Civil Money Penalty (CMP) Methodology

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Kevin Stansbury: Good afternoon everyone here in Baltimore, and a good day to everyone joining virtually, since I don't know what time it is specifically for you. Thank you all for lasting through the day to listen to my session. Again, as Stacey mentioned, I'm Kevin Stansbury, and I'm the acting director for the Division of Compliance Enforcement, which is one of the three divisions that Vikki introduced you to this morning during her welcome remarks.

A high-level introduction to DCE, we are the division responsible for analyzing referrals for potential enforcement actions, and those include CMPs, intermediate sanctions, marketing, and enrollment suspensions for example; and for-cause CMS-initiated MA and Part D contract terminations. DCE works with several internal CMS business partners to coordinate and impose these enforcement actions, and in the case of marketing and enrollment suspensions, we help oversee the sanctioned plans until they have corrected the deficiencies. And at that point we recommend sanction release as appropriate.

A quick personal introduction, I'm the permanent deputy director for DCE, and I've worked here at CMS in various capacities and offices. But I've been in the Medicare Part C and D side of the program for over 10 or those 15 years. I've also held several roles in DCE and MOEG, including technical advisor for the division and special assistant, working closely with Vikki and our former group director, Jerry Mulcahy.

Now I just mentioned that DCE is responsible for imposing several types of enforcement actions, but today's presentation will focus solely on CMPs, or civil money penalties. I want to start by giving you a high-level overview of our CMP regulatory authority. I will also talk about CMS' methodology for calculating CMP issued to plan sponsors, when that started, and how we arrived at the methodology that we're discussing today. I'll walk through a couple sample scenarios from our published methodology so you can see how the calculation works on a violation-by-violation basis. Then I'll briefly tell you what our plan is for the methodology going forward. Lastly, if we have any time, we can take questions with the time we have left. So let's get started.

First off, I'd like to make sure, as Stacey said, these are for MA and Part D program, so I don't want anyone to be confused or confuse these penalties with other types of CMPs the agency might impose, or ones that law enforcement may take, such as the HHS Office of Inspector General. We often get mailbox questions about CMPs for drug manufacturers or nursing homes, et cetera. The CMPs we're talking about today are the ones that DCE is responsible for imposing for Part C and D plan sponsors, and these are administrative penalties found in 42 C.F.R. 422 and 423. For those more familiar with 422 and 423, it's subpart O of these respective part that is covers intermediate sanctions in CMPs.

CMS's ability to impose these CMPs can come from either our authority to terminate a plan sponsor, which is discussed in subpart K, specifically 422.510 for the MA, and the corresponding Part D Section in 423.509. Or it can come from our sanction authority, which, as I said, is in subpart O, and specifically that's 422.750 and 752, and the corresponding 423.750 and 752.

Also, it's important to point out that while CMS usually chooses one course or another to address substantial noncompliance, CMS has the authority to impose CMPs both in lieu of or in addition to contract termination or intermediate sanctions. And you can see those specific

regulations right here for 42 C.F.R. 422.752(b) and (c) and then the corresponding (d) sites.

CMS has historically relied on its termination authority to impose CMPs. Under the termination regulations CMS just has to show that a plan sponsor has met one of three possible criteria. Either the plan sponsor failed substantially to carry out the contract, that the sponsor is carrying out the contract in a manner inconsistent with the effective and efficient administration of 422 or 423, or that the sponsor no longer substantially meets the applicable conditions of Part 422 or 423. It's that first criteria, failed substantially to carry out the contract, that is the most commonly cited in our CMPs. That same reg section goes on to list a number of examples where CMS can make this determination.

If your organization has ever received a CMP, or if you've ever reviewed any of the notices on our enforcement website, you might be familiar with some of the more common reasons listed under the basis for CMP section. These include substantially failing to comply with Part D service access requirements, and that's commonly cited under formulary administration failures of a program audit, and substantially failing to comply with the requirements of subpart F, and that usually relates to appeals and grievance violations found in audit findings under CDAG and ODAG.

When DCE receives a referral for a possible enforcement action we don't work in a vacuum. We often consult with subject matter experts within the center in an effort to carefully evaluate the noncompliance to determine if an action is warranted. We also carefully evaluate whether it's supportable given our regulatory authority. For that second piece, we work closely with attorneys in the HHS Office of General Counsel to scrutinize and clear each action. Enforcement referrals for possible CMPs come from various sources across the agency, but quite often we evaluate deficiencies uncovered during program audit.

In the published methodology that I'm going to talk more about later in the presentation, we listed several standard violations that we impose penalties for that negatively impact beneficiaries. Some of the most common ones include inappropriate delay or denial of access to health services or medications, incorrect premiums charged to or unnecessary costs incurred by beneficiaries, or inaccurate or untimely information provided by the plan sponsor about health and drug benefits. For those first two, those first two are more commonly associated with program audit violations, and the third one that I mentioned can arise through marketing complaints or annual ANOC/EOC compliance evaluation.

