What to know about Medicare drug price negotiation
Moving Medicine

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In this episode of Moving Medicine, Todd Askew, AMA senior vice president of advocacy, presents what physicians need to know about Medicare drug price negotiations for seniors in the U.S. health care system. The topic has ebbed and flowed for many years and has recently been debated again in Congress. Allowing CMS to negotiate drug prices on behalf of its beneficiaries and private plan enrollees would help reduce out-of-pocket spending. Listen in to learn more.

Speakers

- Todd Askew, senior vice president of advocacy, AMA

Host

- Todd Unger, chief experience officer, American Medical Association

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Transcript

Unger: The subject of negotiating Medicare drug prices has ebbed and flowed for many years and has recently been debated again in Congress. Allowing CMS to negotiate drug prices on behalf of its beneficiaries and private plan enrollees would help reduce out-of-pocket spending.
In this episode of Moving Medicine, Todd Askew, AMA senior vice president of advocacy, presents the ins and outs of drug price negotiation in Medicare. This talk was originally given at AMA’s 2022 Annual Meeting.

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**Askew:** Thank you. I appreciate the opportunity to talk a little bit about the drug price negotiation in Medicare and why can't we use the model we see in so many other federal programs, especially the VA, to successfully lower the cost. Mainly, we're talking here about brand-name drugs in the Medicare program.

So just at the start, you're all probably quite familiar with the structure and the statutory barrier to drug price negotiation in the Medicare program. The non-interference clause of the law in 2003 that created the Medicare Part D said explicitly that the federal government cannot interfere in negotiations between the manufacturers and the planned sponsors, and they can't require also any particular formula or price structure for the reimbursement of drugs.

This was a compromised position that the pharmaceutical industry was willing accede to in order to engage with the Medicare program directly. They were concerned about having, let's face it, their largest market for their products suddenly have strong price controls. So, it was a deal with the devil, if you will, in order to pass some sort of drug coverage for individuals.

The structure of the program, of course, you know quite well. Medicare Part D plans and also Medicare Advantage plans, we'll mainly talk about Medicare Part D plans, because that's where most people actually get their drug coverage, compete on themselves. They offer different mixes of coverage, they offer different premiums and cost-sharing structures, and essentially they negotiate themselves as individual plans with manufacturers or through their PBMs with manufacturers and pharmacies to deliver drugs to their beneficiaries.

The disadvantage of that obviously is that you have hundreds, maybe thousands of individual plans doing the negotiation and no single one of them carries anything like the weight that some of the big federal programs do in order to demand better deals, so they kind of start off with a disadvantage from the beginning.

There are also some requirements. Some are helpful, some are hurtful in terms of the price that they're able to get. One is there are six protected classes, therapeutic classes of drugs and the plans essentially have to cover almost every drug with each one of those six classes. So you have this large amount of drugs that the plan has very little leverage to negotiate because they have to cover the drugs and the manufacturers obviously know that.

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An advantage they have is a lot of other programs for Medicaid, there's a particular lowest cost type provision that works against people getting bigger discounts, because the manufacturers will have to give that price to Medicaid. But that doesn't apply to Part D, so manufacturers are able to give lower prices to Medicare Part D plans if they wish without negatively being impacted on the Medicaid side of their business.

So, CBO looks at all these factors and they essentially feel that Medicare Part D plans are generally able to obtain lower costs for prescription drugs than the regular commercial market but as you'll see, they don't do nearly as well as some of the other direct federal purchasers for drugs. This obviously has been an issue with the Medicare Part D program since its inception, and Congress revisits almost annually the question of drug price negotiation.

The Congressional Budget Office has said essentially that if you only gave the secretary the authority to negotiate drugs, they don't think it would really lower prices, because there's no real other leverage since you have to cover so many of the drugs regardless. There would have to be other authorities in addition to just having the authority to negotiate in order to be able to drive prices lower.

There are other federal purchasers that are able to leverage the size of their purchasing power, which is greater than any individual Medicare plan. But as a whole, the Medicare drug spending really dwarfs pretty much any other direct purchaser. So if you gave a lot of authority to the Medicare program, it could negatively impact the deals that these other direct purchasers are able to get because the incentive would be reduced for the plans to negotiate. For instance, give certain prices to Medicaid or other buyers.

Medicaid drugs are actually controlled by a federal rebate statute that limits the increase in drug prices and requires rebates to be paid by the manufacturers for drugs in the Medicaid program. They also are limited in how fast they can grow and then states can use their leverage in their Medicaid programs to directly negotiate with manufacturers and obtain different discounts.

Now Medicaid, initially when this law went into effect, and again, other purchasers had kind of best price agreements, some of the prices went up in some other programs because they didn't want to go too low in Medicaid, because they would have to offer those prices to other purchasers, so they're all kind of interdependent.

