Battle lines have been drawn and heavy political armaments have been moved to the front line as drug-industry partisans fight to protect the parts of their turf endangered by the policy advances proposed in President Donald Trump’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Its aggressive concepts, such as forcing the posting of drug list prices, ending rebate payments to pharmacy benefit managers (PBMs), introducing formulary management to Part B of Medicare, and changing formulary requirements for Part D, have been the equivalent of a trumpet rallying call to manufacturers, PBMs, health insurers, pharmacy professionals, and patient groups, who are often on the opposite sides of any anticipated initiative.

The wide-ranging Blueprint includes 136 questions or possibilities of changes that cover Medicare most heavily, but also affect Medicaid and private plans. The spotlight on the president’s suggestions burns a bit more brightly after Pfizer, Novartis, and Merck claimed national headlines this summer for postponing plans to raise drug prices in the third quarter of 2017 with the intention of giving the Trump administration time to finalize details and actions stemming from the Blueprint.

Some in the pharmaceutical distribution chain have even proposed doing Trump one better. Fanning the flames of the controversy surrounding high list prices, Express Scripts, the giant PBM, thinks drug companies should “reintroduce their products as competing brand drugs, with new/different NDCs [national drug codes], that would allow the market to move to lower list price products.” A spokeswoman for Pharmaceutical Research and Manufacturers of America (PhRMA), the drug manufacturers trade group, declined to comment on that proposal, which goes beyond anything in the Blueprint.

P&T committees could take on both added responsibilities and added burdens as a result of any Trump administration initiatives, particularly with regard to Medicare. The Trump administration wants to allow PBMs to negotiate prices for some or all Part B drugs. Those are pharmaceuticals infused or injected in either a physician’s office or an outpatient clinic. Currently, Medicare pays the list price for those drugs and patients pay for them subject to a Part B deductible of $250. These are often expensive oncology drugs, which, if they were paid for under Part D, as the administration wants, would be subject to formulary management by P&T committees at Part D plans or their PBMs. There is no guarantee, however, that patients would pay less for oncology, hepatitis C, and other expensive drugs under Part D. They could conceivably (in some instances) pay more.

Part D is also under the microscope as far as its formulary and P&T committee policies are concerned. The American Medical Association (AMA) thinks that disclosure of P&T committee information for Part D Medicare plans would constitute “a critical step forward.” There are a few rules today governing P&T committee membership, but very few if any requiring significant “transparency.” An AMA spokesman did not respond to a query asking what kinds of disclosures the group has in mind.

**Backing From Congress Unlikely**

The fact that drug companies are sitting on the edge of their seats waiting for the administration to put a plan in place doesn’t mean a plan will evolve quickly. It clearly won’t. Health and Human Services (HHS) Secretary Alex Azur told the Senate Health, Education, Labor, and Pensions (HELP) Committee on June 26, six weeks after the Blueprint was released, that, for example, he believes his department, through the Food and Drug Administration, has the authority to force drug companies to disclose list prices in television advertisements. But he added that he would welcome legislation to “shore up” that authority because manufacturers will “certainly challenge” any new requirement in court. He went on to say that he would also welcome legislation eliminating the 100% cap on drug rebates imposed under the Patient Protection and Affordable Care Act, “which would create a significant disincentive for drug companies to raise list prices.”

Congress is unlikely to jump at those requests. Senator Dick Durbin (D–Illinois), the second-ranking Democrat in the Senate, introduced the Drug-Price Transparency in Communications Act (S. 2157) in November of 2017. No Republican has cosponsored it and no hearings have been held. In March of 2017, Senator Ron Wyden (D–Oregon) introduced the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017 (S. 637), which would require the HHS to publish rebate PBMs obtained from drug manufacturers under Part D and the Marketplace Exchange insurance program. Again, no action taken, no Republican co-sponsors obtained. Neither the House Energy and Commerce Committee nor the Ways and Means Committee, the two committees with jurisdiction over health care, have held hearings on drug prices, much less the Blueprint.

