JASON PETROSKI: Hi everyone and welcome to the Part D Senior Savings Model Calendar Year 2023 overview and application webinar. My name is Jason Petroski and I'll be doing the introduction today for today's webinar and thank you, everybody for joining us. I know this is a very busy time for everyone and really just want to thank everybody at the beginning, here, for your time today and just joining us for this introduction to the Model and what we’re doing and CY 2023. Next slide please.

JASON PETROSKI: So just before we get started, I wanted to put out a disclaimer here. Really the gist of this slide and our disclaimer is that our goal today here are mainly for educational purposes and general information sharing, as noted on this slide. Next slide please.

JASON PETROSKI: In this slide, I just wanted to generally introduce the team today that you'll be hearing from. As I mentioned my name is Jason Petroski and I’m a director in the Innovation Center. My area’s responsible for health plan innovation Models, including the Part D work and the Part D Senior Savings Model. You'll also hear from a number of our PDSS Model team members that are listed here today on this slide. I also wanted to recognize that our Deputy Director of the Seamless Care Models Group, which is the group that oversees all of this work as well, our Deputy Director Laurie McWright is also on the call to assist. Next slide please.

JASON PETROSKI: Just to get started with what we'll be covering today- our agenda really starts with an overview of the Calendar Year 2023 Part D Senior Savings Model, or the PDSS Model, and its design. We’ll then get into some specifics and just have some high points around the Model application process and what Part D sponsors and folks need to know about applying to the Model for CY 2023 and then we’re going to wrap things up at the end with a Q and A or a question answer period. So if you feel like questions are coming up along the presentation, please put them in the chat will collate or collect those questions and try to answer as many of them, as we can, at the last part of the presentation. Next slide.

JASON PETROSKI: Okay, so I think what we’re going to start with here is the calendar year 2023 Agenda and with that piece or with this part of the presentation, I’ll turn it over to Trudel Pare. Trudel?

TRUDEL PARE: Thanks Jason.

TRUDEL PARE: Alright. So first just to level set, the Part D benefit includes the deductible, the initial coverage phase, the coverage gap phase, and the catastrophic phase under the defined standard Part D benefit. So when the beneficiary is in the coverage gap phase, manufacturers generally, outside the Model, pay a 70% discount on the negotiated price for their drugs, and beneficiaries pay 25%, and then plans are liable for the remaining 5%. Also in today's benefit, Part D sponsors through their enhanced alternative plans may offer supplemental benefits in any benefit phase. There is one additional piece, and that's really what you see on the screen here, which is the special rule for supplemental benefits in the coverage gap. The coverage gap phase of the benefit was designed based on the Manufacturer Coverage Gap Discount Program. So if a plan chooses to offer supplemental benefits for an applicable drug, the plan becomes liable for the entire amount- from the negotiated price of the applicable drugs, to whatever copay they've set. And then, after that the manufacturer will cover 70% of what's left and then the beneficiary pays the remainder. So that structure really provides a strong financial disincentive to plans designing Part D benefits that provide supplemental benefits in the gap for applicable drugs,
one of which is insulin. That means that, outside the Model, beneficiaries are generally left paying a 25% co-insurance through the coverage gap for those drugs.

TRUDEL PARE: And so, put simply, the Model waives the operational special rule for supplemental benefits for insulin, which allows participating insulin manufacturers to buy down their portion of the Part D coverage gap first, and then allows Part D plans participating in the Model to offer a supplemental benefit with a stable, predictable beneficiary copay no greater than $35 from the deductible through the coverage gap for a month’s supply of certain insulins. This is a five-year model that began in January 2021 and not only offers affordable insulin but also allows Part D sponsors to offer Part D Rewards and Incentives for beneficiaries with diabetes and pre-diabetes, as part of programs that incentivize health and promote medication adherence. And we'll talk about those programs a little bit later.