There are a number of federal programs that directly purchase drugs from the manufacturers. There's what's known as the big four, okay. That's the VA, the Department of Defense, the Public Health Service and Indian Health Service and the Coast Guard. That's kind of the big four. Then there are other federal direct purchasers, the bureau prisons, immigration, NASA, state department. None of them very large purchasers but the VA kind of negotiates for this federal supply schedule, which is kind of the federal price that the direct purchasers will pay for drugs. The VA negotiates on everybody's behalf.
Manufacturers, basically if you're going to sell your brand-name drugs in one program, you have to be on this federal supply schedule. So, there's an extreme incentive for the manufacturers to negotiate with the VA on behalf of all these other federal purchasers. Then each of these purchasers have other opportunities to lower costs further in what they purchase.

So just looking at the big four, which is again, VA, DOD, Public Health Service and the Coast Guard, there are additional requirements in federal law where there is a federal ceiling price, which is again, very complicated formulas that I'm not going to pretend to have much insight into how they were derived but essentially it creates a maximum price that any of these purchasers that is even below what the other direct purchasers are able to practice. So, it's kind of the best of two or three different categories. Then there are further means where VA and DOD separately are able to purchase drugs at a further reduced cost.

The VA has two big advantages that the Medicare program and other direct purchasers really don't have. One, they have a national formulary. So, it's one single formulary, you're on it or you're off it but you're not independently negotiating with regional VAs or independent hospitals, you're negotiating with the VA, so they have a lot of bargaining power.

The VA also obviously employs its clinicians directly and so, they have direct control over the prescribing habits of many of their providers. In fact, the VA has a very active academic detailing program to help educate providers on cost-effective prescribing within the system. So, they can kind of control not only what drugs are on the formulary but they can control how those drugs and when those drugs are prescribed.

There's also a theory out there that because so many residents train in the VA system, that manufacturers have a further incentive to give deeper discounts to the VA because those residents then learn and train using those particular pharmaceutical products. When they go into private practice or practice somewhere after their training's complete, they're more likely to continue to use those or prescribe those products. So, that's a big incentive.

All those programs mixed together gives us this. These are brand-name drugs we're talking about here. So, 1.0 being the federal supply schedule, Medicaid with the mandatory rebates, they get the best price. VA and DOD, very good, and then you'll see where Medicare Part D is a little bit higher and above the federal supply schedule.

DOD interestingly enough has lower brand name but actually the cost per prescription in the VA is much lower than the DOD because the VA gets much better deals on generic drugs. Again, as I mentioned, they're able to control the prescribing habits or prescribing patterns to a much greater extent than most other folks are.
The disadvantage, of course, that Medicare Part D plans have is what they would kind of say is their selling points. They're going to offer packages and copays and coverages tailored that you can go out and shop and choose which plan you feel might best meet your needs. They're able to do that because there's thousands of them or hundreds of them. There's over 1,000, I think. So, if you went to a national formulary, you have one, right? Every drug plan is pretty much going to look the same and they feel that they wouldn't have the competitive advantage to market different plans to different populations.

So, the underlying fact that Medicare does not employ the physicians, Medicare does not control their prescribing patterns or have any real influence over it and the fact that you have 1,000 different formularies so you don't have very much leverage to negotiate deeper deals with the manufacturers is really kind of the core reason why we can't just take the VA model and move it right over into the Medicare Part D world without considerably disrupting the plans that are available.

Now, some people may think that's a good trade-off, that that's worth doing. That's certainly up to Congress and the pharmaceutical lobby, which is not a big fan of the idea but this is kind of the trade-off and the deal that was made in order to get drug coverage as part of Medicare at all. That is not to say though that there is no hope that we will be able to pass or enact some policies soon that will impact the price of drugs for Medicare beneficiaries in the Part D program.

You'll recall that the Build Back Better Act probably back in December, January, which died an ugly death when Senator Manchin and Senator Sinema decided they didn't like the energy and climate provisions of the legislation and perhaps the pharmaceutical provisions. That was possible because reconciliation instructions. Reconciliation instructions is this magic thing you can get the Senate that allows very specific types of bills to be passed on a partisan 50-vote basis, no filibuster. Democrats, if they could all get on the same page, have 50 votes. So, they could pass something if it's an imperative.

It is a growing imperative now for them for a couple of reasons. One, the reconciliation instructions expire in September. They're gone, you won't be able to use them again. Two, this is one of the top issues still for voters and then one of the top health care issues for voters is the price of prescription drugs, particularly in the Medicare program. The voters, I think they're growing pretty tired of the excuse that we can't do anything, the pharmaceutical lobby is too powerful. I mean, they have 50 votes, they have reconciliation instructions, they have the tools they need to pass something.

