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Perspective

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# Doughnuts and Discounts — Changes to Medicare Part D under the Bipartisan Budget Act of 2018

Julie M. Donohue, Ph.D., and Haiden A. Huskamp, Ph.D.

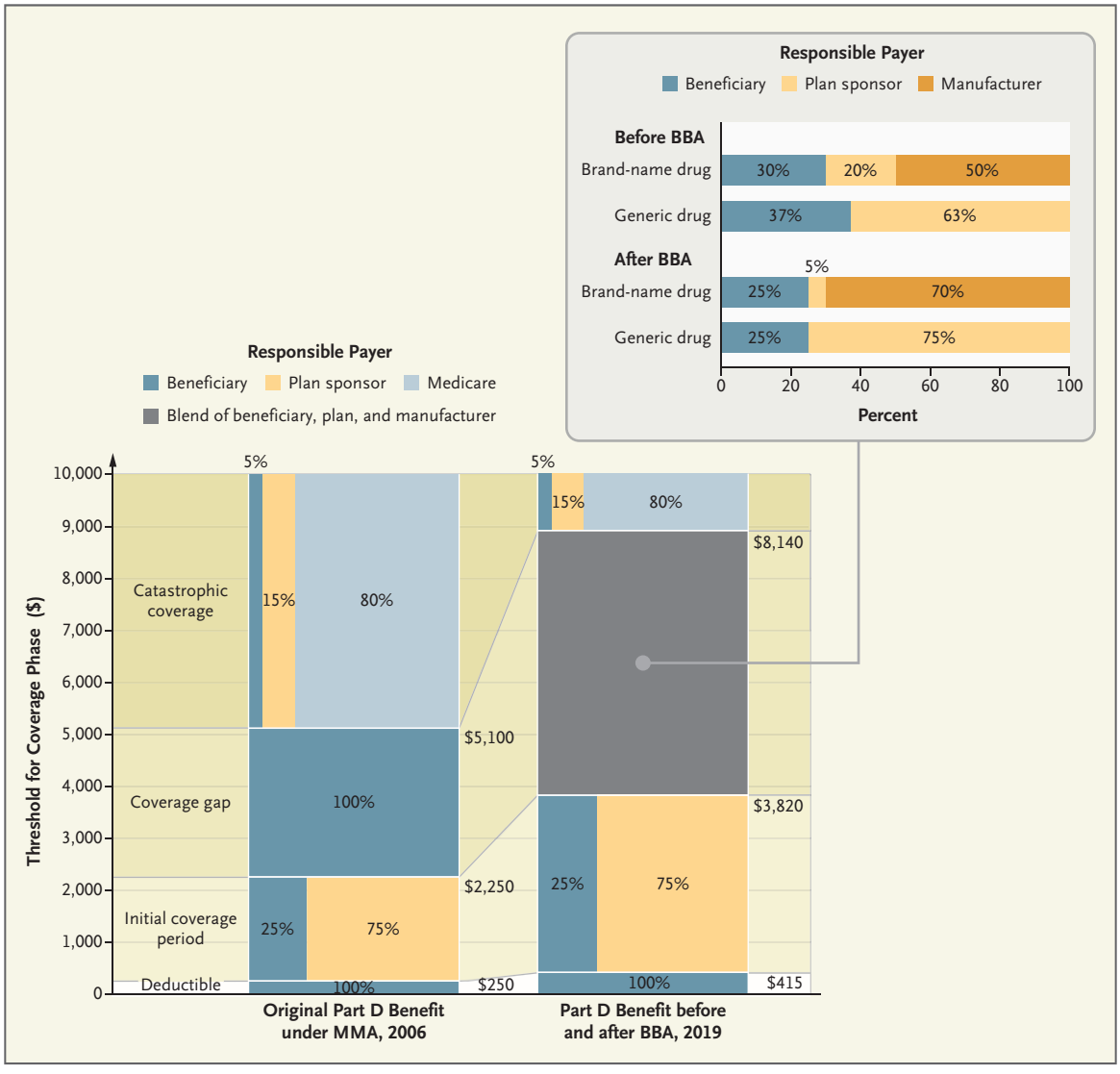
The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 created a new Medicare benefit (Part D), a new insurance product (prescription-drug–only plans), and a new market. Fifteen years later, Part D is widely regarded as a success, providing drug coverage to 42.5 million Medicare beneficiaries and substantially reducing out-of-pocket drug expenditures among enrollees. Many of the statutory and regulatory provisions governing Part D have remained unchanged since its inception, including its reliance on private plans to negotiate drug prices with manufacturers instead of allowing direct negotiation by the government.

