Center for Medicare and Medicaid Services
National Stakeholder Call with the CMS Administrator about the New Medicare Drug Price Negotiation Program
September 7, 2023
3:15 PM–3:45 PM ET

Webinar recording: https://cms.zoomgov.com/rec/play/x-Y88NTEzFdhWknvqbYfE-bu4P3Sjy0UNAHYvKCu2kTPX8wheKS1B5HqfvLamPO27kSNqnK-l8PUvcOl.532PsCsnRCpUCNWp

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Eden Tesfaye: Thank you all for joining. We are going to give it a couple moments to get started so we can let everybody out of the waiting room.

We are going to go ahead and get started here. Thank you all so much for joining. And welcome to the hundreds of folks on the call today. My name is Eden Tesfaye, and I am an Advisor to our CMS Administrator here at the Centers for Medicare and Medicaid Services. Thank you for joining our National Stakeholder Call on the Inflation Reduction Act and the 10 drugs that we recently announced as a part of our first round of negotiations.

I'm going to walk through today's agenda and then turn it over to our speakers. But before I do that, I have a few housekeeping items.

This call is being recorded. Within a week we will be posting the recording and transcript to our CMS National Stakeholder Call site. Please see the link in the chat.

While members of the press are welcome to attend the call, please note any press or media inquiries should be submitted using our media inquiries form, which may be found at CMS.gov/newsroom/media-inquiries.

We will be accepting live questions during the call, and we invite you to place your questions in the Q&A box on your screen. Now we might not be able to get to all of your questions today, but we will do our best to give you guys individual answers. Please know we find them invaluable as we try to refine policies and communication materials.

You can find more information on the Inflation Reduction Act at the Medicare website, which we will put in the chat box for you.

Everyone should be able to see today's agenda on their screen. We have a jam-packed agenda that includes CMS Administrator Chiquita Brooks-LaSure and Dr. Meena Seshamani, Deputy Administrator; and the Director for the Center of Medicare who will be providing an update on the recent announcements on the first 10 drugs selected for the Medicare Drug Price Negotiation Program. We will also hear details from Lara Strawbridge from the Center for Medicare. I will then moderate a session with Dr. Seshamani and Ms. Strawbridge, who will take your questions.

And with that, it is my honor to turn it over to our leader, Administrator Chiquita Brooks-LaSure. Administrator, over to you.

Chiquita Brooks-LaSure: Thank you so much, Eden. Let me say good afternoon, or good morning if you are all the way on the West time zones. Thank so much for joining us today. Announcing the list of the first drugs that have been selected for Medicare price negotiation is another incredible milestone in the Biden-Harris administration's work to lower prescription drug costs.

Since day one, this administration has made it clear that making health care more accessible and affordable is a top priority—a promise to the American people.

Through the Inflation Reduction Act, President Biden is making that promise a reality. The question that I get asked most often as CMS Administrator from people is why their prescription drugs are so expensive. Last year, I had a really meaningful conversation with a couple who live in North Carolina and who had out-of-pocket drug costs of over $18,000 a year, which meant that the wife was unable to retire.

But now, this landmark law is already lowering drug costs for millions of Americans with Medicare through free recommended vaccines and caps on insulin costs, making insurance coverage more affordable and helping the economy work for working families.

Thanks to the Inflation Reduction Act, for the very first time in history, drug companies cannot hike their prices faster than inflation without having to pay a rebate to Medicare. Out-of-pocket drug costs will be capped in Medicare, which will be life-changing to so many, like the couple I just mentioned in North Carolina.

And Medicare now has the authority to directly negotiate lower drug prices. It is no exaggeration to say that allowing Medicare to directly negotiate the prices of covered drugs is helping to change the system for the better. Negotiation will improve access to life-saving drugs by making those drugs more affordable, helping to get medications into the hands of those who need it by ensuring that the price does not keep it out of reach. And it will help ensure lower costs for Medicare and strengthen the program for current and future generations.

In selecting the first 10 drugs, CMS followed the criteria set by Congress in the law. Any agreed-upon prices that result from this process will become effective in 2026. The selected drugs account for $50 billion, or about 20% of total Part D gross Medicare savings—excuse me—spending.

Over 8 million people with Medicare prescription drug coverage use these 10 drugs. This is your mother with arthritis, your father with diabetes, your great aunt with Crohn's disease. Those seniors and other people with Medicare spent over $3.4 billion last year out of their own pocket on the 10 drugs selected for negotiation. To put that in perspective, that would be enough money to pay the average rent for over 166,000 Americans for an entire year. It is more people than live in Paterson, New Jersey; Gainesville, Florida; or Pasadena, California.

