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Medicare Part D Research and Policy Highlights, 2012: Impact and Insights

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Abstract

Background—In the 6 years since the implementation of Medicare Part D in the United States, the program has been reported to improve quality, offer better beneficiary protections, and lower drug costs.

Objective—The purpose of this article was to highlight the latest key peer-reviewed research findings on Medicare Part D and major public policy initiatives for Part D for 2012.

Methods—PubMed was searched for studies on Medicare Part D published in 2011 in biomedical/scientific, peer-reviewed, English-language journals. For the policy update, sources included the Federal Register, the Medicare Prescription Drug Benefit Manual, the 2012 Final Call Letter, and guidance from the Centers for Medicare and Medicaid Services.

Results—Medicare Part D has been associated with increased medication utilization, reduced out-of-pocket expenditures, and an overall decrease in cost-related non-adherence and nonpersistence. Its impact on reduction in non-drug utilization of health services has been more apparent after the transition year in 2006 and among subsets of Medicare beneficiaries. Recent policy changes promise to make Part D more user-friendly, simplify choice, and offer greater protection to beneficiaries. The coverage gap will phase out by 2020. Both the quality rating system for prescription drug plans and medication therapy management programs were enhanced.

Conclusions—Although Part D was designed to improve drug benefits, improvements may be needed in plan selection and simplification, quality assessment (especially with regard to long-term impact and health outcomes), evidence-based improvements in medication therapy management, and disparities among priority subpopulations. Medicare Parts A, B, and D could be coordinated to offset costs by increasing medication expenses and decreasing expenses for nonprescription medical services, thereby improving the overall cost-effectiveness of the Medicare program.

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Keywords

beneficiaries; drug benefits; drug costs; Medicare Part D

INTRODUCTION

In the 6 years since the implementation of Medicare Part D in the United States, the program has been reported to improve quality, offer better beneficiary protections, and lower drug costs.[1] Medicare Part D offers outpatient prescription drug coverage through private plans, either stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug plans (MAPDs). The fundamental structure of the voluntary benefit remains the same, which is based on a standard drug benefit that is updated annually. Updated standard benefit parameters for 2012 versus 2011 are shown in Table I.[2] The current plan year started on January 1, 2012, with a deductible, initial coverage, a coverage gap, and catastrophic coverage, with no annual upper limit. Private plans may vary in premiums, deductibles, formulary design, and utilization management tools, while still adhering to guidelines put forth by the Centers for Medicare & Medicaid Services (CMS). The Part D benefit is means tested. Lower-income beneficiaries, including those dually eligible for Medicare and Medicaid, have reduced or no cost-sharing requirements through the Low Income Subsidy and supplemental pharmacy assistance programs. Higher-income beneficiaries pay a premium supplement.[3] For example, beneficiaries with an annual income between $85,000 and $107,000 pay an additional $11.60/mo directly to the federal government. Approximately 30 million Medicare beneficiaries are enrolled in Part D, of whom 10 million qualify for the Low Income Subsidy.[4] Medicare Part D is widely considered successful in that a growing number of beneficiaries now have drug coverage and their medications are more affordable than if they had no coverage.[5,6] The impact of the program is the subject of much ongoing research.

The purpose of this article was to highlight the latest key peer-reviewed research findings published in 2011 on Medicare Part D and major public policy initiatives for Part D for 2012. The intents are to provide researchers, policymakers, and health care professionals a snapshot of the contemporary issues related to Part D, and to discuss implications that may be addressed by current research and policy initiatives. As Part D undergoes a major policy change with the gradual phase-out of the coverage gap that was started in 2011, this update becomes even more relevant and complements the growing body of literature on Part D.

METHODS

For this research update, a search of PubMed was conducted to identify studies published in 2011 on Medicare Part D in biomedical/scientific, peer-reviewed, English-language journals. Articles that directly examined the impact of Part D and had direct policy implications were selected. Editorials, review articles, as well as descriptive and case studies were excluded. For the policy update, the sources of information included final rules published in the *Federal Register,* the *Medicare Prescription Drug Benefit Manual,* the 2012 Final Call Letter, and nearly 100 CMS guidance memos in 2011 to Part D PDP sponsors. Preference was given to broad policy initiatives versus administrative changes.

