

## The Drug Pricing Debate Gets Real

BY LEAH RALPH



**A**lthough the Trump administration has maintained a steady drumbeat on pharmaceutical pricing in recent months, promising lower costs for patients and less spending for the government, it wasn't until late summer that we started to see what this White House had in mind. In May, the U.S. Department of Health and Human Services (HHS) sought stakeholder input on a drug pricing "blueprint" that laid out myriad policies meant to curb drug spending, including proposals to revive the previously unsuccessful Competitive Acquisition Program (CAP) as an alternative to Medicare Part B's buy-and-bill system and to move drugs from the Medicare Part B benefit to a competitively bid system like Part D (which would bring fundamental changes in access, pricing, and distribution for chemotherapy drugs). The ACCC Drug Pricing Taskforce worked with the Governmental Affairs Committee to weigh in extensively, and we hope that the administration heeds our concerns about these proposals.

### Social Media as a Policy Tool


Using a different tactic, in June, President Trump twitter-shamed several leading drug manufacturers for implementing annual prices hikes. Many companies backed down, and 10 companies released statements that they would hold off on annual increases until at least 2019. Yet, in reality, these announcements were largely symbolic—some companies targeted older products that no longer produce significant revenue, while others froze increases after already having implemented an increase earlier in the year. Time will tell how long this situation will last and whether other companies follow suit; in January, many companies institute their biggest increase of the year.

### Expect Movement on CAP, Rebates, Biosimilars, and Step Therapy

Beyond requests for information and creating pressure on social media, the administration has begun to put some teeth to their drug pricing rhetoric. On the regulatory side, HHS recently issued a more detailed request for information on the specifics of what a revived CAP program could look like, signaling that the agency may use its authority through the Center for Medicare and Medicaid Innovation to implement some form of a private vendor program for providers to acquire Part B drugs. HHS also recently sent a regulation to the Office of Management and Budget that may call into question the legal protections for drug rebates. U.S. Food and Drug Administration Commissioner Scott Gottlieb has said that the system of rebates between payers and manufacturers—with the pharmacy benefit manager as a middleman—drives higher list prices. Though the details of the regulation remain to be seen, safe harbors for pharmacy benefit managers may be in jeopardy. Finally, in August, the administration made its boldest move yet, issuing a memo to Medicare Advantage plans allowing them to employ step therapy for Part B drugs starting January 1, 2019. Medicare Advantage plans, covering one third of Medicare beneficiaries, may now require that a beneficiary who is newly diagnosed with a condition begin treatment on the plan's preferred drug therapy before progressing to another treatment if the first is ineffective. This proposal will have a detrimental impact on cancer patients' abilities to access evidence-based, individualized treatments prescribed by their oncologists.

### 2019 Payment Policies

In late July the Centers for Medicare & Medicaid Services also released its proposed Medicare payment rules for 2019. In the proposed Physician Fee Schedule (PFS) and Outpatient Prospective Payment System (OPPS) rules we're seeing a continued—and more aggressive—push toward "site-neutral" (or lower) payments for hospital outpatient departments. The agency's goal is to ultimately bring outpatient payment rates more in line physician office rates. Most notable, in the OPPS, the agency proposes to reduce payments to grandfathered off-campus outpatient departments for clinic visits and other service line expansions and to expand the 28 percent payment cut for Part B drugs in 340B facilities to "nonexcepted" provider-based departments that are already being reimbursed at 40 percent of OPPS. In the proposed PFS rule, the Centers for Medicare & Medicaid Services is also proposing to reduce reimbursement for new Part B drugs from wholesale acquisition cost (WAC) plus 6 percent to WAC plus 3 percent, until average sales price (ASP) data are available and establish a single blended payment rate for level 2–5 evaluation and management codes, which could result in a 16 to 38 percent drop in reimbursement for complex evaluation and management visits for new and established patients.

As the mid-term elections near and we await release of the final CY 2019 Medicare payment rules, stay tuned for updates from the ACCC policy team. 

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