TRUDEL PARE: Okay. So you can see here a comparison of insulin costs for beneficiaries in the Part D Program outside the Model on the left side of the slide, and then, versus sort of what's possible as a result of the Model on the right side. For enhanced alternative drug plans participating in the Model, the maximum out of pocket costs for a month's supply of insulin drugs covered by the Model is $35 throughout the first three phases of the benefit. That is a substantial difference, as you can see, comparing both sides of that slide. Now I will pass it over to Judy, who will be giving an overview of the Model’s technical specifications. Judy?

JUDITH GEISLER: Great thanks Trudel. I'd now like to take a few minutes to discuss the information here on slide nine and some of the questions that we've received on the Model. So we've received a few questions about how the beneficiary moves through the deductible and the initial coverage phases of the Part D benefit, which is based on the total drug costs accumulated. We did release a memo back in May of 2020 that has additional information on the deductible and initial coverage phases so I'd encourage you to review that memo which can be found on the Model website for additional information on those questions.

The Model benefits do offer flexibility to have different cost sharing at preferred and non-preferred pharmacies, and retail and mail locations. However, at all the pharmacy locations, the enrollee should pay no more than the maximum $35 for a month’s supply of the plan selected Model drugs.

We've also received questions on the one month or a 30 day equivalent supply and to answer this question, the intent of the Model is to follow the plan definition, consistent with the current program regulations and guidance of a one month or a 30 day equivalent supply that's provided in the plan benefit package. For the maximum $35 copay, Part D sponsors have flexibility to offer a lower copay for one or more of the plan selected Model drugs below $35. For example, a lower cost share could be offered for different insulin products, different types of insulins, and or different forms of insulin. And we do encourage sponsors to consider offering lower copays on Model insulins. One thing I did want to note here is, if you want to offer a lower cost share than the Model maximum of $35, that same cost share must be offered in all three phases, consistent through the deductible, initial coverage phase, and the gap coverage phase.

The list of Model drugs for 2023 is posted and available on the Model website so I’d encourage you to take a look at that.
For tier placement of Model drugs, Part D sponsors may include insulin on any formulary tier that's consistent with current program regulations and guidance, including formulary design. The cost sharing for the formulary tier or tiers that contain Model insulin products must be greater than or equal to the cost sharing of Model insulin.

And finally, on this slide as we've noted in a previous slide, LIS enrollees are not eligible for the Model as they already have fixed cost sharing, which is, in many cases, lower than the model’s cost sharing and I would note here that this does include LIS 4 enrollees. Next slide please.

**JUDITH GEISLER:** Now we'll talk a little bit about Part D sponsor eligibility and requirements to participate in the Model. First, I would note that only enhanced alternative plan benefit packages are eligible to participate, this includes both PDP and MA-PD plan types. Chronic condition and institutional special needs plans may also join, but dual eligible special needs plans are not eligible to join. Employer plans are also not eligible to join the Model.

All plans participating must include at least one vial dosage form at U-100 concentration and one pen dosage form at U-100 concentration for each of the different types of Model insulins that are available, which includes the rapid-acting, short-acting, intermediate-acting, and long-acting. And these must be covered at a maximum of $35 copay for a month’s supply, through the deductible, initial coverage, and coverage gap phases of the benefit.

Please note that the catastrophic phase is not included in the Model design and therefore plans are not required offer Model cost sharing in that benefit phase. And while plans specifically have to meet the requirements I just discussed, we encourage Part D sponsors to consider the same level of coverage for all Model insulins offered on the formulary to provide a consistent coverage for enrollees. Next slide please.

