Ep. 22: What's New in Washington: What Congress Is Doing About Drug Pricing and Surprise Medical Billing

November 21, 2019

Jose Garriga: Hello, and welcome to *OnAir with Akin Gump*. I'm your host, Jose Garriga.

A 600 percent increase in the cost of a generic drug. A $100,000 emergency visit to an out-of-network hospital.

Drug pricing and medical billing are perennial big topics that have taken on greater urgency and higher profiles in this runup to the 2020 elections. Beyond media reports of drug price increases in the multiple hundreds of percents and of surprise hospital bills, primaries are around the corner, and questions on how best to address these issues will be directed at Democratic and Republican candidates. While many people and politicians on both sides of the aisle believe that these issues must be addressed in a way that benefits medical services consumers, there are those who push back and point to the costs of such changes as reasons to proceed cautiously.

In today's episode, Akin Gump health care and life sciences senior counsel Taylor Jones and public law and policy senior policy advisor Julie Nolan will discuss the state of play at the federal level as a variety of bills are considered in the U.S. Congress, and how developments at the state level and even internationally may inform the debate and, perhaps, the ultimate form of this critical legislation.

Welcome to the podcast.

Taylor and Julie, thank you both for appearing on the show today. Let's start by providing a bit of context for listeners. What has motivated drug pricing and surprise medical billing legislation at this time, and what does the legislation seek to accomplish? Julie, if you'd kick it off.

Julie Nolan: Sure. Thanks for having us. So, quite simply, the cost of drugs to consumers and surprise medical bills are pocketbook issues. News headlines and in-depth reporting from journalists like Sarah Kliff have shared the stories of patients who were surprised to find out that their health care provider was not covered as an in-network provider or even at an in-network facility by their insurer. President Trump has indicated support for drug pricing policies that do not align with typical Republican proposals, and, in fact, the White House calls the president's approach to addressing health care costs "non-ideological."

For example, he has expressed support for direct Medicare negotiations and for drug pricing importation mechanisms.

Jose Garriga: Thank you, Julie. So, looking, then, at these proposals that I mentioned earlier on, what are the leading contenders among them for the ones that have been circulated to date, and what are some of their noteworthy provisions? Taylor, please?

Taylor Jones: Sure. I would focus on three sources for these proposals. The first is a bill that's recently being considered in the Senate. We also have a House bill that we'll discuss. Then finally we've got a couple of proposals coming straight from the administration itself. The first that we should probably talk about is the Prescription Drug Price Reduction Act or Pricing Reduction Act, which is a bipartisan Senate bill that recently advanced out of the Senate Finance Committee this summer. It had a two-thirds majority vote within the committee, but, interestingly, a majority of the Republicans on the committee actually voted against it because of a provision in which drug companies are penalized to the extent that their drug prices increase higher or more quickly than inflation. Additional key provisions of this bill include adding an out-of-pocket maximum for Medicare beneficiaries and reforming or ultimately getting rid of the Medicare Part D “donut hole” or coverage gap, as it's often referred to.

Although this bill has significant support behind it, there has been some discussion between the administration and the Republican Party that has led some to question whether this bill will be successful, particularly with respect to that inflation penalty that I just referenced. Recently, Sen. Grassley suggested that he plans to file an updated version of the bill. This version will have a number of co-sponsors, and he and others are in negotiations with the White House regarding additional provisions. Time will tell whether that inflation penalty will stay.

In addition to that Senate bill, we've also got a House bill that has been making the rounds. This bill is referred to as the Lower Drug Costs Now Act, and it was unveiled by Speaker Pelosi in September. It has a lot in common, actually, with the Senate bill, but it does have some differences, including a provision that would allow the Department of Health and Human Services [*HHS*] to negotiate prices with the manufacturers of certain selected drugs. Under this bill, those manufacturers would be required to enter into an agreement with HHS, and they would be required to adopt a negotiated price for Medicare reimbursement.

Very interestingly, in addition to requiring that negotiated price to be paid with respect to Medicare, manufacturers would also be required to offer that negotiated price to participating private insurers. This bill would also establish a drug price ceiling for negotiations that's based on prices paid in other countries, and like the Senate Finance bill, this would include a penalty in the form of a mandatory rebate for manufacturers of drugs that increase faster than the price of inflation. Again, like the Senate Finance bill, this House bill includes an out-of-pocket maximum and also reforms the coverage gap or donut hole for Medicare Part D beneficiaries.

At the same time that these bills have been making their way through Congress, the administration has also been putting forth a number of proposals that will potentially affect drug pricing. First that we'll discuss involves an international pricing index. As this was originally described, the international pricing index would take the form of a demonstration plan, in which Medicare would establish the international index for Part B drugs. In addition to the international index, the administration is also considering a couple of programs that would allow for drug importation from other countries. The first of such proposals includes a plan in which states, wholesalers or pharmacists could submit plans for a demonstration project that would be approved by HHS and that would allow states to import drugs from Canada.