RESULTS

Research Highlights

Key studies were categorized into 5 themes: (1) plan selection; (2) drug utilization/ expenditures; (3) drug adherence/persistence; (4) nondrug service use/health outcomes; and (5) medication therapy management (MTM) programs.

Plan Selection—When Part D was implemented in 2006, there was an average of 42 drug plans per region available to beneficiaries, which decreased to 31 by 2012.[7] The high number of plan choices raised questions about how Medicare beneficiaries would make optimal assessments given the decision-making complexity, cognitive demand, and time burden.

Findings: Matching drug claims data with data on plan characteristics (n = 477,393), Abaluck and Gruber[8] reported that although beneficiaries preferred plans with lower premiums and lower out-of-pocket (OOP) expenditures, they placed more weight on premiums than on expected OOP costs. Beneficiaries also appeared to weigh the financial characteristics of a plan as greater than their risk for cost-sharing expenses. Three additional studies employed Internet-based experiments to simulate the official Medicare Web site to examine plan selection. Hanoch et al[9] (n = 129) reported that participants were able to identify the Part D plan with the lowest total annual cost in only 46% of cases. Presenting a menu with more plan choices was less likely to be associated with correctly selecting the lowest-cost plan (odds ratio [OR] = 0.25). This negative association was more pronounced as age increased. Older consumers were more likely to evaluate the attributes of a particular plan (attributed based) rather than compare plans (alternative based) along a single factor (eg, compare total estimated annual cost across plans), possibly explaining why they tended to fail in identifying the least expensive plan. Using the same data, Wood et al[10] reported that higher numeracy (ability to understand basic mathematical concepts) was positively associated (OR = 1.21) with correctly answering questions regarding Part D plans, such as identifying the lowest-cost plan, plans with the most pharmacies, and plans with no mail-order option. Using another Internet-based simulation approach (n = 281), Szrek and Bundorf[11] reported that greater numeracy and cognitive reflection (the ability to reject an intuitive but wrong answer in favor of a reflective and correct answer) were positively associated with making a decision to select a hypothetical plan without delay. However, higher numeracy was associated with a lower willingness to pay for a plan choice, suggesting that plan choices may need to be accompanied by clear information about benefits to the consumer.

Two intervention studies examined the impact of pharmacists' consultation to help beneficiaries in making better choices when selecting plans, as well as applying for low-income subsidy benefits and requesting less expensive therapeutic alternatives.[12,13] Pharmacists are permitted to give objective advice to patients who are researching drug-plan options and seeking guidance. Using 1-on-1 plan counseling, Cutler et al[12] reported that, among 1300 vulnerable, low-income beneficiaries in California, 390 switched their plans to a lower-cost Part D plan during on-site sessions, reducing their expected OOP costs by 68%. Additionally, 72 beneficiaries were identified as eligible for, but not receiving, Low-Income Subsidy benefits, and 55 received assistance with applying online for the subsidy. Among 50 Part D beneficiaries in North Carolina, Alston and Hanrahan[13] reported that 48 subjects had not selected the least expensive plan and had a potential to save $456/y.

Implications: Although the studies were not nationally representative, these findings collectively suggest that the presentation of Part D plans in Medicare Web sites may need to

provide simplified information appropriate for individuals with varying numeracy levels,[10] especially those with low numeracy (defined as ≥2 incorrect responses on a 3-question numeracy instrument) due to potential decision avoidance.[11] Information on plan choices may need further simplification, for example, by reducing the number of choices,[9] restricting choices to the most cost-effective plans,[8] or highlighting clear differences.[11] Decision-making tools may help beneficiaries select plans using alternative-based (versus attribute-based) strategies.[9] Other tools may help consumers to understand their expected medication needs and OOP costs in relation to the financial characteristics of the plan.[8] Furthermore, targeted counseling by pharmacy advocates, such as pharmacists and others who receive specific training to assess Part D plans, may help beneficiaries to enroll in the most optimal plans, request less expensive drug alternatives, and reduce OOP costs.[12,13]

Drug Utilization/Expenditures—Part D was designed to make medications more affordable and thereby expectedly reduce OOP medication costs and increase medication use.

