

Drug Pricing and Surprise Billing: Recent Actions and Outlook

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Recent months have seen a flurry of activity in Congress on prescription drug pricing and surprise medical bills as lawmakers seek to address rising consumer health care costs. Several House and Senate committees have advanced legislation on drug pricing and surprise billing, and additional activity is expected in September following the August recess, including possible floor action.

Drug Pricing

Table 1: Drug Pricing Legislation and Administration Actions

Senate

The complexities inherent in the Senate's legislative path forward on drug pricing can be seen not only in the partisan perspectives but also in the differing concerns and approaches of the multiple committees of jurisdiction.

HELP Committee

On June 26, the Senate Health, Education, Labor and Pensions (HELP) Committee advanced its Lower Health Care Costs Act (S. 1895). The package, which addresses health care costs broadly, includes sections on surprise billing, drug pricing and price transparency. The drug pricing provisions in the bill focus in particular on promoting generic and biosimilar development, including proposals that aim to: modernize the publication of drug patent information by the Food and Drug Administration (FDA); prevent the abuse of FDA citizen petitions in order to delay drug approvals; discourage first-to-file generic drug applicants from delaying the start of their 180-day exclusivity period; streamline the transition of certain products from the drugs pathway to the biologics pathway; and give FDA authority to more promptly approve a follow-on or generic drug. Prior to the markup, committee leaders also added in the CREATES Act (S. 974), which aims to prevent brand drug manufacturers from delaying generic competition by blocking access to product samples. During the markup, the committee voted 16-7 to add the FAIR Drug Pricing Act (S. 1391) to the package. The bill, sponsored by Sen. Tammy Baldwin (D-WI), would require drug manufacturers to notify the Department of Health and Human Services (HHS) and submit a justification report

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before increasing the price of a drug by 10 percent or more over a 12-month period or 25 percent or more over a 36-month period.

Judiciary Committee

The Senate Judiciary Committee marked up its own slate of bills related to drug patents and exclusivities on June 27. The Prescription Pricing for the People Act (S. 1227) would require the Federal Trade Commission (FTC) to conduct a comprehensive study of the state of competition in the drug supply chain, with a particular focus on pharmacy benefit managers (PBMs). The Stop STALLING Act (S. 1224) aims to prevent the filing of sham citizen petitions in order to delay drug competition. The Affordable Prescriptions for Patients Act (S. 1416) would modify the FTC Act to target “product hopping” and “patent thicketing” practices. Finally, the PACED Act (S. 440) would prevent manufacturers from using tribal sovereign immunity in order to extend their drug patents.

Finance Committee

The Senate Finance Committee reported out its much-awaited drug pricing package on July 25. The Prescription Drug Pricing Reduction Act, which was marked up in conceptual form, includes more than two dozen proposals intended to lower drug costs in Medicare Part B, Medicare Part D and Medicaid. Among the more notable provisions is a \$3,100 cap on out-of-pocket costs for Part D beneficiaries and a provision that would require drug manufacturers to refund Medicare for any price increase greater than inflation in Part B or Part D. The package also sets a maximum add-on payment amount for drugs, biologics and biosimilars in Part B and raises the rebate caps in the Medicaid program. The package passed over the objections of a majority of Republicans on the committee, who expressed concerns that the inflationary rebates amount to price controls. The committee also rejected an amendment from Sen. Debbie Stabenow (D-MI) to repeal the noninterference clause and an amendment from Sen. Pat Toomey (R-PA) to block implementation of the administration’s International Pricing Index (IPI) Model. The Chairman and Ranking Member are expected to add several other provisions to the bill before it moves to the floor.

House

In the House, multiple committee interests present complications in the legislative process.

The House Ways and Means Committee acted early on drug pricing, advancing a package of drug price transparency measures during a markup on April 9. The Prescription Drug STAR Act (H.R. 2113) includes a version of the FAIR Drug Pricing Act, as well as provisions requiring manufacturers to submit information to HHS on the samples provided to certain providers for patient use. The bill would also require manufacturers to submit information to HHS on the average sales price (ASP) for physician-administered drugs, and would require HHS to disclose the aggregate rebates and discounts achieved by PBMs on a public website.

On April 30, the House Judiciary Committee advanced several drug pricing bills, including the CREATES Act (H.R. 965), the Stop STALLING Act (H.R. 2374) and the Prescription Pricing for the People Act (H.R. 2376). The committee also approved the Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2375), which would

strengthen the FTC's ability to challenge reverse payment patent settlements, also known as "pay-for-delay" agreements, in which a brand drug company pays a generic competitor to delay market competition.