At this stage, there are four states—I believe they are Vermont, Colorado, Maine and Florida—that have passed laws that are authorizing such importation, but HHS would have to approve it in order for this to move forward. There is a proposed rule that's currently under review at the OMB [*Office of Management and Budget*] regarding this importation by states, and the White House has indicated that it plans to approve Florida's plan. It's unclear whether or not that approval will be separate from the proposed rule, but we'll soon see. In addition to allowing states to import drugs from other countries, there's a second proposal that the administration has put forward that would allow manufacturers to import versions of their drugs that they sell in foreign countries into the U.S. That would allow them to offer American consumers cheaper versions of their drugs. This proposal is somewhat controversial because some view it as a way for manufacturers to avoid paying rebates on their drugs. So, at this stage, that's the summary of the major proposals that we see on the horizon that are likely to affect drug pricing.

Jose Garriga: Thank you, Taylor. Julie, can you talk a bit about surprise medical billing, then, and where we are with that?

Julie Nolan: So, both the House and Senate, at the committee level, have acted on surprise medical billing proposals. In the Senate, the HELP [*Health, Education, Labor and Pensions*] passed out of committee an approach that would require emergency providers who are out of network to ban surprise billing and establish a median in-network rate as their reimbursement rate. The Energy and Commerce Committee reported out the No Surprises Act, which would establish a median in-network rate with an arbitration backstop for emergency providers who are out of network. There are two committees who have yet to act in the House: the Ways and Means Committee and the Education and Labor Committee.

There are proponents in the House of an approach to surprise billing that would allow for arbitration between providers and insurers to determine what the appropriate payment rate would be, rather than establishing a median in-network rate. However, those committees will likely have to wait until Speaker Pelosi's drug pricing bill moves off the floor before they could get underway, so most likely it will not be until December that they consider an approach in those committees. A compromise will likely have to be reached here. There is sort of a lowest common denominator that is a median in-network rate with an arbitration backstop. Policymakers are really working hard to find a balanced solution, one that bans surprise billing but does not create a situation where providers, especially in rural areas, cannot operate because of decreased reimbursement.

Jose Garriga: Thank you, Julie. Following up, then, on some of the things that Taylor had mentioned, what's your view of prospects for the first half of our conversation, which is to say concerning drug pricing on the Hill?

Julie Nolan: In the House, it's pretty clear that Speaker Pelosi's drug pricing bill was, quite frankly, a partisan exercise that will pass the House, which is controlled by Democrats, but will not advance beyond that. The White House has called the solution unworkable. The Senate is Republican-controlled, and there will not be votes to entertain such a drastic proposal that's before the House. On the Senate side, both the chairman of the Senate Finance Committee, with his ranking member, as well as the White House, are really honing in on that proposal as the foundation for what a final solution would look like.

Taylor referenced the Republican opposition, even on committee, to the inflationary rebates that would be required as a penalty for manufacturers who increase prices faster than inflation. That is a big sticking point and a good reason for why a number of Republican members voted against that proposal in committee. So, that issue will have to be worked out. Chairman Grassley has indicated that he wants that proposal to

remain. However, the White House has sent the signal that they would be okay if the Part B and D inflationary rebates from that legislation were removed. The White House has had a guiding hand and has been engaged here, so, in addition to pointing to the Senate Finance Committee bill was the likely solution, it's indicated where a number of changes would be appropriate, and, so, those negotiations are still ongoing.

Jose Garriga: So, let's stay on Capitol Hill then, Julie, for a bit and see, what are the prospects for movement on these topics before the end of the calendar year specifically, particularly given the fact that there are parallel impeachment inquiries underway?

Julie Nolan: Impeachment will be a political factor that informs whether or not drug pricing and surprise billing can get across the finish line by the end of the year. The other factor that's fundamental here is how the government funding debate will resolve itself. Congress is currently operating under a continuing resolution until November 21st, and we'll likely need to extend government funding for some period of time. We expect if the government funding is extended into mid-December, that vehicle is unlikely to include substantial policy provisions that would include drug pricing and surprise billing. However, if, as Speaker Pelosi, we think, would like, the CR extends until early next year, February or March, we expect that policymakers will be motivated to include at least some portion or some version of surprise medical billing solutions and drug pricing on that continuing resolution vehicle.

Jose Garriga: Terrific. Thank you. A reminder, listeners, that we're here today with Akin Gump health care and life sciences senior counsel Taylor Jones and public law and policy senior policy advisor Julie Nolan, discussing government efforts to regulate drug pricing and medical billing.

So, we've been talking about congressional legislation. To what extent is this legislation building on, and taking cues from, state-level legislation on surprise billing?

Julie Nolan: State efforts have certainly informed the debate around surprise medical billing and have been a good example to understand the real-world implications for what a policy that could be enacted at the federal level may look like. Most folks point to the New York model. It was the first state to pass comprehensive solution to ban balanced billing. Again, we're getting some real-world evidence about what that solution looks like in practice. The solution requires baseball-style arbitration. So, a provider and an insurer would come to the table, provide their best offer as to what they think the appropriate payment or reimbursement would be and then an arbiter would make a decision about who is closest to what an appropriate payment would be.