Findings: Three studies have analyzed the net impact of Part D using nationally representative data. Using the 2000–2007 Medicare Current Beneficiary Survey (MCBS; n = 38,798), Briesacher et al[14] reported significant mean per-person increases of 1.8 prescription fills per year in 2006 and 3.4 fills/y in 2007 versus increases of 0.9 fills/y prior to the implementation of Part D. Only after 2007 did prescriptions significantly increase for beneficiaries with fair to poor health. Furthermore, mean OOP drug costs per person decreased significantly, by $143/y in 2006 and $148/y in 2007, above pre–Part D increases of $12/y. Liu et al,[15] examining data from the 2005–2006 Medical Expenditure Panel Survey (MEPS; n = 1105), reported that Part D was associated with an increase of 2.05 prescriptions and a reduction of $179.86 in OOP drug costs per patient-year. These findings were similar, albeit smaller in magnitude, among beneficiaries reporting ≥1 chronic disease. Using 2004–2007 MEPS data (n = 5143), Chen et al[16] investigated racial/ethnic differences in the impact of Part D on drug expenditures and unmet drug needs (ie, delay in filling necessary prescriptions). The study reported that after Part D enrollment, the total OOP payments were more likely to decrease in black Medicare beneficiaries, and unmet drug needs were more likely to decline in Hispanic Medicare/Medicaid dually eligible patients, compared with their white counterparts.

Two studies have examined the impact of coverage among MAPD enrollees with different levels of pre–Part D drug coverage. Using 2005–2007 MAPD claims data from 8 states (n = 248,773), Ettner et al[17] reported that drug utilization and total drug expenditures (patient OOP costs and plan reimbursements) increased among all MAPD enrollees; however, enrollees whose drug benefits became less generous after enrollment (eg, loss of branded-drug coverage) had smaller increases in drug utilization and expenditures compared with enrollees whose benefits gained the most from Part D. The differences were more pronounced among enrollees at high risk for coverage gap entry (ie, those sickest and with the greatest needs for medication). Using 2004–2007 MAPD data (n = 16,002), Zhang et al[18] reported that the use of antihypertensives increased among MAPD enrollees, especially in those without prior drug coverage (OR = 1.40). The proportion of enrollees using angiotensin-II receptor blockers (a drug class more expensive than angiotensin-converting enzyme inhibitors, which are less expensive, equally effective alternatives) increased from 40% to 46% after enrollment.

Conwell et al[19] used 2007 pharmacy claims data (n = 39,599) to examine the impact of the pre-2011 Part D coverage gap on changes in utilization of osteoporosis medications among postmenopausal female Medicare beneficiaries. They reported that over half of the sample reached the coverage gap. During the gap, OOP costs increased considerably for enrollees

who entered the gap, particularly among those using high-cost osteoporosis medications. Findings were consistent between enrollees in MAPDs and those in PDPs.

Implications: As nationally representative Part D usage data become available, future research should validate existing findings on the association of Part D with increased medication utilization and reduced OOP expenditures. More clarity is needed regarding the long-term impact of Part D,[14] the effect of the coverage gap phase-out, and the heterogeneous effects on priority subpopulations.[15] Future research should examine the impact of Part D on drug use, with a focus on cost-effective drugs, to further determine the value of the policy.[18]

Drug Adherence/Persistence—Nonadherence to medications as prescribed is a widely recognized clinical problem. The increase in drug coverage from Part D raises questions about whether access to needed medications would improve, and in turn reduce, rates of cost-related nonadherence (CRN) and nonpersistence.