The House Energy and Commerce Committee advanced a package of drug price transparency bills on July 17. The package includes the FAIR Drug Pricing Act (H.R. 2296) along with provisions from the Public Disclosures of Drug Discounts Act (H.R. 2115), the Prescription Pricing for the People Act (H.R. 2376), the Sunshine for Samples Act (H.R. 2064) and the Drug Price Transparency Act (H.R. 2087). Versions of many of these provisions were included in the House Ways and Means Committee package. The Energy and Commerce Committee also marked up several bills in early April focused on generic and biosimilar drug development, including the CREATES Act.

When Congress returns after Labor Day, the Ways and Means, and Energy and Commerce committees may turn their attention to the bipartisan Medicare Part D drug pricing legislation that was released for comment in May. The legislation would establish a Medicare Part D out-of-pocket cap for beneficiaries and make structural reforms to the Part D benefit.

Trump Administration

Meanwhile, the White House's own drug pricing agenda has suffered several setbacks in recent months, even as an ambitious international pricing proposal remains pending. On July 10, the administration withdrew a final rule that would have effectively eliminated rebates paid by drug manufacturers to PBMs in Medicare and Medicaid. Analyses indicate that the rule would raise federal spending by \$177 billion over the next decade and increase seniors' premiums. On July 8, the U.S. District Court for the District of Columbia blocked implementation of an administration rule requiring drug manufacturers to disclose list prices in direct-to-consumer advertisements, stating that HHS lacked the statutory authority to impose such a requirement.

The administration's IPI Model, first announced in an Advanced Notice of Proposed Rulemaking in October 2018, is now anticipated to be formally proposed in August 2019. The plan, which would tie reimbursement for Part B drugs to an index of international prices, was dealt a blow recently when Senate Finance Committee Chairman Chuck Grassley (R-IA) announced his opposition to the proposal. In addition, although Sen. Toomey's amendment to block the proposal failed on a tie vote during the Finance Committee markup, 13 Republicans supported the amendment, signaling strong opposition in the Senate GOP caucus. There will likely be more battles ahead on the IPI Model if or when it is formally released.

On July 31, HHS released a "Safe Importation Action Plan" outlining steps that the agency will take to allow the importation of prescription drugs from foreign countries. Under Pathway 1, FDA will release a Notice of Proposed Rulemaking that will authorize demonstration projects to allow importation of certain drugs from Canada. Under Pathway 2, FDA will release draft guidance with recommendations for manufacturers to import versions of approved drugs that they sell in foreign markets. FDA officials made clear that the administration is still interested in international reference pricing, and view the IPI Model and the importation plan as complementary.

Outlook

The Senate Finance Committee approved the Prescription Drug Pricing Reduction Act shortly before the start of the August recess; this means that floor action on a Senate package should be expected no earlier than mid-September. Still, Senate committee leaders are holding to their initial plan to combine the Finance, HELP and Judiciary products for floor consideration. Finance Committee leaders may need to shore up additional support for their package; fewer than half of the Republicans on the committee voted to advance the bill during the July 25 markup. Senate GOP Leadership will have to factor in this significant opposition as they seek to combine the three committee products into one package. Majority Leader McConnell is unlikely to bring a bill to the floor that does not have the support of the majority of Senate Republicans. GOP members on the Finance Committee raised particular concern about the inflationary rebate provisions in the Prescription Drug Pricing Reduction Act, arguing that these provisions amount to government price controls. Chairman Grassley, meanwhile, characterizes the bill as a “sensible, commonsense” approach that has enough bipartisan appeal to garner 60 votes in the upper chamber. Sen. Grassley may seek to act quickly in order to frame the broader drug pricing debate in Congress in a way that precludes serious consideration of progressive proposals, such as Medicare price negotiation. At the recent markup, he reaffirmed his opposition to repealing the non-interference clause, which prohibits direct governmental negotiation, and stressed that the issue “isn’t going to go away” if the Senate fails to act promptly on drug pricing.

As Chairman Grassley acknowledged, Medicare drug price negotiation is likely to be the focal point of House Speaker Nancy Pelosi’s (D-CA) forthcoming drug pricing plan. Staff have indicated that the plan, set to be unveiled in September, would require HHS to negotiate prices for at least 250 single-source drugs in Medicare Part B, Part D and Medicaid. Speaker Pelosi had initially proposed targeting only 25 drugs, expanding the plan recently in response to pushback from progressives. The FTC or the Veterans Health Administration would arbitrate if HHS and drug manufacturers are unable to agree on a price, according to staff.