There are a couple of bills that look to that solution: the Stop Surprise Medical Bills Act of 2019, which was introduced by Sens. Cassidy and Hassan, and the Protecting People From Surprise Medical Bill Act, which was introduced by Congressmen Ruiz and Roe. They include arbitration as a way for insurers and providers to resolve surprise medical bills or balanced bills. I will say that the solution has been modified. I think folks have identified what works and what does not work. So, in the case of the bill that Sens. Cassidy and Hassan introduced, they did not include the same criteria that an arbiter must use when considering whether an insurer or a provider is identifying the most appropriate payment.

So, a couple of sticking points at the federal level that remain. The threshold to access arbitration, in terms of the dollar amount for the claim; the criteria that an arbiter must use in determining who, be it the insurer or provider, is submitting the most appropriate payment requests; and then also whether the claims can be bundled together are points of discussion that remain at the federal level. So, arbitration has been adopted in a variety of states, and I think most policymakers are leaning toward including that mechanism in any final surprise billing solution.

Jose Garriga: So, Taylor, let's pick up another thread that had been introduced earlier, which is to say the international pharmaceutical market. Taking a cue from the state-level discussion that Julie just shared with us, what role is the international pharmaceutical market having in these deliberations and negotiations?

Taylor Jones: Well, both the Trump administration plan and the House bill touted by Speaker Pelosi contain provisions that would utilize international pricing to set U.S. prices. To be more specific, the Trump international pricing index plan would establish a demonstration project whereby Part B prices or, given recent rumors, Part B and Part D prices would be based on prices from more than a dozen countries. These include Canada, Britain, Japan and Slovakia. This summer, Trump also referenced a most favored nation executive order on drug prices that would include an international pricing index component, but it was unclear as what he was referring to specifically and whether or not he was discussing the international pricing index demonstration or something separate.

The timing of when such pricing index would take place is somewhat up in the air. The White House has indicated that it's taking its time with respect to this and is doing so in order to get the policy right. That said, there is a regulation under review at OMB that has been there since June 20th of this year. So, in addition to the Trump plan, the House bill Speaker Pelosi has been putting forward also includes a provision that would cap drug prices based on international prices. That cap would be set at 120 percent of the average price paid by six countries, and those six countries are Australia, Canada, France, Germany, Japan and the U.K.

Given these two proposals, it's likely that at least elements of some of them will move forward and become a part of the Medicare pricing structure, although it is interesting that various critics of utilizing international pricing in this context argue that the more appropriate way to correct pricing issues in this country is through trade agreements and, specifically, requiring other countries to adhere to our intellectual property standards for biopharmaceuticals.

Julie Nolan: I will just comment that credit to President Trump for really moving what's happening internationally into the U.S. domestic policy debate. He's cited foreign governments free-riding on the U.S. biopharmaceutical industry's investments in innovation as why there needs to be an importing of prices or perhaps importation from other countries. So that's the reason we find ourselves looking to international, the marketplace there, for solutions.

Jose Garriga: Thank you. Let's wrap up with the notion of important takeaways, short-term takeaways. Obviously, this has a time horizon that goes beyond this year, certainly, as we've been discussing in the context of the 2020 elections and its runup, where this will, I'm sure, heat up and dominate at least part of the conversation. So, shorter term, what are some takeaways that you'd offer listeners regarding the drug pricing and medical billing landscape that you both have discovered? Julie, I'll ask you to take the lead on this one.

Julie Nolan: So, the three takeaways I would offer is that despite policy disagreements, Democrats, Republicans, President Trump want to enact drug pricing and surprise medical billing legislation. Certainly the politics of government funding and impeachment are going to influence the timing for congressional action on these issues, and the administration has tools still in its toolbox to address surprise billing and drug pricing, even if Congress fails to act or fails to act in a timely manner.

Taylor Jones: I would just add that given the partisan tensions, further fomented by the impeachment inquiry, it is looking less and less likely that legislation will successfully come out of Congress, although the recent statement by Sen. Grassley suggesting that he plans to

file an updated version of his bill that he is in the process of negotiating with the White House on may belie that prediction. I also think that it is very likely that administrative action on these issues, on these drug pricing issues, particularly with respect to the international index and the drug importation are likely to continue to move forward, and, so, we will probably see some movement on that front.

Jose Garriga: Thank you both. Listeners, you've been listening to Akin Gump health care and life sciences senior counsel Taylor Jones and public law and policy senior policy advisor Julie Nolan. Thank you both for appearing on the show today and shining a light on what listeners should know and be looking for regarding these critical areas.

And thank you, listeners, for your time and attention. Please make sure to subscribe to *OnAir with Akin Gump* at your favorite podcast provider to ensure you do not miss an episode. We're on, among others, iTunes, SoundCloud and Spotify.

To learn more about Akin Gump and the firm's work in, and thinking on, health care and on public policy, look for health care and public law and policy on the Experience or Insights & News sections on akingump.com, and take a moment to read Taylor and Julie's bios on akingump.com.

Until next time.