medications after reaching the gap included those taking PPIs, antidepressants, and diabetes treatments. Similar evidence of medication discontinuation and nonadherence in the coverage gap had been reported in several small surveys of Part D beneficiaries regarding cost-lowering strategies.^[35, 36]

Generic-Only Gap Coverage

For some enhanced benefit plans and with an added premium, generic drug coverage was offered for beneficiaries who reached the coverage gap. Evidence to date suggests that, for beneficiaries enrolled in such plans, generic-only coverage has increased generic drug use by as high as 25%, but reduced overall medication use by as much as 16% was still observed.^[37] Using 2006 claims data from a large Pennsylvania health plan, one study found that although prescriptions of generics increased and brand-name drugs decreased, overall medication use was reduced by 3% among beneficiaries with generic coverage in the gap. In comparison, beneficiaries lacking any coverage in the doughnut hole reduced their drug use by 14%.^[34]

Using 2005–2006 combined claims and survey data from a network health plan, two studies examined medication nonadherence among beneficiaries with diabetes mellitus.^[38, 39] They found that nonadherence to oral diabetes, hypertension, and lipid drugs were lower, but modest, after beneficiaries entered generic-only gap coverage perhaps due to savings from using generic medications.^[38] However, nonadherence rates for diabetes medications were no better between beneficiaries with generic-only gap coverage and those with no coverage in the gap.^[39] Similar findings were reported in another study using 2008 pharmacy claims data, in which the difference in adherence to diabetes medications was not significant between beneficiaries having generic-only coverage and those without any drug coverage in the coverage gap.^[40] In fact, compared to those with no coverage and those with generic-only coverage, only beneficiaries with both brand-name and generic coverage in the doughnut hole were significantly more likely to continue being adherent to their diabetes medications after entering the gap. These findings suggest that the value of generic-only coverage gap may depend on whether generics are available or optimal for beneficiaries. Although plans with generic-only gap coverage may reduce prescription costs by steering beneficiaries toward more cost-effective medications, there is a lack of evidence regarding the health impact of switching medications for cost-saving purposes.

Utilization Management Tools

Many Part D plans impose supplemental utilization management strategies, including prior authorization, quantity limits, and step therapy that requires several failed trials of drugs before coverage is approved. A recent review finds that no published studies have specifically examined step therapy in the context of Medicare Part D and that existing evidence regarding step therapy's effect on medication quality in non-Part D plans remains inconclusive.^[41] Evidence on utilization restrictions employed in Part D plans come from a few small studies that have focused on psychotropic medication interruptions among beneficiaries with mental disorders.

Treatment Switching/Interruptions

Only two studies have examined the impact of Part D utilization management tools on medication quality. One study of 467 dual-eligible beneficiaries with mental disorders in Michigan found that few beneficiaries experienced treatment interruptions due to utilization

controls; however, beneficiaries in Part D plans that employed utilization management tools were more likely to have psychotropic treatment interruptions and switching than those in plans without such tools.^[42] In a 2006 national survey of 1,490 psychiatrists who treated dual-eligible psychiatric patients, utilization management strategies employed in Part D plans were associated with elevated risk of medication access problems, such as medication discontinuation or temporary termination, and adverse medical events.^[26]

Medication Therapy Management Programs

The key objective of MTM programs under Medicare Part D is to improve quality and safety of medication use and optimize health outcomes for targeted beneficiaries with high medicine needs.^[13] A body of literature has documented the clinical, economic and humanistic outcomes of MTM programs reimbursed by state Medicaid programs and community-based insurance providers.^[43] However, no published studies to date have examined the impact of MTM services offered under Part D on these same outcomes, except for one small survey of 60 Part D beneficiaries that reported high satisfaction rating as a quality of care measure after enrolling in a pharmacist-provided telephone MTM program.^[44] A primary reason for the scarcity of research in this area is that public-use Part D data specific to MTM programs are not available for study purposes. In addition, broadly defined MTM eligibility criteria and services stipulated in initial federal regulations have resulted in a wide variety of different MTM programs, making evaluation of individual MTM program and comparisons across multiple programs difficult.^[43] Finally, the lack of easily measureable outcomes common to MTM programs adds to the complexity of comparing between programs. Despite these limitations, great strides have been made, for example, with the formation of the Pharmacy Quality Alliance to develop and test consensus-based performance measures for MTM services with the ultimate goal of assessing and improving the quality and safety of medication use.^[45]