Should the Senate fail to coalesce around a drug pricing package, House Democrats are likely to advance a more progressive package that would be unacceptable to Senate Republicans, threatening prospects for a year-end deal. Indeed, though the White House had been in contact with Speaker Pelosi’s staff on drug pricing issues, those already tenuous negotiations have become increasingly complicated in recent months. The President is unlikely to support a Democratic-led House bill over a bipartisan Senate alternative, although his reaction to the House Democrats’ proposal certainly will influence the response of the House Republican Conference.

Many of the drug pricing provisions reported by committees have been scored by the Congressional Budget Office as significant cost-savers. A preliminary analysis of the Senate Finance package, for example, estimates that the bill would reduce federal deficits by more than \$100 billion over a decade. Such savings are attractive for lawmakers looking to offset numerous health care “extenders” scheduled to expire at the end of the year, and we expect that these provisions could ride together in a year-end legislative vehicle.

Surprise Billing

Table 2: Comparison of Surprise Billing Proposals

Senate

The Lower Health Care Costs Act (S. 1895) reported out of the Senate HELP Committee contains a number of surprise billing provisions, many of which remain controversial with members. Like other surprise billing measures, S. 1895 holds patients harmless in out-of-network emergency care situations and for care provided by ancillary out-of-network practitioners at in-network facilities. The bill adopts a benchmark payment rate approach with respect to determining reimbursement for providers in these scenarios. Specifically, providers would be paid the median in-network rate based on their geographic area. The surprise billing provisions would also apply to air ambulance services. Senators on both sides of the aisle have raised concerns about the benchmark payment approach, which is seen as favoring insurers. Sen. Bill Cassidy (R-LA) and a bipartisan group of senators had previously released their own proposal, the STOP Surprise Medical Bills Act (S. 1531), which relies on a “baseball-style” arbitration process to resolve payment disputes. HELP Committee Chairman Lamar Alexander (R-TN) has signaled that he is open to making changes to the payment methodology before the bill moves to the Senate floor.

House

The House Energy and Commerce Committee advanced its own surprise billing legislation, the No Surprises Act, on July 17. Like the Senate HELP bill, the No Surprises Act holds patients harmless for out-of-network emergency care and in situations where they cannot reasonably choose a provider. The bill includes some reporting requirements for air ambulance providers and suppliers but does not apply the surprise billing provisions to this sector. The No Surprises Act initially utilized a benchmark payment approach based on the median in-network rate. In response to concerns from several members, however, the committee adopted an amendment from Reps. Raul Ruiz (D-CA) and Larry Bucshon (R-IN) to add an independent dispute resolution process as a backstop to the benchmark approach.

Outlook

Senate leaders are holding to their plan to combine surprise billing and drug pricing legislation into one package before floor consideration. While there is wide bipartisan support for action on surprise billing, a number of members have raised objections with the HELP Committee’s package. Senate Republican leadership recently initiated a process known as “hotlining” in order to gauge support for the bill, finding that more than a dozen Republicans were prepared to place “holds” on the bill due to concerns over the payment methodology in the legislation. In particular, several senators are pushing HELP Chairman Alexander to add an arbitration component to the bill. Sen. Alexander, for his part, said he was optimistic that the holdout Republicans would still support the package if it were put to a floor vote.

Of course, even if the Lower Health Care Costs Act passes the Senate as is, it would need to be reconciled with House legislation. Currently, the Energy and Commerce Committee’s No Surprises Act utilizes a benchmark payment approach with arbitration offered as an optional appeals process.

Meanwhile, the House Education and Labor Committee is expected to mark up the No Surprises Act, though timing for such a markup has not been announced. The House Ways and Means Committee has yet to release its own surprise billing proposal, but

committee leadership has indicated it is taking steps to find a solution to protect patients from surprise bills.

Conclusion

We expect a very active fall as House and Senate leadership attempt to find a path forward on drug pricing and surprise billing. During the August recess, groups on all sides of these debates will be taking their arguments to their members back home. The drug pricing debate could be further complicated should the administration release the pending IPI Model proposed rule, possibly as soon as this month. Also lurking in the background are potential court decisions around the Affordable Care Act and a possible administration plan to replace the health law.

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