Findings: Two survey-based studies have examined the net effect of Part D on self-reported CRN (delay in or not filling a prescription due to cost) and discontinuation. Examining the nationally representative 2005–2006 MCBS (n = 8935), Kennedy et al[20] reported that self-reported CRN rates declined between 2005 and 2006 in all beneficiaries, with the greatest reductions (from 22.1% to 14.3%) among newly insured beneficiaries who gained drug coverage through Part D. Despite having Part D in the transitional year, beneficiaries with poor health, multiple chronic conditions, and/or depression continued to be at high risk for self-reported CRN. Using data from nonprobability-sampling, Web-based surveys administered in 2005 (n = 1220) and 2007 (n = 1024), Urmie et al[21] reported that, comparing 2007 to 2005, Part D was associated with lower rates of discontinuing a prescription due to cost, applying to a drug-assistance program, receiving free prescription samples, and having limited prescription access. In Part D respondents, the likelihood of using cost-saving measures in 2007 (eg, applying to drug-assistance programs, asking a provider for a less expensive prescription) was similar to that in uninsured respondents, perhaps due to the educational interventions of Part D for generic alternatives, higher third-tier copayments, and coverage gap.

Three studies used pharmacy claims data to examine the impact of the Part D coverage gap on CRN (nonadherent if ≤80% days with drug supply), discontinuation (having no claims for ≥30 days), and/or skipping doses (having ≥30 days without medication available between 2 fills for the same medication). Using 2006–2007 data (n = 663,850), Polinski et al[22] reported that among one third of the sample who entered the coverage gap, beneficiaries in plans with no financial assistance during the gap were twice as likely to discontinue a drug on entering the gap compared with beneficiaries in plans with financial assistance during the gap. Beneficiaries who entered the coverage gap were more likely to have CRN than those with no gap. The second and third studies reported that the coverage gap adversely affected medication adherence and persistence among beneficiaries taking drugs for osteoporosis. Using 2007 data (n = 39,599), Conwell et al[19] reported that postmenopausal female beneficiaries in either MAPDs or PDPs with a coverage gap were more likely to discontinue or skip osteoporosis medications than were beneficiaries in plans without a gap. Tamariz et al[23] used 2006 PDP data to examine persistence with selected treatments for chronic conditions—osteoporosis, rheumatoid arthritis, and multiple sclerosis—during the coverage gap. Discontinuation was more likely in plans with a coverage gap versus plans without a gap among enrollees taking osteoporosis medications but not among enrollees taking other medications.

Additional studies have examined the effect of Part D on CRN in beneficiaries with specific chronic conditions. For example, Frankenfield et al,[24] using data from a 2007 survey of PDP enrollees (n = 1329), reported that respondents with end-stage renal disease (ESRD) had a higher risk for self-reported CRN (OR = 1.23) than did respondents without ESRD. Two studies examined beneficiaries with diabetes mellitus. Stuart et al[25]—using 2006 claims data from a random 5% file of Medicare beneficiaries (n = 45,613 PDP enrollees) and from retiree health plans (n = 211,919)—found no statistical difference between PDP and retiree health plan enrollees in medication possession ratios or duration of most therapies for diabetes. Using 2008–2009 claims data (n = 22,546), Zhang et al[26] reported that only 42% of all respondents attained adherence with oral antidiabetic medications but that adherence rates were higher among respondents using mail-order pharmacies than those using walk-in pharmacies (49.7% vs 42.8%). Additionally, 3 studies examined antidepressant/antipsychotic agents. The first 2 claims-based studies reported that Part D was associated with increased adherence and persistence to antidepressants,[27] particularly among beneficiaries who had limited or no drug coverage before the implementation of Part D.[28] The third study, based on a 2006 survey of 986 Medicare/Medicaid dually eligible patients sampled from practicing psychiatrists, reported that 28% of previously stable patients had to discontinue or switch indicated antipsychotics due to coverage restrictions.[29] Because 2006 was a transitional year, dually eligible beneficiaries were mandatorily assigned to Part D plans, and there were reports of problems with the formularies and their appropriateness for individual beneficiaries. Such occurrences gradually resolved over the year and in subsequent years.