A notable exception to the relative stability of Part D policy is its benefit design. In particular, the benefit originally included a large coverage gap, nicknamed "the doughnut hole," which exposed many beneficiaries to 100% of drug expenditures between two spending thresholds (see figure). This gap led to substantial confusion in the early years of Part D and to frustration with the steep jump in out-of-pocket spending for the one third of beneficiaries who entered the gap.[1,2] Furthermore, beneficiaries who did so were significantly less likely to fill prescriptions and more likely to skip doses or discontinue medication than were enrollees of retiree plans without a gap.[1,2]

In response, the Affordable Care Act (ACA) gradually closed the gap beginning in 2011, in part by requiring drug manufacturers to offer substantial discounts on brand-name products (50% in 2020). The recently signed Bipartisan Budget Act (BBA) of 2018 accelerates these changes. But though the BBA changes reduce beneficiaries' out-of-pocket burden in the short run, their effects on drug prices in the long run are less clear.

The coverage gap was a departure from the prevailing wisdom that insurance coverage should increase in generosity with higher levels of health risk. However, it was designed to balance three competing objectives: offering generous coverage up front to entice beneficiaries with low drug costs to take up the new voluntary benefit, providing maximal protection to beneficiaries with catastrophically high drug costs, and meeting the budget constraint set by the budget-reconciliation process.

The standard benefit implemented in 2006 created four bands




**Comparison of 2006 Part D Standard Benefit under Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 with 2019 Standard Benefit under the Affordable Care Act (ACA) and the Bipartisan Budget Act (BBA) of 2018.**

Thresholds for coverage phases are based on total drug expenditures, including beneficiary, plan, manufacturer, and Medicare shares. The estimate of $8,907 does not reflect the BBA changes in the coverage gap for 2019. An updated number is expected to be released in the CMS Final Call Letter in April 2018. Adapted from the Kaiser Family Foundation.

of coverage (see figure) across which cost sharing varied substantially: the deductible, below which beneficiaries pay 100% of drug costs; initial coverage, during which beneficiaries pay 25%; the coverage gap, in which enrollees pay 100%; and catastrophic coverage, at which point beneficiaries pay only 5%. There are two important caveats. First, 12.2 million Part D enrollees in the low-income subsidy program (29% of enrollees) face much lower cost sharing and no gap. Second, 99% of enrollees are in plans with benefits that are actuarially equivalent but not identical to the standard benefit; nevertheless, in 2018, two thirds of stand-alone plans had zero coverage in the gap beyond the standard benefit.

The ACA's gradual closure of the gap, scheduled for completion in 2020, led to substantial reductions in beneficiaries' out-of-pocket spending. For example, in 2013, manufacturer discounts amounted to an average of $2,293

for enrollees who received catastrophic coverage.[3] The BBA makes three important and permanent changes to the gap that take effect in 2019. It accelerates the gap's closure, reducing patients' cost sharing for both brand-name and generic drugs to 25% in 2019 instead of 2020 as under the ACA. It reduces plans' share of spending on brand-name drugs in the gap from 25% to 5%, with the required manufacturer discount increasing from 50% to 70% to make up the difference. (Plans' share of generic-drug spending in the gap remains at the ACA-specified 75%.) Finally, unlike the ACA, the BBA requires manufacturers of biosimilars to begin providing discounts for expenditures in the gap.

By reducing the required cost sharing in the gap to 25% a year early, the BBA will improve financial protection for enrollees with high drug expenditures. Also, thanks to the larger manufacturer discounts (which count as out-of-pocket expenditures for enrollees in determining their eligibility for catastrophic coverage), beneficiaries will reach the catastrophic coverage threshold (after which they face only 5% cost sharing) more rapidly than under ACA rules. Plans are expected to lower their 2019 premium bids once they are responsible for a smaller share of spending in the gap (5% instead of 25%), saving both beneficiaries and the government money in the short run.

Longer-term effects on premiums and drug prices are less clear, since they depend on responses to the BBA's changes by key stakeholders — plan sponsors (in their premium bids), beneficiaries (in their utilization and willingness to overcome inertia in plan choice over time), and particularly manufacturers (in their prices and rebates). For manufacturers, the BBA could lead to substantial reductions in revenues — a loss of $1.9 billion, according to an estimate by the actuarial firm Milliman. Notably, manufacturers lobbied for (but did not receive) a reduction in the required discounts in the Consolidated Appropriations Act of 2018 that was passed in March. However, manufacturers could mitigate revenue losses from the discounts by raising prices or reducing rebates. Although there is limited evidence regarding the industry's response to the ACA requirement for a 50% discount, one study by the Government Accountability Office suggests that the discounts contributed to both rising brand-name drug prices and reductions in rebates.[4] This finding was based on interviews with representatives of Part D plans and pharmacy benefit managers. Once the BBA-required discounts increase to 70%, manufacturers will have stronger incentives to raise prices, lower rebates, or both. Manufacturer rebates are a key mechanism through which plans extract price concessions. In 2017, rebates accounted for 22% of total Part D drug costs, but they vary in magnitude by a factor of more than 5 depending on the drug.[5] Manufacturers will have greater market power for brand-name drugs with no therapeutic substitutes, since plans have less flexibility for removing these drugs from their formularies or requiring higher cost sharing, and less negotiating power as a result.