Another way to think about these numbers—just one of these drugs costs seniors as much as $6,500 in out-of-pocket costs per year. That could cover an entire year's worth of car payments. And people with Medicare prescription drug coverage will have peace of mind next year when their out-of-pocket drug costs begin to be capped through other provisions in the Inflation Reduction Act.

Of course, drug companies need to sit down at the table with us for the law's promise to be realized. The process is entirely voluntary. We are hopeful that drug companies will come to the table and negotiate with us to make this a reality for the American people. This is a significant moment. Our negotiations will be a good-faith effort to achieve fair prices on behalf of people with Medicare, and our goals are to increase access to some of the most expensive drugs, while driving competition and advancing innovation.

Thanks to the ability to negotiate drug prices, CMS is now better equipped to protect the health of people with Medicare by ensuring they can afford the prescription drugs they need. No one should have to choose between putting food on the table and paying for their prescription drugs.

The Inflation Reduction Act is making a real difference in the lives of so many people, particularly those who take some of the most expensive drugs. And it has ripple effects. Millions of family members and others who care for someone with Medicare will see the impact of negotiation with improved access to innovative, life-saving treatments.

As always, your partnership is essential to our success. I believe strongly that the voices of the people we serve make our program stronger. We are committing to listening to you as well as to keeping you up to date on our efforts as we work to implement the landmark reforms of the new law.

Thank you all for your incredible efforts. And I will now turn the call over to Deputy Administrator and Director of the Center for Medicare, Dr. Meena Seshamani.

Dr. Meena Seshamani: Thank you very much, Administrator, and thanks to all of you for being here with us today. I am Dr. Meena Seshamani, Director of the Center for Medicare. At CMS we are hard at work implementing the new prescription drug law and improving access to drugs for the people that need them. One way in which we are doing that is through the Medicare Drug Price Negotiation Program. Now as the Administrator mentioned, the benefits to consumers and patients for Medicare's new ability to negotiate drug prices are enormous. As a result of negotiation, people with Medicare will have greater access to innovative, life-saving treatments at lower costs to Medicare.

Alongside other provisions in the law that make health care and prescription drugs more affordable, negotiation strengthens Medicare's ability to serve people with Medicare now and for generations to come.

That is why I am pleased that CMS, just last week, was able to announce the first 10 drugs covered under Medicare Part D selected for negotiation. The law specifies that these negotiations with participating drug companies will occur in 2023 and 2024, and any negotiated prices will

become effective beginning in 2026. We are hopeful drug companies will come to the table and negotiate with us to make this a reality for the American people.

We are also excited to share details that CMS intends to host a series of patient-focused listening sessions this fall. The 10 virtual public listening sessions will provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties to share input relevant to drugs selected for the first round of negotiations and their therapeutic alternatives.

We hope that all of you will join us in sharing this information with your members and your networks. And more information is available on CMS.gov.

At the end of the day, CMS, drug companies, patients, providers, advocates, and others—we all have the same goals: we want to ensure access to the innovative treatments and therapies people need, when they need them.

But also, let me remind you: the law is more than negotiation. Provisions, including the $35 insulin co-pay cap and $0 vaccines, expansion of the Extra Help Program, and the $2,000 out-of-pocket cap in 2025—they will all be game changing and life changing. And some of them are already impacting millions of people across this country.

We look forward to continuing to work with all interested parties to implement this historic program and law. And now I will turn it over to Lara Strawbridge, Deputy Director for Policy, in the Medicare Drug Rebate and Negotiation Group, Center for Medicare, to walk through some of the details with the negotiation process and the patient-centered listening sessions I mentioned. Lara?

Lara Strawbridge: Thanks so much, Dr. Seshamani. I am Lara Strawbridge, Deputy Director for Policy of the new group in the Center for Medicare that's focused on the new Medicare Inflation Rebate and also Drug Pricing Negotiation Programs.

In January of this year, we issued a timeline that highlighted not only the process but also policy milestones and engagement opportunities for the first cycle of negotiation. We also this spring issued initial guidance and comment opportunities, as well as numerous information collection requests, and subsequently in June, we issued revised guidance providing ample notice for interested parties to engage with us in the negotiation policy and process.

Implementing the criteria set by Congress for the drug selection process, we started with nearly 7,500 drugs covered under Part D in Medicare, and then we applied the statutory criteria to determine the final selected drug list.

The 10 selected drugs for this first cycle of negotiation meet the criteria set out in the Inflation Reduction Act, including that they are some of the most costly drugs to the Medicare program. For the time period between June 1 of 2022 and May 31 of 2023, which is the time period we used to determine which drugs were eligible for negotiation, approximately 8.2 million people

with Medicare Part D coverage used these drugs to treat a variety of conditions, as the Administrator noted. This accounts for nearly 17% of people with Medicare Part D coverage.