**JUDITH GEISLER:** Additionally, through this Model we are testing Part D Rewards and Incentives programs, so wanted to talk about those for a few minutes. The goals of the rewards and incentives program is, in connection with Model-specific medication use, to promote improved health outcomes, medication adherence, and efficient use of healthcare resources. The programs may be designed to target enrollees with pre-diabetes or diabetes, to participate in a disease state management programs specific for pre-diabetes or diabetes. They can be combined with the Part D sponsor’s Medication Therapy Management program. And we encourage Part D sponsors to consider programs that include comprehensive reviews of enrollees’ medications and preventative health services, such as receiving Part D vaccines and programs that encourage enrollee engagement, to gain a better understanding of their Part D plan benefit costs and clinically appropriate coverage alternatives. Please also note that plan sponsors may offer more than one Rewards and Incentives program through the different Models. So both the VBID and the Part D Senior Savings Model, with an aggregate cap of $600 per enrollee per plan year and there is additional information in the Request for Applications located on the Model website, if you need additional details. And we have also provided additional details on rewards and incentives within the Model application this year.

**JUDITH GEISLER:** And now I’d like to turn the presentation over to Abigale to talk in a little more detail about the application process for the Model.
ABIGALE SANFT: Thank you Judy. So this slide provides an overview of the application process for the Model. The first step is really the manufacturer application process, and we already have completed that step, and Eli Lilly, Novo Nordisk, Sanofi, Mannkind, and Mylan will be continuing their participation in the Model for 2023. So a list of model drugs is available on the PDSS Model web page.

So the next step in the process is for Part D sponsors to apply to participate in the Model. There is no notice of intent this year, so Part D sponsors first have to submit an application by April 8 at 11:59pm Pacific. And there are two parts to a complete application- first, Part D sponsors must complete an application online through Qualtrics, which is linked on the Model web page and on a slide which we’ll show shortly, and then secondly, complete an excel template that is linked in the application, as well as linked on the Model website. This template should be completed and then emailed to the Part D Senior Savings mailbox at PartDSavingsModel@cms.hhs.gov.

This process is also summarized in the HPMS memo we released last week, entitled, “Part D Senior Savings Model Pharmaceutical Manufacturer Participation and Part D Sponsor Request for Applications (RFA) for 2023,” which you can also find on the Model web page.

The second part of the application process is submitting a bid that is aligned with the Part D sponsor’s provisionally approved application. So this is due this year by June 6 and the supplemental text file for the PDSS Model is due by June 10.

ABIGALE SANFT: Okay. As I mentioned, all applications, including a completed excel template and online Qualtrics application, are due on April 8th. Each application should be submitted for one parent organization, and this should be based on the parent organization, not the contract name for your contracts, which is listed in HPMS. If you are submitting on behalf of a set of contracts that have two different parent organizations listed, we would expect two different applications- two excel templates, and two online Qualtrics submissions. However, if you have the same parent organization, even if you have separate operational setups for different contracts, we ask that you coordinate submit one joint application for your entire parent organization.

This year we're asking for you to submit your parent organization ID as well as your parent organization name. This parent organization ID can be found in the Contract Information Extract [in HPMS]. If you do not have access to this extract you can email us and we can provide you with directions to gain access. This is really important, so please check if you have access to this parent organization ID now, because you may need to request access to the extract in HPMS if you need it, and it’s better to request it early.

Some organizations may not have this parent organization ID yet, especially new organizations. If you don't have access to this parent organization ID, you can submit the application with ‘000’ as a placeholder and we can work with you to confirm the parent organization ID after you submit your application.

As Judy mentioned, we have provided additional detail on Rewards and Incentives that we hope is helpful as you're designing and submitting your Part D RI proposals for the Model. We encourage you to take a look at this either on the online application or using our application PDF linked on Qualtrics as you’re developing your program to ensure you are in alignment with the guidance that we offer there.
One additional thing to note, while we only have one excel template this year, it does have three tabs, so all of those should be completed with the correct information and submitted to the Part D Senior Savings Model mailbox.

ABIGALE SANFT: And here, you can see the resources we’ve been mentioning that provide further details on the Model and applications. First, the Model website, which includes links to all the materials that follow, then the application materials- the RFA, our most recent HPMS memo, and the application. This is a link to the Qualtrics application, but at this link, you can find both a PDF of the online application questions on Qualtrics, and a link to the excel template, and we have also included here the most updated fact sheet, so you can learn more about the Model.