After CMS has decided that a CMP is the most appropriate enforcement tool to address noncompliance, 422 and 423.760 spell out that CMS considers the following factors in determining the amount of the penalty: The nature of the conduct, the degree of culpability of the sponsoring organization, the adverse effect to enrollees which resulted or could have resulted from the conduct of the plan sponsor, the financial condition of the plan sponsor, the history of prior offenses by the plan sponsor or the principles of the organization, or the catch-all, such other matters as justice may require. CMS has used these principles in developing several components in our methodology, such as the application of aggravating factors that we'll talk about further in just a minute.

Pursuant to Sections 422 and 423.750(b)(1) and (2), CMS determines if the penalty for a deficiency should be calculated on a per-enrollee or per-determination basis. CMS uses per-enrollee penalties when we have a quantifiable number of beneficiaries that have been adversely affected or have had the substantial likelihood of being adversely affected by a sponsor's deficiency. And we use the per-determination penalties when a quantifiable number of adversely affected enrollees is not possible to obtain.

Both types of penalties carry the same limit, and I'll point out here that if you're accustomed to using a published set of C.F.R.s you may notice that up to as recently as the 2016 edition, these amounts have historically

always been listed as $25,000. However, per the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015 -- that's a mouthful -- the CMP limit will increase annually and will be published in the Federal Register. Therefore, the amounts shown on this slide are the most recent that went into effect February 3rd of 2017, and you might also notice that these are different than the limits that were published in the public methodology, which took effect back on October 1 of 2016. Lastly, the third limit is a weekly limit for deficiencies that remain uncorrected after CMS notifies a plan sponsor of its determination. This one was historically listed as $10,000 up until the inflation adjustment took effect.

This is the last slide on CMP authority, I promise, before we get to the overview. But I just would like to point out while we publish our standard methodology in response to increased industry and stakeholder interest, we need to point out that CMS in no way is required by law to even develop or publicly share a CMP methodology. We've done so in the spirit of transparent and because we want to encourage compliance in a fair and consistent way across our plan partners and the industry. That said, using this methodology does not limit the agency's ability to impose any CMP that is permissible under the law. And CMS may determine that a different methodology should be used to calculate a CMP for some other deficiency that was detected outside of a program audit for example. However, if a different methodology would be applied, we would try our best to use the principles outlined in this published methodology as much as possible.

All right, let's move to the history of CMP methodology. The methodology used to calculate CMPs has evolved over time. Prior to 2014, the amount of a CMP varied based on a number of factors, including the severity of the deficiency, the extent to which the deficiency was systemic, and the enrollment of the plan sponsor. In 2014 CMS implemented a pilot methodology that standardized the calculation of CMPs. Under the pilot, CMPs were calculated by applying standard penalty amounts as well as aggravated and mitigating factors that increased or decreased the overall

penalty. CMS also began calculating CMPs on a per-enrollee or per-determination basis.

On September 13th, 2016, CMS published a proposed methodology for public comment that was largely based on the latest version of the pilot methodology. After comments were received and evaluated and updates were made accordingly, CMS published the final version of the methodology on December 15th, 2016. Along with the methodology, we included a helpful Q&A document that synthesized the comments by topic and included our responses to each of those groups of comments. These responses also identified whether we made a wholesale change or just a clarification in the methodology based on each comment.

The major differences between the pilot methodology and the new methodology, in effect, are the slight increases in standard penalty amounts over time in order to encourage better compliance with CMS rules, the enrollment-based limits on maximum CMPs, the maximum amount CMP a sponsor can receive for each deficiency, and the elimination of standard or defined mitigating factors that reduce the calculation.

I think that's enough background for now, so let's get into the meat of the calculation methodology. In this part of the presentation I want to walk you through the four major elements of the methodology, and those are the standard penalty amounts for several types of adverse impact to beneficiaries, the situations where CMS is deemed the application of an aggravating factor is necessary, the standard amounts are both per enrollee and per determination penalties, and the concept of the enrollment-based limit or what some refer to as CMP caps.

Listed here are the three standard per-enrollee penalties that I referenced earlier in the presentation. You can see the dollar amounts that we've assigned to each violation type. Therefore, if the sponsor violated CMS rules in a way that resulted in an inappropriate delay or denial for beneficiaries of a Part C service or Part D drug, that would carry with it a

$200 standard per-enrollee penalty. If incorrect premiums were charged or inappropriate cost-sharing incurred to beneficiaries, that would also trigger a $200 per-enrollee penalty. And the last standard per-enrollee penalty is for the dissemination of inaccurate or untimely plan benefit information, and that carries a $25 per enrollee penalty.