Taylor Haulsee, spokesman for the Senate HELP Committee, did not respond to an inquiry asking whether the committee had plans to take up the Durbin and Wyden bills or to develop its own drug-pricing legislation. If the Republican president expects help from the Republican Congress to smooth the way for some of his more controversial policy proposals, he may be waiting a long time. That said, there is no question that...
the Trump administration has already moved perceptibly in some minor areas on drug pricing. But the Blueprint raises the stakes for drug companies, pharmacy benefit managers, insurance companies, health professionals, and consumers. Here are some of the more flammable, high-profile possibilities:

- requiring drug manufacturers to include list prices in drug ads
- putting a ceiling on out-of-pocket payments by Part D participants
- reducing from two to one the number of drugs offered in the six Part D protected classes
- allowing state Medicaid programs to use formularies and P&T committees
- moving drugs now paid under Part B to Part D and subjecting them to utilization review
- reimbursing for drugs based on their indication
- charging higher prices for a drug when it is used off-label

How Out of Whack Are Drug Prices?
The premise of the Trump administration’s attempt to rein in drug prices is that those prices are out of control. As a general premise, that probably is inaccurate. The American Hospital Association (AHA) cites figures from National Health Expenditures data showing that retail drug spending increased by 1.3% in 2016. But the AHA argues that while that level of growth may appear low, it follows two consecutive years of expansive growth in retail drug spending: 12.4% in 2014 and 8.9% in 2015.4

What are particularly worrisome are launch prices for new brand-name drugs. The AHA cited:4

- Taltz (Eli Lilly), used for treating psoriasis, costs $50,000 a year.
- Keytruda (Merck), used for treating melanoma, costs $152,400 a year.
- Kymriah (Novartis), used for treating leukemia, costs $475,000 for a course of treatment.
- Spinraza (Biogen), used to treat spinal muscular atrophy, costs $750,000 for the first year of treatment and $375,000 per year thereafter.

Moreover, there has been a spate of exorbitant price increases for existing brand-name drugs. America’s Health Insurance Plans (AHIP) says that during June 2018 and the first two days of July, drug companies announced more than 100 separate price increases for prescription drugs with an average increase of 31.5% and median percentage increase of 9.4%. Seemingly unfathomable price increases for old generics have led to Congressional hearings.

High drug prices can also be untenable in some instances for hospitals, where drug prices are bundled into diagnosis-related group (DRG) reimbursement. In 2016, the AHA and the Federation of American Hospitals worked with NORC at the University of Chicago (a nonprofit research institute) to document hospital and health system experience with inpatient drug spending. Specifically, NORC found that, while retail spending on prescription drugs increased by 10.6% between 2013 and 2015, hospital spending on drugs in the inpatient space rose 38.7% per admission during the same period.5 In its comments to the HHS, the AHA stated: “These price increases, from the hospitals’ perspective, appeared to be random, inconsistent and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs.”

Is Value Pricing the Answer?
There are some who argue that seemingly unreasonably high drug prices themselves are not the problem. Jonah Houts, Vice President for Corporate Government Affairs at Express Scripts and the author of the company’s comments, suggested that lowering drug prices as an absolute goal might not even be the smartest thing to do. “The central flaw with focusing on incentivizing lower drug prices is that this concept necessarily assumes clinical efficacy of all drugs are equal across all classes and disease indications,” he wrote. “Incentivizing payments for lower-priced drugs comes at the expense of discouraging considerations of clinical effectiveness or other factors such as likelihood for adherence, then even the ‘cheapest’ drug ends up costing Medicare significantly by failing to potentially treat the patient’s condition according to their needs. Of course, such failures may eventually lead to more costly medical interventions in the future, or worse—patient harm.”

Certainly there is a good argument to be made for value-based drug pricing, which is in its infancy and has had trouble getting out of the crib because of, if one listens to the manufacturers, impediments enounced in federal law such as the Anti-Kickback statute and the rules for reporting the Medicaid Best Price. That said, value-based drug pricing doesn’t help some patients, especially less-well-heeled ones, who may have high deductibles and out-of-pocket costs. The fact that, in the long run, they may avoid the costs and terrible effects of a chronic disease such as hepatitis C may be hard to appreciate if they go bankrupt in the short term.

