



**CMS 2011 MEDICARE ADVANTAGE AND PRESCRIPTION DRUG PLAN**  
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**CMS**

Hello, everybody. There's a lot of you sitting out there today. Okay, today I'm going to be talking to you about topics related to the Part D benefit review. We'll begin with a general overview, followed by benefit review highlights, supplemental file changes, and a few comments on formulary and transition submissions.

Dale has gone over some of these important dates, but I did just want to highlight a couple of them that he has not mentioned. April 18, which is next Monday, is the formulary submission deadline. It's also the deadline for transition at a station, and policy submissions. On June 6, the bid submissions are due, and as Dale mentioned, there will be no exceptions. This is also the deadline for formulary to plan crosswalk finalizations. So any plans or formularies that are not linked at that period in time, CMS will assume that sponsors will not be offering these plans and formularies, and will be expected to withdraw them.

Supplemental file submissions are due on the 13<sup>th</sup>. As soon as bids are written off in the HPMS system, which can occur as early as June 7, we encourage plan sponsors to begin uploading their supplemental files, as the gates will open automatically. We want you to get these in as soon as possible, so that you can meet the deadline. It's also important, because without these files, CMS will not have sufficient information to fully evaluate whether a plan's benefit design meets the non-discrimination requirements. So please get these in. If you do not have them in by June 13, again, we will assume that you do not intend to offer these benefits, and we will ask you to revise your bids accordingly.

There are a number of available tools or guidance. As Dale mentioned, there's the final 2012 call letter that came out on April 4. The call letter addresses a number of topics that directly affect the emerging market -- affect the 2012 bid submissions and benefit reviews, so please read these carefully before preparing and submitting your bids. Also available are Chapters 5 through 7 of the prescription drug benefit manual, which can be located at the web link that I provided on this slide.

And lastly is the out of pocket cost, or the OOPC model, that has been posted on the CMS Web site as of last Friday, April 8, and of course we'll be discussing that in great detail, later on today. For 2012, under the standard benefit, the deductible, the initial coverage limit, or the ICL, the true out of pocket costs, or TROOP, and the out-of-pocket cost thresholds have all increased over 2011. In addition, the portion of the cost of generic drugs that a plan pays in the coverage gap will be increased to 14 percent in 2012, and you can see the increase levels for each of those previous parameters that I've mentioned.

I've included this slide just as a reminder that when we speak of basic benefit types or basic plans, we are referring to defined standard, actuarially equivalent, or basic alternative plans. Enhanced alternative or enhanced plans are plans that provide more value than a basic offering by offering supplemental benefits in addition to basic prescription drug coverage. You can find more information about all of these plan types in Chapter 5 of the prescription drug benefit manual.

In this next section I will highlight the bid design and submission requirements discussed in the 2012 call letter. Before doing that, I want to remind all sponsors that due to a change in the annual election period -- I'm sorry, annual enrollment period -- CMS will have a shorter timeframe for review and approval of bids. We cannot emphasize how important it is for

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sponsors to submit complete, accurate, and consistent bids -- bids that are compliant with all of CMS policy and guidance. CMS encourages sponsors to use the OOPC model to improve their bid submissions and ensure that they meet the meaningful difference requirements.

CMS simply will not have the same amount of time that we've had in the past for negotiations. Therefore, plans may not have an opportunity to resubmit revised bids if their initial submissions do not meet our requirements, and this will put you at risk for having your bids denied this year.

CMS has the authority to non-renew plans that do not have a sufficient number of enrollees needed to establish themselves as viable plan options. As in 2011, CMS will be scrutinizing standalone prescription drug plans, or PDPs, with low enrollment, specifically those that fall in the lowest quintile of enrollment in a PDP region. This does not apply to employer group plans or plans with less than three years of enrollment.

Part D sponsors can view the plan enrollment data on the CMS Web site to determine if they fall into the lowest quintile. CMS also intends to notify sponsors later this month, if they have plans that are considered to have low enrollment. Prior to the 2012 bid submissions, CMS encourages sponsors to withdraw or consolidate any plans that have less than 1,000 enrollees. CMS may use their authority to non-renew a plan, having taken into account all relevant factors such as the population served or the total number of plans in an area. Part D regulations require that plan offerings within a service area must be meaningfully different with respect to benefit packages and cost structures. CMS will only approve Part D bids that are substantially different from other plan offerings by the sponsor in the same service area or region for PDPs.