Implications: Although the net effects of Part D are overall decreases in CRN and nonpersistence,[20,21] additional interventions may be necessary to target beneficiaries with certain health conditions, including ESRD,[24] diabetes,[26] and psychosis.[29] Before the coverage gap is phased out (by 2020), providers should closely monitor CRN and drug discontinuation during the gap to avoid potential adverse clinical consequences,[22] especially in patients on osteoporosis treatments.[19,23] More aggressive interventions may be needed to emphasize switching medications to lower-cost but equally effective alternatives to alleviate the financial burden on beneficiaries.[22] Future research should examine why enrollees continue to employ cost-saving measures,[21] whether mail-order pharmacy use increases CRN,[26] and how CRN and nonpersistence affect health outcomes.

Nondrug Service Use/Health Outcomes—Because Part D does not, by design, affect incentives for nonprescription health care services, it is uncertain whether increased spending on medications under Part D would be offset by subsequent reductions in spending on other health services.

Findings: One study found no evidence of cost offset related to Part D. Using the nationally representative 2005–2006 MEPS (n = 1105), Liu et al[15] reported that the net impact of Part D during the transitional year did not significantly reduce the likelihood of all-cause emergency-department use, all-cause hospitalizations, or overall health measured by preference-based health utility. However, other studies using more recent Part D data reported significant impact on nondrug service utilization. For example, Afendulis et al,[30] examining 2005–2007 hospital discharge data from 23 states, reported that having Part D significantly reduced the hospitalization rates for 8 conditions believed to be sensitive to drug adherence (by 20.5 per 10,000, representing ~42,000 admissions). Using 2004–2007 data from insurance claims linked to the nationally representative Health and Retirement Study (n = 6001), McWilliams et al[31] reported that beneficiaries with limited or no pre–Part D drug coverage were more likely to have decreased nondrug spending after the implementation of Part D on inpatient, skilled-nursing facility, and physician services

relative to beneficiaries with generous prior drug coverage. These results were consistent between MAPD and PDP enrollees. West et al,[29] using data from a 2006 survey of 986 dually eligible patients taking antipsychotic agents, reported that patients who had to switch indicated medications due to plan coverage restrictions were more likely to experience adverse events, including psychiatric emergency-department visits/hospitalizations, violent ideation/behavior, and suicidal ideation/behavior.

Implications: Research providing empirical evidence on the clinical impact and cost offsetting of Part D is important for bolstering the argument for more robust Part D coverage. The latest evidence suggested that under Part D, reduction in nondrug utilization of health services may be more apparent after the transition year (2006)[30,31] and among subsets of Medicare beneficiaries.[29] As more post–Part D data become available to allow a longer follow-up window period, more research will be possible to further examine the clinical impact on health outcomes and downstream nonpharmaceutical service utilization.

Medication Therapy Management Programs—To optimize therapeutic outcomes, Part D plans are required to offer MTM programs for targeted beneficiaries with complex medication regimens, multiple chronic conditions, and/or expected high drug expenses. The original federal regulations for MTM programs have been vague and, as a result, MTM programs have been diverse. Such diversity presents research challenges to uniformly evaluate Part D–sponsored MTM programs; however, questions remain regarding patients' preferences for different MTM attributes and the processes and clinical impact of the programs.