Here are the two standard per-determination penalties from our methodology. The first is the invalid data submission, or IDS condition that sponsors could receive on an audit for failing to provide valid enrollee universes. That would receive the maximum amount permitted, which, as I mentioned earlier, is $37,396 for 2017. All other per-determination violations would carry a maximum of $20,000 each.

Also, as I said earlier, CMS has the authority to issue CMPs up to the maximum amount permitted under regulation for each affected enrollee or per determination. However, CMS does not apply the maximum penalty amount for most standard penalties because we believe, based on program experience, that the penalty amounts under the current methodology are sufficient enough to encourage compliance with CMS rules.

Next we should discuss aggravating factors. Three important points here that I want to explain. First, once we have calculated the standard penalty we will apply any aggravating factors to that violation's penalty amount; second, aggravating factors will always have the effect of increasing the violation's penalty amount; and, third, both per-enrollee and per determination penalties can have aggravating factors.

Here is the list of per-enrollee aggravating factors associated with the first per-enrollee violation type; inappropriate delay or denial of drugs or services. The first aggravating factor that can be applied is if the delay or denial involved a drug that generally required access within 24 hours in order to treat an acute condition or maintain the therapeutic treatment of a non-acute condition. Here we carefully review each drug listed in the

impact analysis to determine if it would have met the aggravating factor criteria when the deficiency occurred.

The next factor is if the plan sponsor has a history of prior offenses. Here CMS will apply the prior offense aggravating factor when it determines that the sponsor received the same finding in the preceding two calendar years. The finding can be cited under previous compliance notice, an audit report, or some other enforcement action would also count. The next one is if a missed adjudication timeframe was missed for an expedited coverage decision. Here we apply the aggravating factor because we've placed emphasis on the need to address beneficiary requests that are urgent in nature.

And the last current enrollee aggravating factor is if the violation was among the top cited conditions in MOEG's annual audit report. Here we will apply the common conditions that were published in the annual report two years before the contract year being audited. For example, if in 2017 -- if, for 2017 program audit, CMS had findings, we would apply the common conditions -- findings that we would take a CMP for, we would apply the common conditions contained in the 2015 annual report that was published in August of 2015.

Here is a list of per-enrollee aggravating factors associated with the second per-enrollee violation type, and that was incorrect premiums charged or unnecessary costs incurred to beneficiaries. The first aggravating factor of a hundred dollars is applied if inappropriate extra cost to the bene was $100 or more. The second and third factors, prior offense and common conditions, work the same way, with this violation as they do with the previous ones, so we're not going to talk about those.

The last group of per enrollee aggravating factors are associated with untimely or inaccurate plan benefit information violation. The prior offense works the same as the other prior offense factors, except we apply a $15 instead of $100 factor. The other aggravating factor is specific to our inaccurate and untimely ANOC/EOC CMPs, and that is applied when

either the documents themselves or the Errata sheets correcting a previously disseminated error were not sent to enrollees before December 31st. So that wraps up all the per-enrollee aggravating factors. Next, I'll explain the per-determination aggravating factors, which are pretty simple by comparison.

For the per-determination aggravating factor list, we just have prior offense factor and a common condition factor, and they are applied in the same manner as the per-enrollee ones. The only difference here is that they are $5,000 per determination instead of the $100 per enrollee. So that concludes the whole aggravating factor portion.

Now, even though the calculation can seem rather simple, I just want to review the actual calculation so you have a full understanding. So, for a per-determination penalty, to get the total penalty amount for a given violation you just multiply the applicable standard penalty amount times the number of contracts. Then you would also multiply any aggravating factors by the amount of applicable contracts. If the violation carried multiple aggravating factors, you would just repeat that multiplication separately for each factor, because the number of contracts could change for a specific aggravating factor. Then you would add those up and the standard penalty -- you would add those up, and then the standard penalty and any aggravating factors, and you'd come up with the total penalty for that violation.

For a per-enrollee-based penalty you, instead, would multiply the applicable standard penalty amount times the number of affected enrollees. You would repeat the same process for the aggravating factors. And it's often the case that the number of affected enrollees is different from aggravating factor to aggravating factor, and also different from the standard penalty amount -- standard penalty enrollees. Once we are finished multiplying all the applicable aggravating factors, we add those all together to come up with the total penalty amount for that per-enrollee violation.

Next I want to take make a couple of important points about the maximum penalty amounts under both the per-determination and per-enrollee scenarios. The per-determination maximum is set forth in regulation, and, as I've already said, that amount is adjusted annually. The per-enrollee maximum penalty is subject to an enrollment-based limit on each violation within a given CMP.