Discussion

Based on our review of the available evidence to date, we find that Part D's overall effect on quality of medication use has been mostly positive although there are some exceptions. Adherence appears to have improved for most patient groups, although low-income and sicker beneficiaries did not increase adherence until the second year of the program, and no adherence benefit was observed in nursing home residents. This suggests that more vulnerable populations may need additional assistance in gaining benefits from Part D. Treatment interruptions during the transition to Part D occurred far less than originally expected for dual eligibles and beneficiaries with chronic conditions. This suggests that the safety net aspects of Part D, such as auto-enrollment and year-round opportunity to switch plans for dual-eligible beneficiaries, may be necessary and effective. Furthermore, based on available evidence, the impact on adverse medical events remains uncertain and needs further investigation. Additional research is needed to confirm the effect of Part D on the use of PIRx.

Policymakers have responded to concerns about the coverage gap in Part D by phasing it out. Current findings on the pre-phase-out period can serve as important baseline information for future quality evaluation studies. Almost all research finds that coverage gap is associated with increased nonadherence and interruptions across multiple drug classes and beneficiaries with different morbidities. Regarding generic drug-only coverage gap, studies show that adherence rates to diabetes medications are no better in gaps with generic-drug coverage relative to rates in gaps with no drug coverage. The value of generic-only coverage gap therefore may depend on whether generics are available or optimal for the beneficiaries. These findings will need to be replicated in other disease areas.

Part D plans may face increasing pressure to employ more stringent utilization management strategies to control prescription costs with the elimination of the coverage gap. The effect of utilization restrictions on quality is uncertain in Part D plans without more research. Limited available data suggest that psychotropic medications were switched or terminated due to utilization management strategies among beneficiaries with mental disorders. However, several challenges complicate the interpretation of utilization management and quality.^[46] For example, distinguishing whether utilization management techniques are employed to ensure proper use of medications or to control prescription costs may be difficult. Fewer drugs subject to prior authorization may create more access, but more restrictions may protect beneficiaries from harmful drugs

Medication therapy management programs offer an important opportunity to address quality and safety of medication use among high-risk Medicare beneficiaries. To date, no published studies have examined quality on medication use, except general satisfaction with care, within the context of Part D-sponsored MTM programs. Evaluations of MTM services, as well as Part D coverage, are confronted by challenges with limited data. It wasn't until 2010 that national public-use Part D data were released to researchers, and there are concerns regarding the linkability of Part D data to other Medicare databases and to other data sources, including state Medicaid data. At the plan level, Medicare Advantage prescription drug plans have access to both medical and pharmacy claims data, and use that data for monitoring and quality improvement; however, stand-alone prescription drug plans have access only to Part D claims data. Ensuring the ability to link data from stand-alone prescription drug plans to other Medicare claims would increase opportunities for measuring MTM program quality and the effect of Part D quality as it relates to physician and hospital services.

Besides linkage concerns, data content on quality is also limited. For example, many of the measures currently collected nationally on Part D plans are related to operational or procedural functions; however, more measures related to health outcomes or health services utilization are needed to better understand and improve Part D quality. CMS could encourage quality improvement activities by further requiring and publishing information on developed measures that already exist, such as measures for sub-optimal drug therapy, drug interactions and inappropriate use, and adherence.^[47] Furthermore, information specific to MTM programs are not available in the released Part D data.

Studies regarding the impact of Part D must go beyond medication utilization rates and examine quality of use and its association with health outcomes. Future studies should examine other meaningful indicators of quality – including suboptimal prescribing, underuse and overuse of essential medications, drug interactions, polypharmacy, and adverse drug-related events, among others – that can be reliably measured using pharmacy data already collected in health plans. Developing new quality measures and refining established ones will also help address evolving clinical evidence, and facilitate comparison of Part D plans and MTM services in the effort to ensure optimal outcomes for beneficiaries.

Proper monitoring and evaluation of Part D are needed to ensure that beneficiaries appropriately and safely use appropriate medications and that optimal health outcomes will be achieved, while minimizing adverse drug events. Future research will need to further address the added value of Part D, and examine whether it optimizes health outcomes in the Medicare population. Potentially unintended negative consequences such as greater reliance on utilization management tools in Part D plans also will need to be investigated. It is important to note that the current economic recession may have negative consequences on medication adherence and overall outcomes as premiums and out-of-pocket costs increase and beneficiaries' ability to pay decreases. Many states are looking for ways to restrict their

spending in Medicaid programs and state pharmaceutical assistance programs, thereby potentially limiting subsidies and supplemental coverage of non-Part D drugs for dual eligible beneficiaries. The impact of these restrictions on quality and health outcomes will need to be further studied.

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