Republicans Resolve to Address High Drug Prices

Rhetoric Meets Reality With PPACA Replacement

Stephen Barlas

When the Washington Post headlined a story on February 27 that White House thinking on health care reform is “in flux,” it noted that President Trump was somewhat uninvolved in many of the emerging issues except for a few near to his heart, such as controlling drug price increases. President Trump has taken up the issue of drug prices in a way President Obama never did. In Trump’s January meeting with chief executive officers of drug companies, he said drug companies are “getting away with murder.” He indicated that he would support allowing Medicare to negotiate pricing with drug companies, an issue he waffled on during his campaign. That is anathema to drug manufacturers. “We’re the largest buyer of drugs in the world, and yet we don’t bid properly, and we’re going to start bidding, and we’re going to save billions of dollars over a period of time,” the President said.

Now that rhetoric is about to meet reality as Republicans draft legislation to replace the Patient Protection and Affordable Care Act (PPACA). That bill will be a magnet for all sorts of amendments, some of them dealing with controlling drug prices, some expanding or contracting drug access, others incentivizing the development of generic drugs. Public outrage over high drug prices and Trump’s repeated allusions to them ensure that pharmaceutical issues, if not at the heart of changes to the individual marketplace, Medicare, and Medicaid, will be in its blood. “The issue of drug prices consistently polls high among our members,” says David Certner, Legislative Counsel to the AARP. “It is up there if not the top area of complaint, and we are not the only ones seeing that data. But like anything else, you need bipartisan support to get anything through.”

Changes to the PPACA will afford the White House and Republicans in Congress the first bite at making significant changes in prescription drug policy. But there are a number of congressional bills on drug development and pricing that won’t fit with Obamacare repeal-and-replace legislation, and instead will be considered in a second round of action as the House and Senate write the latest iteration of the Prescription Drug User Fee Act (PDUFA) and its generic counterpart (GDUF). Shoshana Krilow, Vice President of Public Policy and Government Relations for Vizient, agrees there is growing bipartisan concern over rising drug prices, and both the White House and Congress have shown an interest in tackling the issue. She adds, “That said, there is also a lot of opposition regarding some of the more-often mentioned solutions to drug pricing issues, so it’s not an easy fix.” Vizient is a large supplier of operational and supply chain services to hospitals.

For example, there is significant bipartisan support for allowing pharmacies to import or reimport U.S.-made drugs under certain conditions. “When very well regulated by the FDA [Food and Drug Administration]—and when needed to respond to a shortage in the U.S.—importation can be very important and helpful to hospitals and patients,” Krilow states. “In fact, we previously encouraged it when there was a shortage of IV [intravenous] fluid. But when unregulated and when there is no clean chain of custody [or] no clean provenance, then it can be quite dangerous.”

But even some hospital groups oppose that initiative. Christopher Topelski, Director of Federal Legislative Affairs for the American Society of Health-System Pharmacists (ASHP), says ASHP would not be supportive of bills that would allow for importation/reimportation of drugs or biologics. “The purchaser doesn’t know the quality of the product, if it is adulterated or not, it creates track-and-trace issues, and would generally not have a pharmacist as part of the dispensing process,” he explains.

Consumer groups such as AARP and narrow patient groups who are alarmed by sudden spikes in specific drugs—the outrageous price increases for importation/reimportation of drugs or biologics is much less remarked on. Typically, the costs of the IV drugs that are the staple of hospitals are bundled into diagnosis-related groups. But that doesn’t mean sudden large price increases don’t hurt, says Brian Benson, RPh, PharmD, Executive Director of Pharmacy for Lutheran Hospital, one of 32 hospitals that are part of UnityPoint Health, a large health system that operates facilities throughout Iowa, Illinois, and Wisconsin. He mentions Isuprel (isoproterenol hydrochloride, Hospira), a heart medication IV, the price of which shot up dramatically when Valeant bought it from Marathon Pharmaceuticals in 2015. Its price also rose in 2016. “We have to eat those increases when they occur during the year,” he explains. By “we” he means the pharmacy department, which had a budget of about $16 million in 2016. “Isuprel may be an extreme example, but there are maybe 20 to 30 medications with varying degrees of that magnitude a price jump.”

340B Rule

Though the Obama administration did little to arrest high drug prices, in a sign of which way the wind is blowing, it did

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.
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slip in a little-noticed shot at brand-name manufacturers in the waning days of its tenure. In January, the Office of Pharmacy Affairs (OPA) published a late-breaking and significant final rule that was a setback for drug manufacturers. The OPA is a part of the Health Resources and Services Administration (HRSA), which is within the Department of Health and Human Services (HHS). The rule essentially put meat on the bones of a provision in the PPACA that allows HHS to levy fines of up to $5,000 on drug companies that incorrectly charge too-high prices to safety-net hospitals participating in the 340B program.

The rule had long been delayed. The fact that it was finally published after Trump won the election may have been the result, in some small part, of the Obama administration acknowledging that a Trump administration was going to be tough on brand-name drug manufacturers. The effective date of the final rule was March 6, 2017.