So, for violations that lend themselves to a per-determination calculation, penalties are limited to the maximum allowable amount in regulation, which is $37,396 for 2017. As I showed a few slides ago, per-determination penalties are multiplied by the number of effected contracts; that is, the contracts where the deficiency applied. So, for example, if the number of affected contracts is ten, the maximum penalty that can be imposed for that violation would be $373,960. However, the total CMP can include multiple violations and be based on both per-determination and per-enrollee penalties.

On this slide we have the enrollment-based caps from the published methodology. CMS will use this table to limit the penalty amount for each per-enrollee violation within a CMP. This concept was put into place because CMS realizes the potential for CMPs to become quite high, given the potential for large number of enrollees to be impacted by certain program errors or compliance breakdowns. In applying these limits, CMS strives to strike a balance between adequately encouraging compliance without creating an undue hardship for plan sponsors.

Now I want to walk through a couple of examples to reinforce what I've explained about the CMP calculation so far. So for the first example let's pretend we have a large plan sponsor that underwent a program audit. And during that audit CMS discovered a serious formulary administration violation that involved 2,500 beneficiaries being inappropriately denied access to the Part D drugs that should have been covered. So, as we know from a few slides ago, that violation carries a $200 per enrollee standard penalty. So with that information we can calculate the standard penalty portion would be $500,000 for this particular violation.

Next, we would look to see if there's any applicable aggravating factors. So after checking the applicable annual report, we see that the condition cited was a top condition; therefore, we would apply the $100 aggravating factor to all the beneficiaries involved in this violation, for a $250,000 aggravating factor. And then upon further review, we also find that 500 of the affected enrollees were denied drugs that required access within 24 hours. So we would apply another $100 aggravating factor to those 500 beneficiaries, resulting in a $50,000 aggravating penalty. So after adding the two aggravating factors to the standard penalty now, we come up with a total penalty of $800,000 for that violation.

So now let's look at an example to simulate how the enrollment-based limit would work for a per-enrollee violation. In the second example let's assume that a different plan sponsor with an enrollment size of 400,000 beneficiaries had a similar audit finding that involved 6,000 enrollees. We would calculate our standard penalty amount of $1.2 million before evaluating the findings for applicable aggravating factors.

Let's say the same two aggravating factors from the first example applied here as well, except in this case 1,580 beneficiaries involved drug that is required access within 24 hours. We would calculate each aggravating factor accordingly to come up with two aggravating factors in the amount of $600,000, and $158,000 respectively. Then, as we did in the first example, we would add up the standard penalty amounts with the aggravating factor amounts to come up with a pre-capped penalty total. Then, in line with our enrollment-based limits, we would adjust the CMP total for this particular violation to $1 million, given the size of the sponsor. If you're interested, there are a few other examples listed in our methodology, so feel free to review those as well as you have time.

In conclusion, I just want to provide a couple points about our plans for moving forward with in methodology. CMS intends not only to apply the published methodology to CMPs in 2017, but also in 2018, and going forward, so long as we do not modify the methodology. If CMS does

revise the methodology, we will publish any proposed changes in advance of implementation and provide the industry with an opportunity to comment. Once a revised methodology is finalized CMS will apply it to audit referrals, or any other CMP referrals for that matter, that occur in the contract year following publication.

Finally, I hope this presentation has helped clarify a few things for those of you who may have already reviewed the CMP methodology or commented on the draft or proposed version. And for those of you who haven't had the chance to read it in detail, I have provided the link to it on our enforcement webpage. You'll find it in the download section towards the bottom of that particular webpage, underneath the table of CMP and sanction notices. I've also included the address to the MOEG compliance mailbox, so if you have any questions after today, or later, once you've read the methodology, you can feel free to send them into us.

So I think that we have some time left over to take any questions you have. But before we do, I just wanted to thank you all for your attention today and your interest in the CMP methodology.

Stacey Plizga: Do we have any questions from our in-house audience? You guys have gotten quiet as the day has gone on.

Kevin Stansbury: They're tired.

Stacey Plizga: Yes, they are. Okay, well I do have a couple questions that we received that we will address from our virtual audience. So the first one is, "How does CMS come up with the common conditions, and when will they be released to stakeholders?"

Kevin Stansbury: So I did point this out, and Jen and Greg have talked about that in depth, I think. We take those from the annual audit report that's published in an annual cycle. This year's was released just this week -- or 2016's was released just this week, and 2015's was back in August.

Stacey Plizga: Okay. All right. And the last one that we have here is, "When are CMP notices posted on the CMS website?"

Kevin Stansbury: Okay. So this answer depends. So we post all of our CMPs that we issue as a result of program audits before the end of February, the preceding year. But for CMPs related to non-program audits, we post those immediately after we impose them.

Stacey Plizga: Okay. Are there any additional questions? No? Okay. Then I would like to thank Kevin for joining us today, if you could help me. Okay. And go ahead and evaluate session six, please.