EDITORIAL AND COMMENT

The Present and the Future of Cost-Related Non-Adherence in Medicare Part D

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With so much recent change in the healthcare system, it is easy to forget that Medicare Part D was only implemented in 2006. At the time, it represented the largest expansion in coverage for seniors since the introduction of Medicare in 1965. For the first time, seniors could voluntarily enroll in a government-subsidized, privately offered insurance program to make medications affordable, and 37 million of our most vulnerable Americans have enrolled to date.¹ The program is widely acknowledged as a great success, expanding access to treatment, helping to improve health outcomes, and likely even reducing the overall costs to Medicare by improving patient health and reducing the need for other, more expensive health care services.²⁻⁵ As many of our most common chronic conditions can now be managed entirely with highly effective and low-cost generic medications,⁶ there may be no more cost-effective way to enhance coverage that will meaningfully improve health and, at the same time, bend the cost curve in the right direction.

Musich and colleagues offer important new evidence about Medicare beneficiaries' experience within Part D in this issue of the *Journal of General Internal Medicine*.⁷ The main finding is that even among well-covered beneficiaries (those with standard Part D coverage and enhanced with supplemental Medigap coverage), drug costs continue to be an issue for seniors. In fact, approximately 40 % of these well-covered seniors use cost-saving strategies to mitigate their out-of-pocket medication expenses, the most common of which are the use of free samples and pill-splitting.

But is it a "bad sign" that patients employ cost-saving measures when taking their medications? We would expect seniors to consider cost when purchasing food at the grocery store, when selecting their gas station, and when heating their homes. The overwhelming majority of Americans do. Do we want medications to be so inexpensive that patients are not at all sensitive to their cost?

Cost-conscious shopping is one thing; going without essential medications is another. Musich and colleagues find that, compared to patients who do not use cost-saving strategies,

those who do have 18–45 % increased odds of non-adherence to their medications. Cost-related non-adherence persists even among the most generously covered Part D beneficiaries, those receiving low-income subsidies,⁸ although these patients have benefited most from the expansion in coverage. Musich did not report the absolute rate of cost-related non-adherence in this population, however, which is the outcome of primary interest.

The emergence of specialty medications as the key source of growth in benefit costs will likely increase the magnitude and direction of Musich's findings. These findings relate largely to medications that are relatively inexpensive as compared to specialty medications, defined as drugs that cost more than \$600 per month, are often difficult to administer, and require special handling and/or ongoing clinical assessment. Spending on specialty medications is growing by over 15 % annually, and is expected to make up approximately half of total pharmacy spend by the end of this decade (approximately \$235 billion annually).⁹ In Medicare Part D, an estimated 3–5 % of beneficiaries used a specialty drug between 2007 and 2011, but per-beneficiary spending on specialty drugs increased 47 % during that time.¹⁰

The emergence of new, expensive and highly effective treatments for hepatitis C has changed the discussion around affordability and value in drug benefits, as approximately 350,000 Medicare beneficiaries are eligible for these treatments.¹⁰ While the medications offer important advances in curing a disease that causes enormous suffering, they are expensive, at nearly \$1000 a pill and approximately \$84,000 for a course of therapy, with an estimated \$7,000 in out-of-pocket costs for Part D beneficiaries who complete the recommended 12-week course of therapy.¹¹ Medicare will soon face an entirely new challenge, as the PCSK9 class of medications awaits approval from the FDA for the treatment of cholesterol. The class is extremely effective at reducing LDL cholesterol, but will be far more costly than existing cholesterol-lowering therapies. The eligible patient population will likely be considerable, and patients initiated on therapy would be expected to continue on therapy indefinitely.

The growth of specialty drug use forces us to reevaluate patients' exposure to out-of-pocket costs for medications. Specialty medications that target more common chronic conditions could substantially increase payers' total healthcare

costs, but may also produce highly desirable health outcomes. Thoughtful approaches to limiting inappropriate use are critical to reducing unnecessary costs while maintaining access for the patients who are expected to benefit most. While payers and policymakers must be mindful of maximizing limited financial resources to provide drug coverage, we literally cannot “afford” to limit access to essential chronic medications that improve clinical outcomes and quality of life.

As we rethink how we manage specialty medication costs, studies like this one by Musich et al. will be instrumental in helping us understand how to best construct a benefit that optimizes health outcomes and patient experiences while reducing the total cost of health care delivery. We must continue to study patients’ barriers to medication use, their ability to navigate their pharmacy benefits, and their access to medications that improve health and quality of life. Only by doing so will we find the right balance in promoting comprehensive coverage while limiting unnecessary spending.

Conflict of Interest: Drs. Shrank and Polinski are employed by CVS Health, a company that operates Silverscript, a large Part D insurance program.

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