Sponsors may offer no more than three PDPs in a region -- that's one basic plan, which is required, and a maximum of two enhanced offerings. This is unchanged from 2011. The cost-sharing OOPC differential analysis for PDPs is used by CMS to establish meaningful differences between basic and enhanced plans, as well as between enhanced plan offerings by a sponsor in the same region. This analysis allows CMS to set target differential thresholds to ensure that beneficiaries who pay premiums for any enhanced plan will receive a minimum additional value over basic coverage, and between enhanced coverage offerings.

This analysis incorporates a uniform basket of drugs from a representative population of Medicare beneficiaries that is run through each plan's benefit package. The analysis does not take into account premiums, and it does not take into account plan-specific enrollee utilization. For 2012, the PDP/OOPC threshold between a basic and enhanced plan will remain at \$22, where a beneficiary is expected to pay at least \$22 less each month for an enhanced plan over a basic plan in the same region. If a sponsor intends to offer two enhanced plans in a region, both must meet this \$22 OOPC differential as compared to the basic plan, and there must be at least \$16 difference between the two enhanced plans, in terms of the OOPCs.

Similar to 2011, if a second enhanced plan is going to be offered, CMS expects that they will be offering additional gap coverage of brand drugs that constitute ten to 65 percent of the unique formulary entities on their formularies. In terms of the gap coverage level descriptions that are found in the *Medicare and You* handbook, this translates into some brand coverage, and if you want to have more information about how these labels are defined or calculated, you can refer to the 2010 call letter. Please remember that any additional brand coverage in the gap applies before the manufacturer discount of 50 percent.

I apologize, I didn't switch to the next slide. For 2012, CMS has provided plans with a cost-sharing OOPC model so that they can calculate OOPCs for their benefit offerings prior to bid submission, the same way that CMS does calculate the OOPCs after the bids come in. Plans should use this OOPC model to ensure that there are meaningful differences between their plan offerings within a region. CMS expects that initial bid submissions will meet these requirements, especially given that the tools are available to calculate before submitting your bids. CMS will notify sponsors whose benefit structures do not meet the meaningful differences requirement, and as I noted before, revised submissions may not be allowed for initial submissions that do not meet these requirement, in which case sponsors will be asked to withdraw their PDPs.

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Tiered cost-sharing benefit designs may not exceed levels annually determined by CMS to be discriminatory. Consistent with prior years, CMS will examine 2012 PDPs and MAPDs to determine acceptable cost-sharing thresholds and identify cost-sharing outliers relative to competing benefit packages. For 2012, the co-pay threshold values established for tiers one through three were \$10, \$45, and \$95, respectively, where tier one represented generic drugs, tier two was considered preferred brand, and tier three was considered non-preferred brand cost-sharing. Assuming similar benefit designs will be submitted for 2012 as 2011, sponsors can expect that CMS will set thresholds that are reasonably consistent with prior year experience.

Because of the additional standardization in tier designs required for 2012, CMS will be able to refine target cost-sharing thresholds and expects to establish threshold levels for all submitted 2012 PBP tiers. CMS will continue to scrutinize coinsurance tiers that are greater than the standard benefit of 25%. We will use 2010 PDE data mapped to your 2012 formularies, in order to derive the average expected cost-sharing amounts for sponsors' coinsurance tiers. In addition, we may require documentation from sponsors on the average expected cost of drugs that sit on these tiers.

Consistent with the meaningful differences review, CMS will notify sponsors whose benefit structures do not meet the discriminatory cost-sharing requirements. Over the past few years, CMS has heard from beneficiary and advocacy stakeholders, as well as Part D sponsors, that it's confusing to have a large number of tiers, duplicative tiers, non-standardized tier labels, or tier labels that include multiple drug type descriptions in them. These tier attributes do not lend themselves to a common understanding of how competing plans compare in terms of their tier offerings, and it presents challenges in evaluating bids for the discriminatory cost-sharing analyses. Therefore, CMS has established additional standardization of tier structure and number for the 2012 bid submissions.

Please be advised that although the PBP software will allow tier labeling and hierarchy that differs from these models, CMS expects that plan submissions will be consistent with the 2012 models, and we'll go over those in a moment. As in 2011, a maximum of six tiers may be submitted. However, new for 2012, the six tier offering must represent a meaningful benefit offering, such as a tier for excluded drugs only, or a \$0 vaccine tier. CMS will permit customization of six tier labels in the PBP, via hard copy changes, for any tiers that cannot be adequately described using the PBP options. For example, plans will be permitted to customize the six tier label if they are offering a \$0 vaccine only tier. In addition, plans may use the Rx notes section of the PBP software in order to describe their six-tier offering, but keep in mind that this is limited to 225 characters, and this is not a change from last year.