I won't get to get too much into the weeds but the Affordable Care Act was expanded during the pandemic so that more folks could have access to care through the Affordable Care Act and premiums were significantly lowered because of some of the additional subsidization. That expires at the end of this calendar year. So January 1, those steep discounts are gone and heavy subsidies of people on the ACA plans. Millions of people took up ACA because of the availability of those subsidies.
So, the people that have ACA coverage, millions and millions and millions of them, in October a week or two before the election are going to get a notice in their mail from their health insurance carrier saying, “Your premiums are going up for 2023.” When I say going up, a family of four making $45,000 a year currently under the subsidized ACA pays about $342 a year for their coverage. Next year, it’ll be $2,200, okay? Over $2,200.

A family of four making $120,000 currently pays for ACA coverage about $10,000 a year for the family and premiums for the entire year, it goes up to over $16,000. With everything else going up, Democrats in the Senate don't want these notices landing in people’s mailboxes a couple of weeks before the election. There’s another terrible problem with Medicaid too that needs to be addressed too but I won't get into that.

But the reconciliation instructions are probably the only vehicle they have to advance a fix to that program and the only way they have to pay for a fix for the ACA subsidies is the provisions that they've already negotiated amongst themselves to lower prescription drug prices in Medicare. So that is the hope that this year and it could happen very quickly, because essentially, I don't have the calendar here but by the first week of August, Congress is done. They’ll come back after the election and fix some stuff but real policymaking is going to give way to pure partisan politics. We’re kind of already there but the real opportunity to pass something is we have weeks, not months and not the rest of the year to address this.

So, you have sitting out there this package of already negotiated Medicare prescription drug policies that have the support. Senator Manchin even said last week that, oh, he supports those things now, we ought to just do that. Now he also said, "If we can't get agreement on climate and energy," which he doesn't want an agreement on, he said, "We should just move on the drug bill." So, this is their opportunity to do it.

Three components of the bill that I think they've already agreed on that you'll probably see, hopefully, will see some action on. One is to lower the cap in Medicare for prescription drugs out of pocket cost to $2,000. Currently, it is 34, 35, it's somewhere up in there. But while that is good in and of itself, just capping it is not really going to lower the price of drugs. The way you lower the price of drugs here is currently in the catastrophic phase, the federal government picks up 85% of the cost of the drugs. The plans themselves have very little incentive to negotiate lower costs for really expensive drugs because the federal government's going to pay for it anyway.

Under this proposal, that flips and the plans themselves become liable for the cost of prescription drugs in that catastrophic phase, or not all of it, but a vast majority of it. So, that's an incredible incentive for plans to start in their PBMs to get tougher and negotiate better deals with the manufacturers and the pharmacies because right now they have no real incentive to do that.
Also, this provision I mentioned in the Medicaid program, the limiting the increases in cost on drugs above the rate of inflation, which has proven very successful in the Medicaid program. You saw how much lower the prices were in the Medicaid program because over time the lack of big increases really kind of starts to compound. So, having provisions like that in the Medicare program to rebate back to the federal government spending in excess of inflationary increases in prescription drugs is the second element of that legislative package.

The third element of that legislative package is prescription drug negotiation, direct negotiation. Now the longer they negotiate on this provision, the narrower and narrower and narrower it gets. I think this is actually probably a pretty weak ... I haven't seen the CBO, the Congressional Budget Office, say how much they think this will really save but you're limited to only a handful of drugs being negotiated each year.

It's only after the exclusivity periods expire for both the small molecule drugs and the biologics. So, it's not the new drugs that are coming online that are really expensive, it's after those exclusivity periods exist. So, there is some expectation that you see some discounts pretty steep on some drugs, but of course, the number of drugs that they've negotiated down to get agreement on is fairly limited.

But it is something, it is a beginning, it is a model that they can see if it works in Medicare, if Medicare is actually able to negotiate this, again, without the advantages of having a formulary or other sanctions. Basically, if they don't do this, the penalty is very high excise taxes on their drugs. Which isn't going to lower the cost of it but it's certainly a disincentive for the plans not to negotiate. We will see. I would think of this provision as an experiment to see whether or not they are going to be able to negotiate.

Is this going to pass? I have no idea. They have every incentive to get this done and to get it done in the next couple of months but I'm never going to go broke betting on inaction from Congress. So, we'll give it a shot and hope for the best but this is I think the best chance we've had in a long time to get some lower drug prices in the Medicare program.

So, I hope that you will all take advantage of the time to call your member of Congress and to write your senators and insist that they get this done this year.

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