The HHS raises the possibility of “indication-based” pricing, in which consumer and payer costs are linked to the effectiveness of a drug’s indication. Joint comments submitted by a large number of patient advocacy organizations across many disease states said, “This is highly concerning for patients for a number of reasons. Patients using the medications in higher-priced indications would be discriminated against through higher cost-sharing and could have impeded access as a result.”

High List Prices and Their Link to Cost-Sharing
Those higher out-of-pocket costs are often linked to the “list prices” posted by the drug companies. The health insurers use those prices to determine coinsurance and deductible amounts. But the insurer doesn’t pay the list price because it, or its PBMs, negotiates discounts and rebates, which don’t find their way to the pharmacy counter when the consumer reaches for his or her wallet. Patient out-of-pocket costs under Medicare Part D are distributed unevenly each year, such that patients face 100% coinsurance until they reach their deductible ($405 in 2018), up to 25% coinsurance until the patient reaches the initial coverage limit ($3,750 in 2018), 35% coinsurance in the coverage gap until the patient reaches the out-of-pocket threshold ($5,000 in 2018), and finally up to 5% coinsurance above that threshold. “For example, in 2015, beneficiaries
without low-income subsidies who had spending above the catastrophic threshold (over 1,000,000 individuals) spent on average $5,200.92,” Bristol-Myers Squibb said in its comments. “These high out-of-pocket costs present affordability challenges that jeopardize patient adherence to needed medicines, which could in turn increase costs to the broader health care system.”

According to PhRMA, more than half of all new brand-name osteoporosis prescriptions, more than 40% of all new brand-name autoimmune and oral antidiabetic prescriptions, and more than 30% of all new brand-name antipsychotic prescriptions brought to a pharmacy in 2016 had cost sharing greater than $250. “Not surprisingly, many of these prescriptions went unfilled,” the group stated.

Two Part D reforms included in the president’s fiscal year 2019 budget proposal would provide much-needed financial relief for beneficiaries facing high cost-sharing and high annual out-of-pocket costs:

1. Requiring plan sponsors to pass through a substantial share of negotiated rebates at the point of sale would immediately lower out-of-pocket costs for millions of beneficiaries.
2. Establishing a maximum annual limit on beneficiary out-of-pocket spending would provide a true catastrophic benefit to protect the sickest patients.

The drug manufacturers have been pushing hard behind the proposal to force PBMs to fork over rebates at the pharmacy counter, a proposal the Trump administration appears to favor indirectly in the form of replacing rebates with a fixed price discounting model for PBMs. Big pharma believes rebates are bad, high list prices are not so bad. What they object to is the health insurers basing coinsurance and deductibles on those list prices. Manufacturers believe the health plans should pay all or a portion of all rebates off those list prices to the consumers who pick up that drug at the pharmacy counter instead of using the rebates to lower premiums for all members of a plan.

Their argument appears to be that all plan members ought to share of negotiated rebates at the point of sale would in turn increase costs to the broader health care system.”

Although the list price/rebate relationship is frequently cited as the main cause of high consumer drug prices, AHIP argues that rebates are not prevalent, including for the most expensive drugs. A report by the consultant Milliman found that nearly 90% of Part D drug claims were for drugs with no rebates. The Milliman report also found that, when measured on an individual drug basis (i.e., not a script count basis), approximately 70% of brand-name drugs did not have significant rebates. Further, physician-administered drugs paid for under Part B, which account for 30% of prescription drug spending, typically do not receive rebates.

