Enforcement Analysis Process

Ann Levinstim, CM

Kaye Rabel: Our next session will provide an overview of how the Division of Compliance Enforcement analyzes program audit referrals to determine if the enforcement actions are warranted. From the Division of Compliance Performance, I am pleased to introduce Ann Levinstim.

[Applause]

Ann Levinstim: Good morning, everyone.

I'm Ann Levinstim. I work in the Division Compliance Enforcement. I'm the technical advisor there. I want to apologize for my voice and potential cough today. Of course of all the weeks that one could get a cold, this was the week that I got a cold.

I'm sure that most of you don't like the word "enforcement" or don't like the idea of receiving an enforcement action; but I hope that after hearing this presentation today, you'll recognize the importance of our work and understand a little bit more about the process that we take in order to make determinations on whether or not an enforcement action is warranted.

The Division of Compliance Enforcement, also known as DCE, is the division that is responsible for taking all enforcement actions against Medicare Advantage organizations, prescription drug sponsors, cost plans, and PACE organizations. As you can see, we are also in the same

group as the audit divisions. Although that may be the case, we view ourselves as independent from the other divisions as well as other components within CMS, as it is our job to ensure that the violations that come to us meet the regulatory standard for an enforcement action. We do take that job very seriously as we recognize the impact that it has on sponsors.

Today I'm going to be mostly talking about – well, first I'm going to just give a very brief overview on enforcement actions; but mostly I'm going to be talking about the process that we work through to determine whether or not a CNP is issued in the program audit world. Specifically, I will be discussing how we get referrals; how we analyze the case; what data we look at; how we look at impact analysis. I will also be talking about our CMP calculation process and the changes and enhancements that we have made...also, the increased transparency that we have on this process.

I will also be talking a little bit about the sanction process and how we analyze cases for that. Then I will also talk about other referrals that we receive that result in enforcement actions. Finally, if everyone is paying attention, we will have some polling questions at the end for you to answer and then hopefully some time for questions and answers from the audience.

Most of you probably are very familiar with the types of actions that we take, although just a quick refresher; and if anyone is new to this, there are three types of enforcement actions that we can impose against sponsors. Those are civil money penalties, also known as, CMPs; intermediate sanctions; and terminations. Although we can use the same bases for any of these actions, the reasons why we impose them are very different; and they do go in order of severity.

For example, the CMP is the least severe of the actions; but it is also most commonly imposed. That is the action that we impose on sponsors who have past non-compliance that impacted beneficiaries.

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We impose intermediate sanctions when we have significant concerns that there are widespread issues within the organization or if the organization is not able to correct those issues quickly. When we impose intermediate sanctions, we often suspend the sponsor's ability to market to or enroll beneficiaries; and that will last until the sponsor can demonstrate correction, which could be about a year-long process.

The top one, terminations, is obviously the least common that we impose; but it is the most severe enforcement action that we can take. Those would be on the most egregious violations that would occur...also, potential financial insolvency issues as well as if there's any statutory reason for us to terminate if a sponsor doesn't meet certain criteria.

The purpose of our enforcement actions is twofold. One, it's to ensure that sponsors meet the regulatory violations and also to ensure that our beneficiaries are protected.

You are probably all wondering what we do in our enforcement world. You wonder if we are sitting in a cubicle flipping a coin deciding who's going to get a CMP and who's going to get a sanction. Of course, I'm just kidding; but really, what do we do? What kind of information are we looking at? How do we get the referrals? How do we look at the data? How do we look at impact analysis that you send us to make those determinations?

I'm going to talk about the step-by-step process of a life cycle for how we make determinations on whether or not a CMP is warranted.

The first step is we receive the referral. So in the audit world, you receive an Engagement Letter; and then you go through an audit process. Then you probably are wondering what's going to happen next in the enforcement world. Well, the next step is that DCE would receive a referral from our Division of Audit Operations based on certain criteria; and that includes the sponsor's audit score, whether or not the sponsor

had any ICARs, and how many beneficiaries are impacted for various violations.

Once we receive the referral, we will outreach to the sponsor to notify the sponsor that we've received the referral. That doesn't necessarily mean that you're going to get an action or a sponsor is going to get an action. We notify the sponsor that we've received the referral and that we're investigating it. That will usually be around the time that the sponsor receives the Draft Audit Report, but it could happen earlier in the process.

Once we receive the referral, we gather all of the documentation that the audit team has collected; and that includes work papers, audit sample documentation, impact analysis data from the sponsor, as well as details from the Audit Report. If we have questions about the audit results or if we're unclear of what happened on the audit, we're in regular contact and conduct outreach with the audit team to discuss any of those questions that we have on the various conditions. If we have further questions, especially around impact analysis data that came from the sponsor, we will also conduct outreach to the sponsor.

This year, if your organization is selected for audit, please expect to hear from us even more with our outreach attempts as we're continuing to try to improve our process for analysis on these cases.