We have also included a link to register for the VBID Model webinar tomorrow. There’s also an office hour session for VBID that will be held on April 5, 2022 from 3 to 4pm Eastern time, to offer attendees an opportunity to ask questions related to the VBID Model, the hospice benefit component, and the Model application process. Registration for that as well as for the webinar tomorrow, can be found on the VBID website, which we will put in the chat.

Included on this slide are also the key dates that we’ve mentioned. So Part D sponsors that apply and are approved to participate, will receive a provisional approval in May, and a final approval prior to contract signature. The full application and bid cycle process is anticipated to be complete with Part D sponsor participants and CMS signing a PDSS Model contract addendum in the early fall. Now I'll turn back to Jason to get us started on Q and A.

JASON PETROSKI: Okay, thanks a lot Abigale, and thanks for the plug on our Value Based Insurance Design webinar tomorrow at 3pm. I would encourage anyone that is interested or would like more information about that project or that Model to please join. So we’re just gonna- we’re at the point where we’re going to take questions and answers. If folks could just give us a second to compile some of the questions will be back with some responses, hopefully, another minute or so, so please hold.

JASON PETROSKI: Okay, so we have we have received a number of questions and we’re going to go ahead and get started here with the question and answer portion of the webinar. And I think I’ll start things off with a question for Judy. Judy, the question that we got is a question we often get, which is when will the slides from this presentation be available? I think this was also posted in the in the chat or the Q and A, but can you comment on that one.

JUDITH GEISLER: Thanks Jason yes, just to let everyone know, the slides, the transcript, and the audio recording of the webinar will be posted to the Model web page for download approximately week after the webinar today.

JASON PETROSKI: Okay, thanks Judy and here's another one, Judy, that you might be able to help with. So my organization is applying to offer a new Part D plan and would like to include the new plan in the Part D Senior Savings Model, how should I submit the PBP number (or the plan benefit package number), if my PBP number isn't set up yet? Judy, can you can you help with that one?

JUDITH GEISLER: Thanks Jason. Yeah, this is a question we received- so for new plans, you can still apply to participate in the Model. For the plan benefit package numbers that are not yet determined, you may use a placeholder ID. The placeholder ID does need to be three characters and, similar to the plan number, it can include both characters or numbers. And if you have multiple new plans, please do use a
different placeholder ID to differentiate between the different plan numbers. For example, you could use PA1 or PA2 and then, once the PBP numbers are set up in HPMS you would need to update your calendar year 2023 excel template to the application and send that to the Part D Senior Savings Model mailbox as an update to your application.

JASON PETROSKI: Thanks for that response, Judy. Looks like we have another question relevant to the application and filling out the information requested. This one, I think I'm going to ask Trudel if you can help out with. So the question is, I don't know where to locate my Parent Org ID. Where can I find it in HPMS? Can you take that one?

TRUDEL PARE: Sure, thanks Jason. Okay, so to locate this information in HPMS, you would first log into HPMS, and then access the Data Extract Facility, and you would click on the Contract Information Extract. If you don't see this extract available it's likely that you don't have access and then you should email the HPMS user access mailbox, or you know, you can email us directly at PartDSavingsModel@cms.hhs.gov to ask for access to the Contract Information Extract. We require this on the application as it helps us uniquely identify your organization and link you to your organization in HPMS. Even if you haven't started on your application yet, you may want to check in to see if you have access to the Contract Information Extract in HPMS so you can request it, if needed. And please remember that you can submit your application with a placeholder for this field, if needed, and we can work with you to confirm your parent organization ID after you submit.

JASON PETROSKI: Thanks a lot Trudel. Okay, so I think we're seeing some questions, a couple of questions about MCG group, so I think I'm going to turn back to Judy for this one. Judy can you explain what is an MCG group and how do applicants to know what number to assign for this this identifier?

