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The Trump administration, with its rhetoric and, more importantly, its actions, has been making an aggressive effort to lower the prices of prescription drugs. A very detailed report produced in February by the White House’s Council of Economic Advisers (CEA) lays out a menu of ideas, a few already implemented or in motion, for driving drug prices down further. Those ideas germinated from two main goals: 1) reduce overpricing by promoting competition and reforming public reimbursement policies, and 2) cut the cost and raise the rewards for innovation through domestic reforms and limiting underpricing of drugs, particularly through “free riding” abroad.

“My view is that they have come to the table with some very thoughtful ideas,” says Dan Mendelson, President of Avalere Health, a D.C.-based health care consulting firm. “The administration has some very good people who understand the pharmaceutical industry and that is a big advantage.” Mendelson singled out Scott Gottlieb, MD, Commissioner of the Food and Drug Administration, and Alex Azar, Secretary of the Department of Health and Human Services. Dr. Gottlieb worked at Avalere in a previous incarnation, and Azar was a client of Avalere’s when he was at Eli Lilly.

In early March, Dr. Gottlieb criticized the drug distribution payment system dominated by hidden rebates when he told a meeting sponsored by America’s Health Insurance Plans, the trade group for health insurers, that “a rigged payment system” was partly responsible for high drug prices. In those comments, he was echoing a line in the CEA report which said: “The overall Part D benefit structure creates perverse incentives for plan sponsors and pharmacy benefit managers (PBMs) to generate formularies that favor high-price, high-rebate drugs that speed patients through the early phases of the benefit structure where plans are most liable for costs.”1

The Centers for Medicare and Medicaid Services (CMS) is currently considering whether to force Medicare Part D plans to pass rebates to plan members when they pay for prescriptions at the pharmacy counter. The PBM industry hotly opposes that idea. The health insurance industry is slowly warming to the concept, with UnitedHealthcare announcing in March it would provide pharmacy rebates for a percentage of its client base. Drug manufacturers are the leading advocates for rebates to consumers.

The CEA report criticizes PBMs not just for defending the current rebate system, but also because three big companies dominate the market. The report states: “Policies to decrease concentration in the PBM market and other segments of the supply chain (i.e., wholesalers and pharmacies) can increase competition and further reduce the price of drugs paid by consumers.” However, the report does not offer any strategies to do that.

Nor does the report offer any strategies for addressing another “market” problem in which foreign countries force drug prices below what drug manufacturers can charge their American consumers. That accounts for the report’s charge that foreign countries are “free riding” on U.S. consumers. But again, the report comes up dry on remedies, saying only: “The United States could take actions that change the incentives for these countries to price drugs at levels that appropriately reward innovation, rather than disproportionately putting that burden on American patients and taxpayers.”1

Mendelson says this problem of foreign “free riding” was known during the Clinton administration in which he served. But he says Dr. Gottlieb is already moving on one prescription in the report: giving expedited approval to new brand-name drugs that may be the second or third drug in a class or category where no generic option exists. On this the report says: “To avoid imposing policies retroactively on the industry, this policy change could be phased in slowly so that current drug manufacturers of single-source drugs would retain the value of their efforts to be the first in a given therapeutic space.”1

Substantial space is given in the report for discussions of various federal health programs and how drug price competition can be injected into them. The Trump administration has already introduced a radical payment change into the 340B program by reducing Medicare reimbursement for outpatient drugs that many hospitals serving a high proportion of Medicaid patients buy as a means of building revenue. The President’s fiscal year 2019 (which starts October 1, 2018) budget request to Congress contains some of the prescriptions in the CEA report. For example, the budget would loosen Part D plan formulary standards by requiring plans to cover a minimum of one drug per drug category or class, down from the current two-drug requirement. Plans would also get new flexibility in the use of utilization management tools for specialty drugs and drugs in the six protected classes: anticonvulsants, antidepressants, antineoplastics, anti-psychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

The budget proposals don’t go as far as the CEA’s in terms of reducing physician reimbursement for administration of Part B drugs, typically expensive specialty and cancer drugs infused or injected in a physician’s office. Physicians continued on page 286

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bill the CMS for the average sale price (ASP) of the drug plus 6%. The CEA suggested establishing an inflation limit for reimbursement of Part B drugs with the growth in the ASP portion of Medicare’s reimbursement to physicians limited to growth in the consumer price index.

The Trump administration is at least probing for ways to reduce specialty drug prices, and the CEA report provides a detailed road map. But many of the proposals face opposition. Nonetheless, some headway is being made, albeit slowly.

REFERENCE