EDITORIALS

Medicare Part D—Lessons Learned and Guidance for Health-care Reform

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After years of debate about the role of the marketplace, consumerism, and the government in providing prescription drug benefits to seniors, evaluations of Medicare Part D are beginning to trickle in. Despite controversy about the design and complexity of the Part D benefit, evidence suggests that the program has successfully enhanced drug coverage for America's seniors, increased utilization of and adherence to essential medications, and reduced out-of-pocket costs for prescription drugs. In this issue of *JGIM*, Safran and colleagues evaluated seniors' longitudinal responses to survey questions about their medication use and costs, and found that seniors, on the whole, have improved access to medications as a result of the Part D benefit,¹ confirming results from a growing number of claims-based and survey-based studies. While Part D appears to have filled important gaps in coverage for America's seniors who had no previous drug insurance or who had inadequate benefits, this study also highlights notable concerns about the under-enrollment of low-income, sicker Medicare beneficiaries into Part D. This study also documents an erosion of employer-sponsored drug coverage benefits that coincided with Part D coverage expansion. As the nation grapples with options for health-care reform, both the successes and failures of the Part D benefit noted by Safran should inform policy design and implementation.

What we know worked. Survey respondents in Safran's study confirmed enrollment rates reported by Medicare: implementation of Medicare Part D coverage dramatically increased rates of prescription drug coverage in the elderly. Among elderly patients who were previously without coverage, the majority enrolled in a Part D plan, and among those who were previously insured by their employers, the majority maintained that coverage.

There is also convincing evidence that coverage expansion has led to increased utilization of, adherence to, and reduced out-of-pocket costs for prescription drugs. Safran found that all subgroups of patients who enrolled in Part D, except those previously enrolled in Medicaid, increased use of prescription drugs after enrollment, and all subgroups, with the exception of those who previously had employer-sponsored coverage, experienced reduced out-of-pocket costs during the study period. Cost-related non-adherence dropped substantially

after Part D implementation, from 26% to 19.4% among all survey respondents.

Maybe the most reassuring data from Safran's study indicate that patients dually eligible for Medicaid and Medicare, who previously received their drug benefit from Medicaid, experienced no significant interruption in prescription drug use and reported reduced out-of-pocket costs after transition to Part D, consistent with recent claims-based findings.² Many had expressed concern that this vulnerable population would struggle with changing formularies and new out-of-pocket requirements. Part D policy required that all dually eligible beneficiaries be automatically enrolled in a stand-alone, generous, benchmark drug plan on the day Part D was implemented, yet patients retained the opportunity to change plans if they desired. This approach successfully protected dually eligible patients from the complexity of the benefit while maintaining choice.

What we know worked less well. Low-income seniors who were not Medicaid beneficiaries had difficulty navigating the complex Part D benefit. Many of these patients were eligible for low-income subsidies, and their failure to enroll marked a missed opportunity to support necessary medication use. Safran's findings are buttressed by other studies showing poorer knowledge about the Part D benefit, lower enrollment, and a lack of awareness of the low-income subsidy (LIS) among socioeconomically disadvantaged, sicker beneficiaries and among African Americans as compared to whites.^{3–5} Safran found that cost-related non-adherence was very common in the subgroup of patients eligible for LIS. Why did these patients struggle with Part D while a similarly vulnerable subgroup, dually eligible patients, maintained their medication use? Part D required these low-income patients to enroll on their own, a process that likely was intimidating for many. The lack of systematic auto-enrollment, as well as the need for seniors to engage the system and make difficult decisions, was an important barrier to their obtaining drug coverage.

Questions that remain. While we are reassured to learn that expansions in prescription drug coverage led to greater medication use, reduced costs for patients, and better adherence, we would certainly hope and expect this to be true. However, several key policy questions related to Part D coverage expansion remain. Most importantly, we do not know whether or not expanding prescription drug coverage meaningfully affected patient health outcomes and whether an investment in prescription drugs for seniors was associated with reductions in health services utilization-related costs.

While preliminary results in a small and non-generalizable sample were encouraging,⁶ we await more convincing evidence.

Several claims-based evaluations of the Part D coverage gap indicate immediate reductions in prescription drug use when coverage lapses,^{7–9} but we do not know whether the coverage gap has a meaningful effect on patient health outcomes. Studies of prescription drug caps in other systems indicate that health suffers under caps,¹⁰ but little is known about the effect of gaps in Part D coverage. We also need to know how alternate benefit designs, such as the provision of generic coverage through the coverage gap, affect health outcomes. Further, we have little data to evaluate whether expanded drug coverage affected use of “overused” medications, potentially harmful medications, and medications that are not cost-effective.

Lessons for broader health care reform. Our experience with Part D suggests that expanding health-care coverage is likely to increase access to essential medications and preventive health-care services utilization. However, the extent to which health-care coverage expansion will improve health is hard to predict, as is the expected cost offset from reductions in health-care services use associated with adverse health outcomes. Nonetheless, if coverage is offered and subsidized by the government, our experience with Part D suggests that large numbers of patients will enroll and utilize the benefit. At the same time, the marketplace will produce a wide variety of plan options from which patients can choose.

But, with more consumer choice comes greater complexity. All the health-care reform proposals currently under consideration rely on greater competition to create efficiencies and reduce health-care costs. They also use varying incentives to encourage Americans to enroll, with government subsidies to assist those who are most vulnerable. However, it is important to note that a “build it and they will come” approach may not be sufficient. Experience with Part D indicates that we either need to automatically enroll low-income patients into low cost plans, and permit them to opt out, or make extraordinary efforts to identify potential beneficiaries and assist them with enrollment. Any less will likely leave many of our most vulnerable patients without coverage and may contribute to existing disparities in care. Policymakers are learning that improved outreach is necessary to support Part D enrollment: Section 113 of the Medicare Improvements for Patients and Providers Act, which will take effect in 2010, mandates improved cooperation between the Social Security Administration (SSA), which handles LIS enrollment, and Medicaid state offices in order to improve identification of LIS-eligible beneficiaries.¹¹

Patients who had employer-sponsored drug benefits in 2003 experienced significantly increased out-of-pocket costs and reported higher levels of cost-related non-adherence following the implementation of Part D, regardless of whether they kept their employer-sponsored coverage or transitioned to Part D in 2006. This erosion of benefits is concerning, given that the backbone of the American health insurance system depends on employer-sponsored coverage. If those who had no previous drug coverage improved their access to and out-of-pocket spending for drugs, but those who did have previous employer-sponsored coverage saw their access to drugs decline and out-of-pocket spending increase, the data suggest that we may be regressing towards a drug insurance “mean” benefit marked by a predominance of coverage gaps and/or increasing out-of-

pocket costs. Such trends ought to be considered as we specify requirements about acceptable coverage for broader health reform. These findings also offer a call for more innovative benefit designs that guarantee access to the most effective and cost-effective care.¹²

As changes to our health-care system are passed by Congress, parallel processes to provide timely access to data to evaluate these changes should also be developed and written into the law(s). Medicare Part D was implemented in 2006, yet Medicare Part D data were not made available until early winter 2008, and comprehensive evaluations of the policy using these data are just starting to surface. With accessible, timely data, we can assess reforms’ effects on the health outcomes we care about most: improved access to essential health services, improved longevity and quality of life, reductions in over-use of health services and drugs, and reductions in costs. Such evaluations are needed to develop best practices and to implement evidence-based policy. Prompt policy assessment is crucial to ensure that we use our limited health-care resources most effectively and that we adjust our policies to the real-world challenges our patients face.

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