The Medicare Payment Advisory Commission (MedPAC) reports that recent growth in federal Part D outlays, which it considers unsustainable, was driven largely by higher prices for drugs used by enrollees receiving catastrophic coverage, who now account for 57% of Part D spending.[5] Under the BBA, the government would still pay 80% of catastrophic-coverage expenditures, creating less incentive for plans to closely manage drug spending for the highest spenders than they would have if they were responsible for a larger share. Because the BBA accelerates the transition from the gap to catastrophic coverage owing to the increased manufacturer discounts, federal outlays would probably increase for these enrollees.

In 2016, MedPAC recommended dramatic reforms, including no longer counting manufacturer discounts as enrollee out-of-pocket expenditures and dropping all beneficiary cost sharing once spending exceeds the catastrophic threshold.[3] If these changes were enacted by Congress, their effects on beneficiaries would be both negative (it would take longer for enrollees to reach catastrophic coverage) and positive (the highest-spending beneficiaries would have an out-of-pocket maximum instead of open-ended financial liability), with the net effect varying according to the level of beneficiary expenditures. MedPAC also recommended a major restructuring of payments to plans, requiring them to pay 80% of expenditures over the catastrophic-coverage threshold (up from 15%, with the government paying only 20%) to encourage plans to manage drug spending more carefully for the highest spenders. In the absence of such changes, the BBA offers short-term financial relief for Part D enrollees but does little to

*An audio interview with Dr. Donohue is available at NEJM.org*

disrupt the trend of substantial cost growth for the program.

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From the University of Pittsburgh, Pittsburgh (J.M.D.); and Harvard Medical School, Boston (H.A.H.).

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# Subscribing to Your Patients — Reimagining the Future of Electronic Health Records

Katherine Choi, M.D., Yevgeniy Gitelman, M.D., and David A. Asch, M.D.

Nearly all U.S. health care systems and many physician practices have by now migrated from paper charts to electronic health records (EHRs). But though this shift could have been a transformative change, current EHRs are largely digital remakes of traditional systems, just as many early motion pictures were merely plays captured on celluloid. In time, movies began using on-location settings and special effects to make the two-dimensional screen deeper than the three-dimensional stage.

As compared with other digital transformations that have redefined the way we consume information, the effect of EHRs on clinicians' engagement seems limited and effortful. Physicians in the hospital can keep up with feeds on the Philadelphia Eagles, Taylor Swift, and the price of Bitcoin without consulting a newspaper. Yet they must still go to the chart to check on their patients. What would it be like to instead subscribe to Ms. Jones in room 328?

For one thing, receipt of important information on patients' conditions would depend less on physicians' remembering to search the chart. For stewardship of antibiotics and antiepileptics for inpatients, for example, Penn Medicine had established automatic medication expiration, but the system required that residents remember when renewals were due. Necessary medications were not reordered in 10% of cases because a physician didn't check the chart in time or didn't notice the need for renewal. So we developed a Web application to pull real-time information from our health system's multiple digital sources and allow it to be reassembled into customizable dashboards, mobile displays, and push notifications. The result was a platform that can tailor streams of data for particular clinical scenarios — and measure the impact.

In an early pilot, residents who opted in were subscribed to push notices about their patients' medication expirations. Residents did not need to visit the chart to learn of an expiration, and the percentage of doses of antibiotics and antiepileptics that were missed was cut by a third. Digitizing the chart made clinical data more legible and accessible remotely, but the more transformative change was eliminating the need to be in the chart to know that a task had been overlooked in the first place.

Similarly, inpatient teams subscribed to text reminders for their patients who needed total parenteral nutrition reordered before the 3 p.m. administrative deadline. Subscribing to this "last call" kept residents on top of this small but important task, for which some had previously created phone alarms. It was one more checklist item that providers were relieved to have off their minds. So many health care processes are built around passive engagement with a medical record, relying on the hope that physicians will get to the chart on time, see what they need to do, and do it.

A second change is that subscription services can shorten the lag time between when information becomes available and when it's used. Our old approach evaluated mechanically ventilated patients to see whether they could breathe without assistance when ICU rounds were over, and patients' readiness was evaluated