That brings me to the discussion on what we look at when we're reviewing impact analysis data because that is data that is provided from the sponsors, and that is often what we conduct a lot of outreach on. We do analyze the information in the impact analysis very carefully. If there's information that is missing because the sponsor did not complete certain columns or maybe wrote "N/A" where it should have actually been data, we will conduct outreach to get that information if we need it. If we need additional columns completed because we need additional information from the sponsor, we will ask the sponsor to complete additional columns.

Also, if there are any discrepancies in the IA, we will contact the sponsor...for example, if a sponsor had a formulary condition and the IA showed that the beneficiaries did not receive their medication within a certain period of time and that number did not match up with dates within the IA. We're going to be conducting outreach to the sponsor to understand where the discrepancy is. With that being said, we expect sponsors are, during the audit, spending time completing their IAs fully and also validating to ensure that their IAs are correct.

However, we will be conducting outreach to clarify information; so sponsors will be given that opportunity. At some point though, after significant numbers of outreach attempts and discussion with the sponsor on additional information that we need, if the sponsor cannot gather that, we will have to move on with the information that we have in making our determination.

In addition to our detailed review of the impact analysis, we also conduct an IA validation...or we may conduct an IA validation for sponsors. What that entails is that we would contact the sponsor and let them know which particular IAs we're going to be validating. We will be conducting a webinar and asking the sponsor to walk through exactly how the data was pulled from their system and is inputted into the impact analysis. Most of the time, the impact analysis validations are done on formulary conditions; however, this year and going forward, we're most likely going to be expanding that into other program areas.

Also, I would like to just discuss one more thing about our outreach to sponsors in that it is a separate investigation from what is going on with the audit team. Sponsors may find that during the time where we're conducting outreach and asking questions, you are still working with the audit team in finalizing audit data. But our questions are really not to be necessarily meshed with the questions and the work that's going on in the audit team because our investigation and our analysis is slightly different from what is going on in the audit, and we may need additional information that the auditors don't necessarily need.

We will make sure that sponsors are aware when we're conducting this outreach that this is specifically for an enforcement investigation and not necessarily related to the audit.

Then finally, we do also look at documentation from the sponsor. You're given an opportunity to respond to the Draft Audit Report; and so if sponsors have concerns or disagree with findings in the Audit Report, they should make that known in their responses to the Draft Audit Report. We will look at that and take that into consideration.

Once we have all of our documentation, our next step is to conduct our analysis. We have certain criteria that we have to meet in order to make that determination of a CMP. The first one is that we have to see that there was a violation of a clear requirement, and then the second step is that we have to see that that violation was substantial...meaning systemic. In our world, when we look whether or not something is substantial, we may look at how many beneficiaries were impacted; and that includes both the percentage of beneficiaries that were impacted and also the number of beneficiaries that were impacted.

We also look at how many cases failed on audit...if there was a significant number of cases that shows that the issue might be substantial. And then we also look at the root cause. Depending on what the root cause is from the sponsor can indicate whether or not an issue is substantial. So it's not just one of these that we look at; it's all of them holistically together that we look at when making substantial decisions.

Our next step that we have to meet is that there has to be adverse impact for the substantial likelihood of adverse impact to enrollees. The most common examples of that on audit are denial of medications or services, or that the access to the appeal process was impeded either because the sponsor did not make timely decisions or maybe there was a misclassification issue. Then the last one we often see is enrollees being impact financially.

The first two are fairly easy to see. Often IAs show when the beneficiary has been denied a medication or if a coverage determination or organization determination was late. The last one can be a little more tricky because it's related to financial impact, and this one often shows up in the ODAG portion of the audit and when there are inappropriately denied claims, such as for plan-directed care, emergency care, or other coverage services.

I would like you all to know that if there is a substantial likelihood that if enrollees could have been billed by a non-contract provider, we will impose a CMP for any enrollee that had the potential to be billed. This is important for all sponsors to be aware of because what we have seen sometimes is that there has been a denial of, say, plan-directed care; and then the sponsor writes zero dollar liability for the member on their EOB. But in all cases where there is a non-contract provider, that non-contract provider can bill the beneficiary; and if it's an inappropriate denial and there is that potential for that beneficiary getting a bill, or they *were* billed, we will consider that adverse effect. It does not have to be whether or not the beneficiary actually paid the bill.

Finally, the last thing that we look at is just for generally other considerations. The other considerations really feed into the first three prongs that we have to meet. But some things that we also look at when determining whether a CMP is issued is whether or not the issue was discovered by the sponsor on their own, whether or not the sponsor notified the account manager of the issue, whether or not the sponsor quickly corrected the issues for the beneficiaries.

We can still impose a CMP even if the issue has been fixed because CMPs are for past non-compliance; however, if we see that a sponsor is proactive in identifying the issue quickly and that they remediated beneficiaries quickly, we will take that into consideration when determining whether or not a CMP should be imposed. If we see that maybe the organization just didn't discover the issue, or that even if the organization discovered the issue they didn't take the steps to remediate

the beneficiaries and it had to be told on audit that they had to remediate beneficiaries, that will raise the chances that a CMP could be imposed.