Findings: Hong et al[32] examined patient preferences and willingness to pay for MTM attributes by asking participants to choose services based on specific attributes. Using 2007–2008 data collected among ambulatory beneficiaries in senior centers in Memphis, Tennessee (n = 355), the study reported that the most valued MTM attribute was price, followed by service setting, provider's years of practice, and provider's years of experience in geriatrics. Community-based pharmacies were the most preferred setting for MTM services, whereas telephone consultation was the least preferred setting. Participants were willing to spend more for clinic-based services than for telephone-based MTM.[32] Other studies have evaluated MTM initiatives. Using 2008 telephone-based MTM data from a large PDP plan (n = 4277), Perera et al[33] reported that the rate of prescribers' approval of pharmacists' recommendations of drug therapy changes in MTM beneficiaries was 47.2% overall, with higher approval rates involving cost-saving issues and lower rates involving safety concerns and guideline adherence. Overall, primary care physicians had higher approval rates than did specialists. Using 2007 data from a regional Part D plan in Texas (n = 120), Moczygemba et al[34] reported that compared with beneficiaries not enrolled in MTM, beneficiaries participating in telephone-based MTM had significantly more medication or health-related problems identified and resolved but no significant changes in medication adherence or total drug expenditures.

Implications: Health plans may need to consider developing more community pharmacy–based MTM options with experienced pharmacists for ambulatory beneficiaries[32]; however, additional research should examine preferences among other beneficiaries, including those who are frail and homebound. Telephone-based MTM may help to identify and resolve medication/health-related problems[34]; however, effective educational methods may be needed to improve medication adherence and to decrease costs. More empirical evidence is needed to inform MTM best practices, including ways to promote pharmacist–prescriber collaborations.[33]

Policy Highlights

Policy changes for 2012 included modifications to improve the beneficiary experience with Part D and to standardize plan offerings while preserving competition and choice. Some provisions were passed as part of the Affordable Care Act of 2010 (enacted to allow for the Coverage Gap Discount Program to begin eliminating the coverage gap starting in 2011) and were implemented or continued in 2012, such as the closure of the coverage gap and improvements to MTM programs. There was also an increased emphasis on quality ratings for Part D. Key policy updates were categorized into 4 themes: (1) improvements for beneficiaries; (2) coverage gap discount program; (3) quality ratings; and (4) improvements to MTM programs.

Improvements for Beneficiaries—To reduce the overall number of plan choices, CMS made efforts to ensure that Part D plan offerings represented meaningful differences to beneficiaries with respect to benefits packages and plan cost structures, and that offerings had sufficient enrollment to warrant a separate benefit design.[35] Based on evidence that many beneficiaries did not understand all of the offerings in terms of expected value, CMS approved plans for 2012 only if the benefit package or cost structure was meaningfully different from those of other plan offerings within a Part D region from the same sponsor. Additionally, CMS determined that it would not renew plans with low enrollment. As a result, CMS had approved the lowest number of Part D plans (1014, an average of 31 per region), down from a high of 1875 in 2007.[7]

To address an important subgroup of Part D beneficiaries, CMS expanded the $0-copayment program for institutionalized dually eligible patients to include dually eligible patients receiving home- and community-based services who otherwise would be institutionalized.[2] Prior to 2012, the $0-copayment program applied only to dually eligible patients who were residents of long-term care facilities and dually eligible patients in any setting who reached catastrophic coverage.

To improve clarity and consistency of formulary tier designs among plans, CMS accepted a maximum of 6 drug tiers and established a uniform set of tier label description options based on the most common names used by Part D sponsors.[2] Each year, the US Pharmacopeial Convention releases the Medicare Model Guidelines, a voluntary standard used in the yearly evaluation of drug plan formularies by CMS. Plans are afforded flexibility in formulary design, such as utilization restrictions and tier design. CMS maintained that the specialty tier was restricted to drugs with negotiated prices of >$600/mo.

To improve beneficiaries' access to the exceptions and appeals processes, the Affordable Care Act required all plan sponsors to use single, uniform exceptions and appeals processes for Part D and to provide instant access to these processes through a toll-free telephone number and a Web site. CMS developed model forms for requesting a coverage determination (1 for beneficiaries and 1 for prescribers) and outlined processes for improved communication to beneficiaries.[36]