JUDITH GEISLER: Thanks Jason. So that MCG group is a Model coverage group and it's the number that's assigned to this specific list of RXCUIs that the Part D sponsor is proposing for their plan selected Model drug coverage, so plans that are submitting multiple contracts and plan IDs that will share the same list of RXCUIs can use this group number to attach to the list. For example, if you have two contracts and want to offer the same list of RXCUIs for four plans within those contracts, then you could assign an MCG group of one and then use that to link the two contracts and those four associated plan numbers on both the CY 2023 PDSS plan info worksheet in the excel template, and then you would provide one list of RXCUIs associated with that MCG group of one on the drug coverage worksheet within the template.

JASON PETROSKI: Okay, thanks, a lot for that explanation and walk through Judy. Let's see- give us another second here to just compile another set of- or another list of questions and we'll be back in momentarily.

JASON PETROSKI: Okay here's the question Trudel, do you mind helping with this one? The question is, when will applicants receive provisional approvals?

TRUDEL PARE: Thanks, Jason. Sure. So we are aiming to get provisional approvals to applicants in early May so that's when you can expect to hear from us about that.

JASON PETROSKI: Okay, and then I'm going to jump in here with a follow on question, we received a question about whether applications are binding. The actual application itself is not binding, but we do require that Part D sponsors that are applying to the Model receive provisional approval prior to the bid-
the bid is the piece and is the related aspect tying the Model to the actual program that is binding, so specifically again- is the application binding, it's not. Plans can withdraw before the June bid deadline.

JASON PETROSKI: Okay let's see what other questions we have here. Trudel, I have another one for you. Where can I locate a copy of the application questions for the online portion of the application?

TRUDEL PARE: Ok, so a PDF of the application questions is available on the Qualtrics online application, so if you go to the link that we had on our slide, which you know we can show again, which is just to the sort of main starting page of the Qualtrics application- on the first page there, there's a link to a 508 compliant PDF of the application questions, and the other information included in the application that you can review as you're developing your Model benefits and structure.

JASON PETROSKI: Okay, thanks for that Trudel. And I'm going to come back with another one, because I think this was one of the slides that you presented, where it shows the average out of pocket costs or copay for insulin outside of the Model versus in the Model. There was a question about whether the $35 cap in the Model applies to the catastrophic phase. Can you clarify that question?

TRUDEL PARE: Thanks, Jason. Sure. So the Model does not extend to the catastrophic phase. So I'm happy to share that slide again in case that would help. I think that's this one. So, as you can see here, you know what we put here for the catastrophic phase is sort of a general estimate, but the Model itself does not extend into the catastrophic phase and Part D sponsors participating in the Model, do not have to, you know, apply supplemental benefits in that phase.

JASON PETROSKI: Okay, thanks a lot for clarifying that Trudel. We're going to hold for another minute while we get some more questions that we can answer so just hold on one second.

JASON PETROSKI: Okay, here we go. I'm going to turn back to Judy for some questions on some of the copays and how to fill this out. So Judy the question for you is- if you offer reduced copays at preferred pharmacies, can you keep the copay for Model insulin at $35 for preferred and non-preferred, or do we need to reduce it for preferred pharmacies? Can you help with that one, Judy?

JUDITH GEISLER: Sure, thanks Jason. So if you offer both preferred and standard cost sharing, the cost sharing at the preferred pharmacies has to be the same or lower than the standard cost sharing. So let's say, for example, you wanted to offer a $35 cost sharing at standard pharmacies, it could be $35 at preferred pharmacies as well. It can't be greater- and the other thing that I would note, is that in looking at the tier that the drug sits on, the cost sharing for preferred pharmacies, you know, would have to be at $35 or higher for the other non-Model drugs that are on that tier at the preferred cost sharing. So hopefully that provides a little clarification for that question.

