Weekly Checkup

# A Regulatory Flurry

TARA O'NEILL HAYES | AUGUST 24, 2018

While most of the regulatory news during the Trump Administration thus far has been about *deregulation*, health care is one sector where the administration has implemented or proposed an onslaught of new regulations. In particular, the administration has focused on reforming Medicare and drug pricing.

Since April, the Centers for Medicare and Medicaid Services (CMS) published 45 final or proposed rules, primarily relating to the Medicare program. A summary of some of the most noteworthy provisions can be found here. Most of the changes are aimed at providing beneficiaries with greater choice and access to more tailored benefits and reduced costs. Other provisions aim to eliminate policies that unnecessarily increase costs. Finally, CMS continues to work to move the traditional Medicare program toward a more value-based payment system through continued reform of the Accountable Care Organization models.

The administration has also been looking for ways to reduce drug costs for consumers and taxpayers, through regulations. This week, officials at the Department of Health and Human Services (HHS) touted their myriad accomplishments since the administration published its drug pricing blueprint 100 days ago. Some of these "accomplishments" are more deserving of that descriptor than others, but progress toward lower medication costs—even if incremental—is being made nonetheless.

Most of the progress has come from increasing the supply of drugs, which puts downward pressure on prices through increased competition, and the administration likely will continue with this strategy as it is likely to be the most effective in our market-based economy. The Food and Drug Administration (FDA) approved a record number of generic drugs in July, including the first product deemed a "competitive generic therapy" under a new pathway created by Congress to expedite approval for products where there is limited competition. The FDA also published guidance to stop abuse of the Risk Evaluation and Mitigation Strategy (REMS) system that some brand-name manufacturers have employed to prevent generic competition.

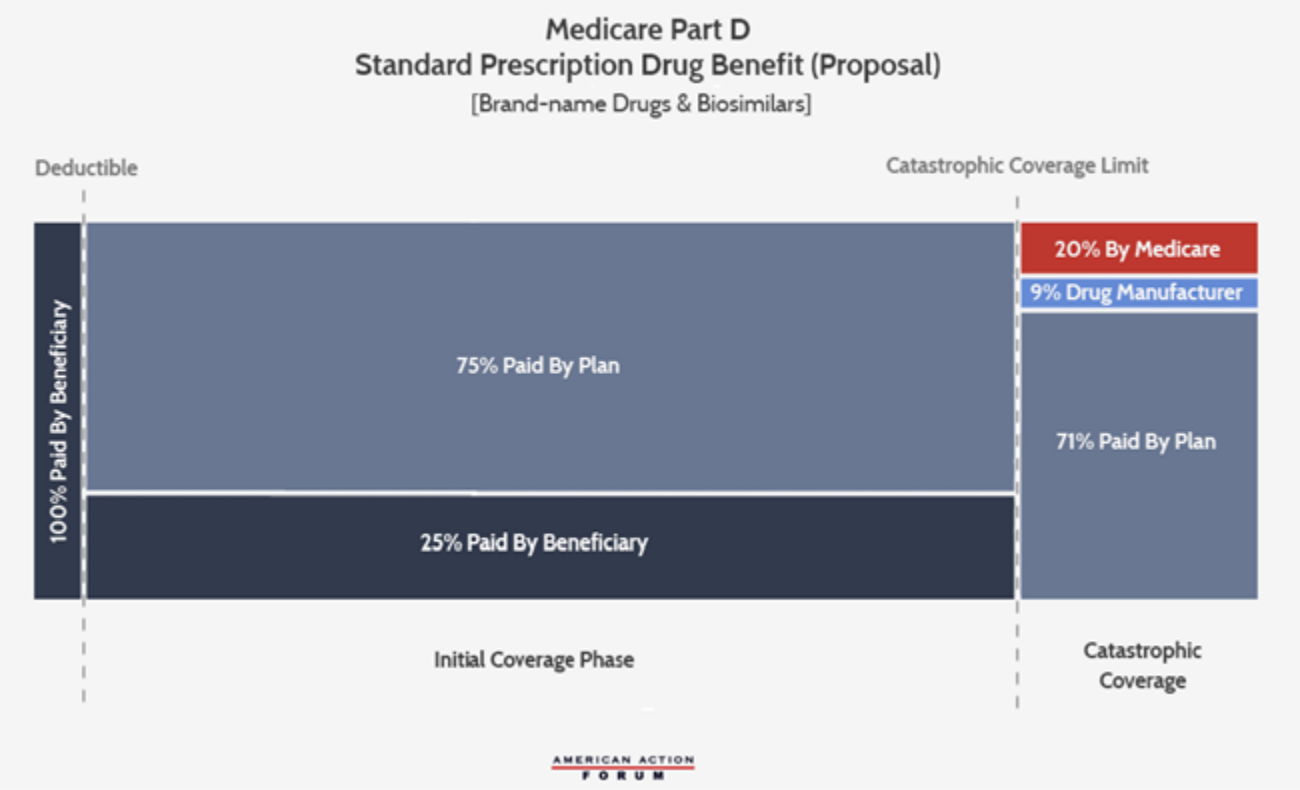
Other actions will change what Medicare and consumers pay for their drugs, even if the price of those drugs doesn't actually change. CMS has notified Part D plans that the use of "gag clauses" in their pharmacy contracts (provisions that prevent pharmacists from notifying patients when paying cash for a drug would be cheaper than using their insurance) will no longer be tolerated. CMS plans to extend its decision to reduce Medicare's reimbursement rate for 340B drugs to off-campus hospital sites and to modify the calculation of the average sales price for biosimilars in a way that will reduce reimbursements. All of these changes will reduce Medicare patients' out-of-pocket costs.

As Doug Holtz-Eakin pointed out in the Daily Dish on Tuesday, anyone expecting a miracle in 100 days would be foolish; the drug supply chain and pricing policies are quite complex. There is no silver bullet. But the evidence shows the administration is very aware of this reality, and if they continue attacking this issue from many angles, they stand a chance of making real progress.

# CHART REVIEW

Tara O'Neill Hayes, Deputy Director of Health Care Policy

AAF recently examined a new proposal for reforming the Medicare Part D benefit structure. This proposal would restructure the standard Part D benefit in a way that realigns incentives—placing greater financial risk for high-cost beneficiaries on both insurers and drug manufacturers—while also protecting beneficiaries from catastrophic financial risk through the imposition of an out-of-pocket cap. AAF's analysis finds these changes are likely to lead stakeholders to alter their behavior in ways that reduce overall Part D expenditures for all stakeholders and ensure the program's continued success.




# WORTH A LOOK

Wall Street Journal: What Does Knee Surgery Cost? Few Know, and That's a Problem

Health Affairs: CMS Approves Maryland's 1332 Waiver For State-Based Reinsurance Program

Axios: New rules would force drugmakers to disclose their prices