Implications: These policy changes were designed to make Part D more user-friendly, simplify beneficiary choice of plans, standardize certain elements of plans, and offer greater protection to beneficiaries. Reducing the number of plan choices so that only plans with meaningful differences are available from a sponsor is a step toward improving the beneficiary experience. There are still concerns regarding the appropriate number of plans and the clarity of the information. There may be value in personal assistance by a qualified provider, such as a pharmacist, in a proposed "Welcome to Medicare Part D" visit. The choice of a Part D plan should be based on a complete medication assessment in addition to beneficiary factors such as cost, coverage, and convenience. The expansion of the $0-

copayment program to dually eligible patients who receive home- and community-based services addressed an important subgroup of dually eligible patients. The standardization of formulary tier design and tier labels is expected to improve the comparability of plan offerings by beneficiaries. Finally, clarification and standardization of the exceptions and appeals processes is expected to make it easier for beneficiaries to access these important safeguards.

Coverage Gap Discount Program—With the implementation of the Affordable Care Act, the coverage gap is expected to be eliminated by 2020, after which beneficiaries will be responsible for a coinsurance payment of 25% (or an actuarial equivalent) of the cost of all Part D drugs up to the OOP threshold and catastrophic coverage[37] (Table II). In 2012, the Coverage Gap Discount Program began requiring beneficiaries to pay coinsurance costs of 86% for generic drugs and 50% for branded drugs. Discounts are considered incurred costs and count toward beneficiaries' OOP costs.[35]

Implications: During the coverage gap phase-out, beneficiaries are expected pay less for drugs while in the gap, which may lead to greater medication adherence and fewer adverse health events.[36] Nonetheless, other factors might affect the affordability of medications under Part D, including drug prices, beneficiary copayments, and the copayment tiers set by Part D plans and various supplemental pharmacy-assistance programs. The affordability of Part D—striking a balance between coverage and cost—will continue to be an important issue for researchers and policymakers.

Quality Ratings—The Affordable Care Act placed increased emphasis on Part D quality ratings by offering bonus payments to MAPDs that provide higher-quality care to their enrollees. CMS applied this approach to their quality-rating system for both MAPDs and PDPs and offers beneficiaries 1 enrollment period in which they can switch to another MAPD or PDP that has a 5-star plan performance rating assigned by CMS.[38,39] Conversely, CMS can use the performance ratings to terminate contracts with plans that consistently performed below the average of 3 stars.[2] The ratings (on a 5-star scale, with 1 star indicating poor performance; 5 stars, exemplary performance) are based on specific performance measures in 4 domains: (1) drug plan customer service; (2) member complaints and problems; (3) member experience with the drug plan; and (4) drug pricing and medication safety.[40] In general, stars are awarded on a curve so that plans are rated relative to one another. CMS created a fixed threshold for awarding 4 or 5 stars. New measures will be incorporated into the plan ratings, which are published each year on the Medicare Plan Finder Web site (www.medicare.gov).[2]

Implications: Although only 4 PDPs and 8 MAPDs received 5-star ratings in the first year,[40] it is expected that more plans will work to achieve the 5-star rating status. The 5-star special enrollment period is a significant incentive for more plans to improve their quality and for beneficiaries to seek plans that have higher ratings than does their current plan. CMS is considering new measures for the quality ratings, including medication adherence, voluntary disenrollment rates, and appropriate transition processes to ensure continuity of care.[2] The potential for quality ratings to influence meaningful patient choice warrants refinement.

Improvements to Medication Therapy Management Programs—Based on the changes mandated by the Affordable Care Act, CMS developed a complete description of MTM program requirements.[41] Enrollment in MTM programs must use an opt-out method only, meaning that targeted beneficiaries are automatically enrolled in MTM if they meet the enrollment criteria. The minimum level of MTM services should include interventions for

both beneficiaries and prescribers, an annual comprehensive medication review with written summaries, and quarterly targeted medication reviews with follow-up interventions when necessary. CMS outlined more specific targeting criteria for plan sponsors. For example, plans cannot require >3 chronic diseases as the minimum number of covered multiple chronic diseases, and sponsors must target ≥4 chronic diseases from a list of 7 that are specified by CMS (hypertension, heart failure, diabetes, dyslipidemia, respiratory disease, bone disease, and psychiatric health). Sponsors cannot require >8 Part D drugs as the minimum number of multiple covered Part D drugs, and beneficiaries must be likely to incur annual costs of ≥$3000/y for all covered Part D drugs. CMS has integrated MTM program information into the online Medicare Plan Finder.[42] Beneficiaries are able to use this information during the open enrollment period to compare eligibility requirements for available Part D plans, and to look for programs available for their specific health conditions or drug utilization. Beneficiaries are encouraged to contact each drug plan for more details about their MTM program.