The final rule is a warning to drug companies to more closely watch the prices they charge to 340B “covered entities,” a group that includes more than 2,000 hospitals and local health clinics. They depend on heavily discounted drug prices to produce the revenues to fund health programs and capital improvements. Dr. Benson of UnityPoint’s Lutheran Hospital says his hospital’s participation in 340B produced $4 million in savings on drug prices in 2016. His department’s budget was $15.7 million. “That $4 million helped us offset charity care, bad debt, and it funded pharmacy and infusion services,” he explains. “In addition, it served as a buffer against unexpected, aggressive price increases for drugs such as Isuprel.”

This final rule—and its pro-hospital revenue provisions—is particularly important to hospitals this year. They face the threat of the loss of Medicaid reimbursement for those working poor in 31 states covered thanks to the Medicaid expansion in the PPACA, which is likely to be cancelled. The final rule the OPA issued in early January 2017 establishes the calculation of 340B ceiling prices and when civil monetary penalties (CMPs) can be assessed for violation of those ceiling prices. The final decisions of the OPA indicate that pharmaceutical manufacturers took a near-total drubbing on key issues, including the pricing formula—in particular, the “penny-pricing” policy—and on the latitude given the Office of the Inspector General (OIG) at the HHS to assess CMPs.

Drug companies pleaded with the OPA to provide some alternatives to penny pricing. “Penny pricing is especially troubling and irrational where controlled substances, such as our prescription opioid products, are concerned,” said LaDonna Steiner, Associate General Counsel of Purdue Pharma LP. “At a time when opioid products, are concerned,” said LaDonna Steiner, Associate General Counsel of Purdue Pharma LP. “At a time when opioid abuse is of national concern, the proposed penny-pricing policy would have manufacturers make unlimited quantities of such products available for sale at a mere penny per unit, without any effective mechanism to prevent improper diversion.”

In the final rule, the OPA stuck with the current penny-pricing policy: “the proposed alternatives to penny pricing would be inconsistent with the 340B ceiling-price formula … and would raise 340B ceiling prices above the statutory formula in ways that would be inconsistent with the statutory scheme.”

With regard to CMPs, there were extensive comments from pharmaceutical companies as to how they would like to see the OPA define what constitutes knowingly and intentionally charging a price above the ceiling price. In the proposed rule it issued in April 2016, the OPA set out four definitions it might use to determine whether a company had knowingly and intentionally overcharged a 340B-covered entity. The Pharmaceutical Research and Manufacturers of America (PhRMA) opposed finalizing the four definitions (as did the 340B Coalition, composed of different covered entity groups, for that matter). Instead, it urged the OPA to define “knowingly and intentionally” as a manufacturer denying the covered entity the 340B ceiling price, knowing that the purchaser is a covered entity, that the entity is seeking the 340B price and is entitled to it in that circumstance, and that the price the manufacturer charges to the entity exceeds the correct 340B ceiling price, and that therefore the manufacturer is acting with a conscious intent to violate the 340B law.

Covered entities wanted a much broader definition, which would catch more drug manufacturers in its web. The 340B Coalition said the OPA should use the OIG’s definition of “knowingly,” which says that a company submits an improper claim if it had actual knowledge that the claim was improper, acted in deliberate ignorance of the truth or falsity of the information presented, or acted in reckless disregard of the truth or falsity of the information presented. The 340B organizations also requested that HRSA define “intentionally” as “not due to a mathematical miscalculation, clerical oversight, or similar inadvertent error.”

The final rule attempts to thread the needle. It drops the four proposed definitions opposed by the drug companies. Instead, it gives the OIG authority to determine whether there are overcharges in any individual instance, apparently siding with the 340B Coalition, and provides some examples of circumstances where HHS would assume that a manufacturer did not “knowingly and intentionally” overcharge a covered entity.

Changes to Medicaid

Drug price savings turned into revenue under the 340B program are particularly important to safety-net hospitals that face the potential loss of reimbursement for care provided to individuals who have been served by the Medicaid expansion in the PPACA. Currently, each state appropriates dollars from its state revenues to fund its Medicaid program, and the state has no flexibility over who it can cover. If an individual meets Medicaid criteria, he or she must be covered. Then the federal government matches those funds on a 1:1 basis. In the past, hospitals have received payments from the federal government when they serve large percentages of indigent people: those are called disproportionate share payments, but those have been slated to go away because some of those patients without insurance who received uncompensated care are now enrolled in Medicaid.

But states face a double whammy of sorts. Not only will 31 of them almost certainly lose “expansion” funding, but Republicans will also change the program so that the federal government no longer matches state funds on a 1:1 basis. Instead, the federal contribution will be in the form of a block grant or some sort of capitation arrangement. So it will become even more important for states to squeeze additional savings out of their Medicaid programs. More states will move more recipients into managed care, which now accounts for about 75% of individuals in the program.
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States will also look for savings in their drug buys. While pharmaceuticals account for only about 6% of Medicaid spending, the costs for all states increased 24% in 2014, according to a January 2016 report from the Medicaid and Children’s Health Insurance Program Payment and Access Commission. Total outpatient spending was $22 billion. Both managed care organizations and fee-for-service programs face significant obstacles to reducing the impact of expensive specialty drugs. Drug prices are locked in, although mandated rebates can be considerable. There is no negotiation between plan pharmacy benefit managers (PBMs) and manufacturers on price as there is, for example, in Medicare Advantage, though not Part D. So if direct negotiation between the federal government on behalf of Medicare Part D and drug manufacturers becomes a reality, it is hard to imagine that it won’t be applied to Medicaid, though that potential has been talked about less.