**Power to the P&T Committee?**

Insurance companies and their PBMs argue that with regard to the Part D program, the best way to cut costs would be to allow P&T committees more leeway in formulary development. That could entail decreasing from two to one the number of drugs that formularies have to offer in each class and category and doing away with the “all or almost all” language that forces

Part D plans to offer all drugs in six categories, the so-called “protected” classes: immunosuppressants, antidepressants, anti-psychotics, anticonvulsants, antiretrovirals, and antineoplastics. CVS believes Part D plans’ P&T committees are well qualified and structured to ensure that beneficiaries have an appropriate choice of drugs in these six classes on the plan’s formulary. Another reason CVS feels the six protected classes ought to be eliminated is that plans cannot impose any type of utilization management edits on the use of the drugs, even if these are based on clinical criteria. This is because Part D plans may only apply prior authorizations and transition fill limitations to beneficiaries who are considered new starters to these drugs. When beneficiaries are new to the plan, however, the plan frequently does not have enough claims history (at least 108 days) to determine whether the drug is considered new as opposed to ongoing therapy. In this case, the plan is required to assume that the drug is ongoing therapy and to provide it without the opportunity to recommend more cost-effective or clinically superior therapies.

**Part B**

While P&T committees are limited in certain respects, in terms of what they can do in Part D, they do not even have a role in Part B, which pays for physician-administered drugs, often expensive oncology medications. Part B drugs are provided “incident to” physician services and include some antigens, injectable osteoporosis drugs, erythropoiesis-stimulating drugs, blood-clotting factors, oral end-stage renal disease drugs, cancer medications, parenteral and enteral nutrition, nebulizers, immunosuppressive agents, intravenous immune globulin, and vaccines. Part D drugs are infused either in a physician’s office or a hospital outpatient clinic.

HHS Secretary Azar noted at a June 12, 2018, Senate HELP hearing that cost-savings are the key rationale for moving drugs from Part B to Part D, saying that “right now, we’re paying sticker price for these drugs, no discounting. We ought to be able to get 20 to 40% discounting, as we do in Part D, on those drugs. That’s $30 billion of spend.” The Blueprint, however, doesn’t specify which drugs might be switched to Part D, and what would happen if a Medicare recipient did not have a Part D plan.

For a variety of reasons, however, there are some categories of drugs now paid for under Part B that might have a smoother path than others into Part D, including insulin, antiemetics, inhalants, immunosuppressants, and oral anticancer medications, according to the Pharmaceutical Care Management Association, which represents PBMs and like seemingly every interest group—including PhRMA, which is totally opposed to the switch—has concerns about a Part B-to-D move.

**Site Neutrality**

A potential Part B-to-D shift for drugs brings up another potential Trump administration move likely to affect hospital outpatient clinics, where many Part B drugs are infused. The HHS is considering a site-neutral payment policy to account for differences in reimbursement between the outpatient prospective payment system and the physician fee schedule for drug administration services. In short, hospital outpatient reimbursement for Part B would be reduced.

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The AHA opposes a site-neutral payment policy for drug administration services under Medicare Part B. Hospitals with newer off-campus hospital outpatient departments are already subject to significant payment reductions for the “nonexcepted” services they furnish in these settings.

The Blueprint has a host of other suggestions related to the uptake of biosimilars, risk evaluation and mitigation strategies (which have been cited as reasons to deny generic-drug companies samples of brand-name drugs), 340B, Medicaid, and so-called “gag clauses” imposed on pharmacists and other programs. For Medicaid, the Blueprint suggests a new demonstration authority for up to five states to test drug coverage and financing reforms that build on private-sector best practices. This would open the door to “closed formularies” developed by P&T committees, now absent from state Medicaid drug programs. But there is opposition to that limited initiative, as there is to everything the Blueprint considers, from one corner of the industry or another. As to formularies in Medicaid, GlaxoSmithKline says, “We strongly oppose any proposals that ration access to prescription drugs in Medicaid through a closed formulary.”

One thing stands out from reading through some of the 3,000 comments on the Blueprint. They all start out pledging fealty to the Trump administration’s efforts to lower drug prices. Then they all degenerate into opposition to most of the Blueprint’s suggestions. Normally that reaction—and it is broad and deep—would be enough to sink any significant reforms. Of course, President Trump has been known to remain impervious to any cloud of negativity surrounding him—witness trade tariffs or immigration, for instance. Will drug pricing be the next arena in which he upends conventional thinking?

REFERENCES