Implications: Now that CMS has more experience with MTM, requirements have been revised to ensure better outcomes. One example is the requirement for an interactive, person-to-person consultation with the beneficiary. The new integration of MTM program information into the Medicare Plan Finder supports the commitment of CMS to increasing beneficiaries' awareness about MTM programs and helping them to make informed decisions regarding prescription drug plans. Greater concerns may be the independence of MTM providers, and the freedom from potential conflicts of interest with pharmacy drug dispensing. For 2013, CMS has proposed that long-term care pharmacists work in an independent capacity as MTM providers, separate from those services provided for the dispensing or delivery of drug products.[43] These proposals may lead to support for MTM pharmacies as independent services, separate from PDPs and paid separately, not through the administrative fees of Part D plans. Policy that supports direct payment to pharmacists as providers of MTM services may help to expand the potential of MTM.

CONCLUSIONS

Medicare Part D will continue to evolve with ongoing research, beneficiary experience, and stakeholder feedback. The purpose of this article was to highlight the latest major research findings and policy initiatives related to Part D and thereby complement the growing body of literature on the topic. Policy changes were designed to improve drug benefits; however, some stakeholders would argue that these changes are not enough. Challenges remain in plan selection and simplification, quality assessment (especially with regard to long-term impact and health outcomes), evidence-based improvements in MTM, and disparities among priority subpopulations. There is potential for greater coordination of Medicare Parts A, B, and D to further offset costs by increasing medication expenses and decreasing expenses for nondrug health services, thereby improving the overall cost-effectiveness of the Medicare program. Larger questions remain, such as whether Part D should continue to be privately administered, and the impact of private competition on beneficiary choice and prices. The future of Part D will affect the changing face of health care for Medicare beneficiaries in the United States.

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Table I

Medicare Part D standard benefit parameters for 2011 and 2012. Data are US $ unless otherwise specified.

Parameter	2011	2012
Standard benefit		
Deductible	310	320
Initial coverage limit	2840	2930
Out-of-pocket threshold	4550	4700
Total covered Part D spending at out-of-pocket threshold	6447.50	6657.50
Full subsidy-FBDE individuals		
Deductible	0.00	0.00
Copayments for institutionalized beneficiaries	0.00	0.00
Copayments for beneficiaries receiving home- and community-based services	—	0.00
Copayments for all other FBDE individuals at ≤100% of FPL		
Generic/brand	1.10/3.30	1.10/3.30
Above the out-of-pocket threshold	0.00	0.00
Copayments for all other FBDE individuals at >100% of FPL		
Generic/brand	2.50/6.30	2.60/6.50
Above the out-of-pocket threshold	0.00	0.00
Partial subsidy (income <150% FPL and resources <$11,140/individual or <$22,260/couple)		
Deductible	63.00	65.00
Coinsurance up to out-of-pocket threshold	15%	4700
Copayments above out-of-pocket threshold	15%	4700
Generic/brand	2.50/6.30	2.60/6.50

Adapted from reference 2.

FBDE = full benefit dual eligible; FPL = federal poverty level.

Table II

Medicare Part D beneficiary annual coinsurance rates for branded and generic drugs during the Coverage Gap Discount Program.

	Drug Coinsurance Rate, %	
Year	**Branded**	**Generic**
2011	50	93
2012	50	86
2013	47.5	79
2014	45	65
2015	45	65
2016	45	58
2017	40	51
2018	35	44
2019	30	37
2020	25	25

Adapted from reference 37.