Jeff Myers, President and CEO of Medicaid Health Plans of America, says his members are considering proposing legislative changes within any PPACA repeal-and-replace bill to give the plans more flexibility on drug pricing, much like Medicare Advantage plans have now. That will require changes to the Medicaid rebate law. With regard to negotiating value-based drug contracts, for example, that is prevented by concerns that drug manufacturers have expressed, which relate to the possibility of being sued based on federal antikickback and inducement laws because of imposing adherence requirements on individuals taking drugs covered by a value-based contract.

More flexibility to states on their Medicaid programs may also lead to changes in the rebate law, which would allow them to expand prior-authorization programs. For the new expensive hepatitis C drugs, for example, several states have implemented stringent prior-authorization requirements, including high disease-severity requirements (e.g., fibrosis scores of F3 or higher) and abstinence from alcohol or drug use for several months. However, such requirements have raised questions as to how far states may go in their prior-authorization requirements and still meet the coverage requirements of the drug rebate program, with many advocacy groups considering lawsuits to improve access to these drugs. The Centers for Medicare and Medicaid Services (CMS) issued a letter to states expressing concern that some state restrictions on new hepatitis C drugs are contrary to Medicaid laws.

Medicare Part D

Changes to drug purchasing under Medicare Part D will also be up for debate, particularly because Trump has been vocal on that issue, although one could make the case that direct negotiation is a more pressing issue within Medicaid because Part D plans work through PBMs who do have some negotiating leverage. Of course, seniors have more political muscle than the working poor, so Medicare Part D drug prices are a more potent issue than Medicaid drug issues. Drug companies oppose direct negotiation, and Republicans on Capitol Hill have been more solid in opposition than they have been, for example, with regard to importation or reimportation of foreign drugs. So the key to any legislative action on direct renegotiation will be, according to AARP’s Certner, whether the Trump administration plays a prominent role in this particular debate.

Individual Mandate

While it is not clear what an Obamacare repeal will mean for Part D, there is no suspense over its elimination of the individual mandate that requires individuals and small companies to buy or provide health insurance or pay a penalty instead. One of the key components of the individual mandate is that insurance companies provide 10 categories of essential health benefits. One of those is pharmaceuticals.

The CMS addressed that benefit over the course of the past few years, putting in various requirements, particularly with regard to what formularies had to offer. The potential loss of those pharmaceutical protections worries patient advocacy organizations, some members of which will have to buy individual insurance when their Obamacare policies disappear. In a February letter to Tom Price, Secretary of HHS, the I Am Essential Coalition, which is composed of 200 patient and community organizations, lobbied for retaining requirements that make formularies and cost-sharing information accessible to both enrollees and potential enrollees, including tiering and utilization management information; cover a minimum number of drugs in each U.S. Pharmacopoeial Convention therapeutic class that is based on a benchmark that each state selects; use P&T committees to develop and regularly update their formularies with newly approved drugs and according to treatment guidelines; and other requirements.

Incentivizing Generic Development

Once Obamacare replacement is cleared away, there will be a second opportunity to affect drug prices presented by the reauthorization of PDUFA and GDUFA—both required by the end of September 2017. A number of bills, particularly on generic drugs, will be slated as potential amendments. The Lower Drug Costs Through Competition Act (H.R. 749) is one example. The bill has been introduced by U.S. Representative Greg Walden (R-Oregon), supports the bill. This bill amends the Federal Food, Drug, and Cosmetic Act to speed approval of generics where there are shortage situations and allows the FDA to provide vouchers to companies for priority review.

Passage of this bill would seem to be easy given that PhRMA supports it. Brand-name companies don’t always sign on to bills promoting their generic competitors. But PhRMA’s support may indicate that this particular bill isn’t far reaching. “It is pro-generics, but I don’t think it does much for the generics industry in the end,” according to Kirt R. Karst, an attorney in Washington with Hyman, Phelps & McNamara, PC. He adds that the Association for Accessible Medicines (formerly known as the Generic Pharmaceutical Association) seems lukewarm on the bill.

Other bills with bipartisan support include the Preserve Access to Affordable Generics Act (S. 124) sponsored by U.S. Senators Amy Klobuchar (D-Minnesota) and Chuck Grassley (R-Iowa). This bill would make it harder for brand-name drug companies to induce generic competitors to delay introduction of generics. The bill, like H.R. 749, has been introduced in past Congresses and has gone nowhere. So the fate of these

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bills and others like them may be the true test of whether the Trump administration and the Republican-controlled Congress are ready to back up their rhetoric about outrageous drug price increases with action.

REFERENCES