The new tier labels and hierarchy reflect the industry standards, and will provide for a more comprehensible description of the overall tier offering, as it relates to the drug content and the associated cost-sharing. Because the tier names on the formulary submissions are the labels that the sponsor anticipates submitting in the PBP, the formulary tier names should be consistent with these models as well. We have clarified in the call letter that despite the standardization in tier names, sponsors may continue to include a mix of brand and generic drugs on the same tier, regardless of the fact that the tier label or name that's used in the PBP might only represent one of those multiple drug types you have on that tier.

For 2012 there is no change in the excluded drug tier name options that are found in the PBP. So whatever options you see there on the PBP, all of those options are still viable. This is just taken from the final call letter, and it's broken up into two slides, so that you all can have any chance of trying to read what it says. I want to point out that for those cells where there are more than one option, this is an either/or scenario, so for example, in tier one of a two-tier formulary, you can label that tier as either generic or as preferred generic, but not a combination of the two.

It will be difficult for CMS to determine whether a plan's cost-sharing is discriminatory for any bids that do not follow these models, and because of the shortened time period, due to the change in the annual election period, CMS may not have enough time to improve bids that are incomplete or otherwise challenging to evaluate. This will put sponsors at risk for being denied participation in the program. If you have any doubt about what you are planning to submit for 2012 with regard to these labels or any other requirements, please reach out to CMS well in advance of submitting your bids for 2012.

CMS will scrutinize 2012 plans offering additional gap coverage that represents 70 percent cost-sharing for the beneficiary or greater. Enhanced alternative plans may offer additional gap coverage through a supplemental Part D benefit that is above and beyond the standard generic benefit, or in addition to the gap coverage discount program for brand drugs.

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However, if additional gap coverage is offered, it must represent meaningful enhancements over the standard prescription drug benefit, which is why we will be looking at any plans that are offering less than 30 percent of the cost of generic or brand drugs in the coverage gap.

Dale covered a lot of what's on this slide. I just did want to mention that plan correction requests are only allowed for approved contracts, and the PBP changes must be supported by the BPT. There are only two supplemental file changes for 2012. The first relates to how supplemental files will be linked to formularies. There are five supplemental file types -- the excluded drug, OTC, partial gap, free first fill, and home infusion. In previous years, with the exception of the OTC supplemental file, Part D sponsors had the ability to link multiple plans to a single formulary ID, even though these plans had different versions of a given supplemental file type. However, for 2012, if two or more plans will be linked to the same formulary ID, they must use the same version of a supplemental file for any supplemental file types that are in common. This may lead to some formulary proliferation for 2012.

This concept may be better understood by looking at the supplemental file submission examples provided in this table. As you can see, three plans are linked to formulary ID 99999. Plans two and three have an excluded drug supplemental file type in common; however these two plans are using that same version of that supplemental file type and therefore can be linked to the same formulary ID, whereas Plan 4, although it has three files in common with Plan 3, it has a different excluded drug supplemental file version and therefore must be linked to a different formulary ID. The same is true for Plan 5, that has three files in common with Plans 3 and 4 but has a different excluded drug version and a different OTC version.

There was a formulary training webinar released on March 9 that has additional charts and instructions for submitting the 2012 supplemental files. The second supplemental file change is a change in the record layout for the excluded drug file. There is a new variable called the gap coverage yes/no variable, which indicates whether a drug will be covered in the coverage gap. Okay, we're almost done. I'll just briefly mention a few things about the formulary and transition submissions for 2012. For 2012, the initial formulary submission will continue to include a full or comprehensive formulary file, and if applicable, PA and step therapy file. The formulary upload question are unchanged from 2011, but the formulary record layout has a new change type field.

During the initial submissions, the value in this field for every formulary record submitted should be ADD for addition. After April 18, when the formulary review begins, any subsequent formulary PA or step therapy submissions will only include changes. In the change type field that we just mentioned, plans will describe the change as an addition, a deletion, or an update. This new system allows for line level review process, after conditional formulary approval, CMS will use this line level review to deny only those aspects of formulary submissions that do not meet our requirements, instead of denying the entire submission, as in all previous years.

For more information about the 2012 submissions, you can utilize the formulary webinar I mentioned before at the link provided on this slide. And lastly, Part D sponsors are reminded that they must provide for an appropriate transition process. Transition out of stations and policies must be completed through HPMS by Monday, April 18.

If you have any Part D benefit review or submission questions, please send them to the Part D benefits mailbox address listed on this slide, or contact Roslyn, Frank, or myself. I appreciate your time. Thank you, and enjoy the rest of the conference.