JASON PETROSKI: Yeah that's really helpful, Judy, and I'm going to send one more question your way. This one is- will member cost shares be identified in a bid template like for 2022, or an excel file like for 2021?

JUDITH GEISLER: Thanks, Jason. I think what this question is referring to is how the cost sharing for Model drugs will be submitted. So the excel template that's part of the application will just collect the RXCUIs for the plan-selected Model drugs, as was done for 2022. And there are some questions related to the cost sharing in the Qualtrics portion of the online application for 2023 that will need to be answered, when that portion of the application is completed. And then, when the bid is submitted,
there is the section of the plan benefit package for the Part D Senior Savings Model that will collect the specific cost sharing related to the cohort.

**JASON PETROSKI:** Judy, thanks for clarifying that. Okay, so I think we're going to switch gears here to another area of the Model where we're getting some questions that I think are really important. And this has to do with the low-income subsidy population and how that relates or doesn't relate to the Model. So let's see. Is this correct that LIS members are not eligible for the PDSS cost sharing for Model drugs, even if they have LIS 4 subsidy and 15% of the drug costs is greater than $35? Trudel, you mind commenting on LIS members and the PDSS Model?

**TRUDEL PARE:** Thanks, Jason. So as we mentioned earlier, beneficiaries that have LIS are not eligible for Model benefits. You know, as you stated there Jason, and it varies sort of between LIS levels, but LIS Members already had set cost sharing generally. They're not eligible for the Model.

**JASON PETROSKI:** Right, thanks, Trudel, and that that does include LIS 4 level beneficiaries. Okay, so let's just see- I think we're going to take maybe one or two more questions before we wrap up here, give us one more second to compile the last list and we'll be back.

**JASON PETROSKI:** Okay here's another question that has to do with the application process and some of the PBP work. Judy, I'm going to ask you to help with this one- if a Part D sponsor's planning to crosswalk one PBP into another, should they assume that the surviving PBP would be listed on the excel docs that they're submitting?

**JUDITH GEISLER:** Yeah thanks Jason, yes, I believe that would be correct. The PBP number that would be going forward should be included on the excel template, and if there's some type of extenuating circumstance or specific question, if you would submit that into the Part D Senior Savings mailbox, you know, we'd be happy to take a look and provide additional assistance.

And Jason- I'm going to answer one other question that came in around the document that needs to be submitted in June, after the bid. I believe this question is referring to the supplemental file that needs to be submitted for the Part D Senior Savings Model and that supplemental file would contain the RXCUIs and cohorts that are contained within the plan benefit package and that would be due on Friday after bids are submitted at 11:59am Eastern time.

**JASON PETROSKI:** Thanks Judy. Okay, so I think we're going to take one more question here just give us one second.

**JASON PETROSKI:** Okay, sorry for the delay there, folks. So some of the questions that we received are whether there's been changes in the Model from 2022 to 2023. In general- I'll take this one, in general, the Model remains similar to the Model that we're currently testing in CY 2022. There is one change, though, for 2023, CMS will no longer be offering an option of a narrowed first threshold risk corridor for Part D sponsors, as this option was only planed for CY 2021 and CY 2022. So other than this change, the Model remains pretty much the same as what we have been testing in calendar year 2021 and also 2022.

So with that, I think, you know, there are some other questions that we received. We'll try to take those back, you know, make sure that we're updating our materials on our website, etc, to help address some of the questions that we're getting. Also, please feel free to email us at the Part D Senior Savings Model
mailbox which we had mentioned previously. And you know send us your questions, we’re happy to assist, happy to answer those questions. And last but not least, just wanted to again thank everybody for their time today, for your interest in the Part D Senior Savings Model and in general the Innovation Center at CMS and the Models that we’re testing. Thanks again, and we will definitely follow up with, you know, copies of the slides on our Model website as soon as we’re able to post them. Thanks again!