Among the selected drugs, seven of the 10 are approved by the Food and Drug Administration for chronic cardiovascular and metabolic diseases, including stroke, heart failure, diabetes, and chronic kidney disease, that are very common in the Medicare population. Among these drugs are ones which have been shown to reduce the risk of stroke, hospitalization, and cardiovascular death and to improve blood sugar control. Two of the 10 selected drugs are injectable biologics indicated for chronic autoimmune conditions, including rheumatoid arthritis and inflammatory bowel disease. These drugs have been shown to reduce serious symptoms from these autoimmune conditions. Finally, one of the 10 drugs is indicated for certain forms of blood cancer or leukemia, and it was shown to increase overall survival for these patients.

Just to run down the list of the 10 drugs themselves in alphabetical order, they are: Eliquis, Enbrel, Entresto, Farxiga, Imbruvica, Januvia, Jardiance, an insulin drug named Fiasp—also called Fiasp FlexTouch or Fiasp PenFill—NovoLog, NovoLog FlexPen, and NovoLog PenFill. Continuing on the list, we also have Stelara and Xarelto. These selected drugs accounted for approximately $50 billion in total Part D gross covered prescription drug costs, which is about 20% of total Part D gross covered prescription drug costs during that time period.

So, as we begin negotiating with participating drug companies in the weeks and months ahead, CMS is providing opportunities for public engagement about these drugs and their therapeutic alternatives during the negotiation process. These include meetings with participating drug companies, with a selected drug in the fall of this year, as well as—as Dr. Seshamani mentioned, a planned, CMS-hosted, patient-focused listening session for each selected drug.

The listening sessions will be open to the public and will provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and any other interested party to share patient-focused input on therapeutic alternatives and the selected drugs themselves, how the selected drugs address unmet medical need, and the impact of selected drugs on specific populations.

The listening sessions are currently planned to be held between October 30 and November 15 of this year, and registration to apply to be a speaker is open now and it will close on October 2, 2023—so, in less than one month's time. We encourage folks to register to be a speaker now if they are interested.

In addition, and separately, members of the public are also invited to submit data to us on the selected drugs and therapeutic alternatives, as well as, again, data related to unmet medical need and impacts on specific populations. Again, these data are due to us by October 2 of this year.

After we have received all of these data and heard from folks during listening sessions, we will be negotiating with participating drug companies through offer exchanges and meetings, and the negotiations will end by August 1 of next year. The negotiated maximum fair prices of the selected drugs for those participating drug companies will be published by September 1 of next year, and prices will become effective in January of 2026.

We're looking forward to continuing to work with all interested parties to implement the Medicare Drug Price Negotiation Program and the IRA more generally.

I can see that we already have a number of questions that have been coming in to us, so I will be turning things over now to Eden Tesfaye for Q&A. Thank you so much.

Eden Tesfaye: Thank you, Lara. And now we will turn to our Q&A section of this program. With that, Dr. Seshamani, my first question is for you. How will patients directly benefit from negotiated MFPs, versus any resulting discounts going to the Medicare program?

Dr. Meena Seshamani: Thank you for that question. This is a historic time for Medicare to be able to negotiate with our goal of getting to agreement on what is a fair price for a drug which benefits both people in the Medicare program and the Medicare program and American taxpayers, and importantly, as part of this negotiation, really having a conversation about how these drugs benefit people—being able to think about—these drugs have been on the market for seven years, 11 years, or longer. How did they actually work in the real world? When people are taking these medications in their communities to try to keep themselves healthy. So, that we can further innovation in those ways that people need to keep themselves healthy. I think in all of those ways, negotiation really will benefit the people who are on Medicare and the broader population.

Eden Tesfaye: Thank you, Dr. Seshamani. My next question is also for you. If CMS determines that a drug will face generic/biosimiliar competition before 2026, will that drug be replaced?

Dr. Meena Seshamani: That's also a great question. We will be regularly monitoring the competition for all of the drugs, and if there is a drug that we have selected in this 10 that turns out to, in fact, have competition, then it will not have negotiation apply to them, and we laid out those parameters in our guidance, depending on the timing of when competition emerges. But that drug would not be replaced on the selection list with a different drug at that point.

Eden Tesfaye: Got it. Thank you so much, Dr. Seshamani. Lara, this next question is for you. Are only patients going to be selected to speak, or will other individuals, such as health care providers, also be eligible to be chosen? As a follow-up to that, will the list of speakers for each listening session be made public ahead of time?

Lara Strawbridge: Those are both great questions. Thanks so much. To the first question, in terms of who is potentially eligible to be a speaker at the patient-focused listening sessions, any member of the public. Any interested party is eligible to submit to potentially be a speaker, and then we will be randomly selecting speakers from those who are interested in participating in the listening sessions. We encourage anyone who is interested to submit a request. I will flag, again—to the extent that you want to make sure your voice is heard, and you are not sure if you will be selected or not, you should also submit a written submission to us as well, which we are happy to accept. And as I mentioned, we are accepting written feedback from folks through October 2 of this year. And you can find that information on our Inflation Reduction Act website

as well. In terms of posting speakers ahead of time, that is not something we are currently planning to do.

Eden Tesfaye: Thank you, Lara. Our next question is—I think either Dr. Seshamani or Lara could take this—will Medicare seek to negotiate the price on other drugs in the future? Will the currently selected drugs remain at their negotiated rate indefinitely?

Dr. Meena Seshamani: Thanks. I can start, and Lara, maybe you can fill in. As written in the new drug law, we start with 10 drugs this year. Next year we will select 15 drugs from the Part D Prescription Drug Program, and then we move into B or D, and then we move to 20. So, each year we are negotiating other drugs and the number of drugs increases. Also laid out in the law, and further discussed in our guidance, we provide information on when a negotiated price no longer holds. For example, when competition comes about, etc. So there are provisions in the law that mean that a price does not hold indefinitely. There are various scenarios in which it does not that's in the law and in our guidance. And, Lara, I don't know if you want to add anything there.

Lara Strawbridge: No, I think that is great.

Eden Tesfaye: Thank you both. Our next question—I think, Lara, this can go to you, and Dr. Seshamani, please jump in if you like. How can we be assured pharmaceutical companies will not recoup lost revenue by charging even more for drugs to the non-Medicare beneficiaries?

Lara Strawbridge: I will start, and Dr. Seshamani should definitely chime in here that the provisions of the law we are implementing are specific to Medicare and the guidance we are working to implement now are specific to Medicare prices.

Dr. Meena Seshamani: And, I would add two things. Number one, right now the commercial market has forces at play around what prices are. There is negotiation happening between health plans and, you know, pharmaceutical companies, and that will certainly continue. Number two, in the inflation rebate—as you may recall, the Administrator mentioned that there is this provision of the inflation rebate where if prices increase faster than inflation, then a rebate is owed—commercial prices are taken into consideration in determining if the overall price is higher than what would have been expected with inflation. So, there is that trigger that could get hit that would discourage increases in prices as well.

And I think the third thing that I would say is, a lot of the work we are doing in this negotiation process—the data we are seeking to collect, the back-and-forth negotiation—are things that we will publish in a narrative on how we came to this agreed-upon fair price. And we will also be publishing those maximum fair prices. And that is information that anybody could use as they want. Again, to echo what Lara said, where we have the authority in the law is with Medicare program and Medicare population, but there is a benefit to the added transparency and information and data and conversations that will be brought through this process that extend beyond just the Medicare population.

Eden Tesfaye: Thank you so much, Dr. Seshamani. I think this is going to have to be our last question, given that we are almost at time. Will there be publicly available summaries of the patient-focused listening sessions, as well as key things that CMS will consider as a result of the listening sessions, moving forward?

Lara Strawbridge: That's a great question. I can start with this one. I will say we are planning to live stream the patient-focused listening sessions so anyone that would like to follow along, even if you do not register to speak, you are welcome to do that.

We are aware that folks will be very interested to hear what is learned from those listening sessions, and I will just flag in our revised guidance that I mentioned that we put out this June, we described that we plan to post an explanation of the maximum fare price that we negotiate with participating drug companies. When we post that explanation, we also plan to provide additional information to the public about different pieces of information that we have received over the course of the negotiation process, which includes data that might be submitted to us in written form, now through October 2, and would potentially also include some artifacts from the listening sessions as well. And to the extent folks are interested in receiving something like a summary of a patient-focused listening session sooner, we'd be curious to hear about how that might be helpful to you, and we can certainly consider whether that is feasible.

Eden Tesfaye: Dr. Seshamani and Lara, thank you so much. Really appreciate you all. I want to close with my sincere thanks for you all who joined us today taking time from your busy schedules. We are committed here at CMS to keeping a dialogue open and being a great partner as we advance the limitation of new prescription drug law and our collective mission of bettering the health for all peoples.

With that, we are going to go ahead and end the session. Thanks again and I hope you have a wonderful rest of your day.