So we've gotten to our final determination. The three prongs have to be met. We have to have the violation, the regulatory failure; we have to have a substantial violation; and we have to have adverse or a substantial likelihood of adverse effect on the enrollees. If those three prongs are met, we will most likely move forward with a CMP for that particular condition. That may be one condition in the audit; that may be many conditions in the audit. The sponsor may have received an amazing audit score or not a great audit score, and each condition is evaluated through these prongs to determine whether or not a CMP would be met.

Sometimes though, you may see that we combined conditions or combined information; and that is because the root cause or the violation was very similar...most often that my current transition type conditions where the root cause for a transition failure was the same.

So once we have decided that a CMP is warranted for a particular condition, our next step is to figure out how we calculate that CMP for that particular condition. If we have impact analysis data, we will use that data to calculate the CMP based on the number of enrollees that were impacted. Each beneficiary is only counted once for one particular IA; however, a beneficiary may be counted multiple times if they've been impacted by different violations.

For example, if a beneficiary was impacted by a financial condition and then also impacted maybe for a misclassification condition, that beneficiary would be counted once for the formulary violation and then once for the misclassification violation.

Our standard penalty amount is tied to each beneficiary impacted; and for CMPs in the program world, those result in a $200 standard penalty per our CMP methodology. Then aggravating factors can be added to the standard penalty amount for each enrollee that's impacted by an

aggravating factor. The examples of those include the beneficiary was delayed beyond 24 hours for a medication that was needed for acute care or that the sponsor has had a history of prior offense for that particular violation. That could be from another CMP; that could be from another audit or even a compliance notice.

Another aggravating factor is for expedited cases in the CDAG and ODAG world if there are expedited cases and they have been delayed, and aggravating factor will be added to those. Another aggravating factor for financial conditions is if a beneficiary has been charged in excess of $100.

So here's an example of a calculation worksheet that we prepare when determining our amount. As I'll be discussing on the next several slides, we are now sharing these calculation worksheets with sponsors. You can see here this is not a real case scenario; I just made up these numbers. But here an example is for this violation 533 enrollees were impacted. The standard penalty amount of that is $200. Therefore, the standard penalty amount for the 533 enrollees is $106,600.

Forty-six of those enrollees had a delay of a medication that was used to treat acute conditions, and it was beyond 24 hours. So those 46 enrollees out of the 533 received an additional $100 tacked onto their CMP amount. So the aggravating factor for this particular condition is $4,600...for a total amount for this particular condition of $111,200.

Last year we published our first CMP methodology, and there were a couple of significant changes with how we calculated CMPs starting in 2017. The first one is that we created more enrollment bands for our CMP cap amounts. We create enrollment bands because in order to have CMP amounts that do not become too unreasonable, we establish caps for various buckets of enrollment for sponsors in our CMP methodology so that a CMP for each violation doesn't exceed a certain amount. And this was really done, we added more bands, so that smaller organizations are not put into financial hardship due to CMP amount.

The second major change that we instituted was removal of the mitigating factor. Prior to the issuance of our CMP methodology, we would discount certain beneficiaries if we found that their adverse impact was substantially mitigated. Now we remove those beneficiaries from the calculation completely. For example, if a beneficiary was denied at the point of sale for a medication but then subsequently received that medication that same day, we would consider that beneficiary substantially mitigated and remove that beneficiary.

Given that...and there are other reasons why we might remove beneficiaries as well...but given this change, a sponsor may see that the number of enrollees impacted for a particular violation in their CMP amount is different from what is in the Audit Report.

Another major change that we have this year is now we're sharing our calculation worksheet, which I showed you on the previous slide. We really do that so that everybody is aware of how we're calculating the CMP, how many beneficiaries were impacted, and the aggravating factors that were tacked on.

So once our CMP is calculated and been developed, we have to go through several clearances. We have to ensure that we receive clearance from our senior leadership, as well as the Office of General Counsel, who also gets in contact with DOJ and OIG. So there are a lot of clearance processes that we have to go through. But once we receive approval from all those clearances, we will contact the sponsor prior to issuing that CMP and discuss the action with them. Then we will e-mail the notice to the CEO or the highest senior leader in the organization. At that time is when we share the calculation worksheet that I showed you.

If there are any questions from the sponsors, we are very open to having discussions; and we really encourage sponsors to contact us if they have any questions. Of course, all of our actions do have an appeal process included. Appeals are due 60 days after the date of the issuance of the

CMP. But if the sponsor chooses not to CMP, they may pay the CMP at any time up to day 61; and they can choose to pay it by check, wire transfer, or deduction of monthly payment. We, of course, provide the details on how to pay those amounts if necessary.

Next I'd like to move on to sanctions and discuss a little bit about that process because it does differ from CMPs. I'm sure you all wonder like what would drive us from moving a sponsor from a CMP analysis to a sanction analysis. Several things that show up on audit can cause us to start heading down that analysis path.

The first thing is the number of conditions. If there are just a lot of conditions on an audit that can be a warning sign for us that this may be a sanction. Also, the type of condition may be a warning sign to us. Some conditions may have had some really significant beneficiary impact; or, in other cases, maybe a condition is not that commonly seen in other audits. So that can be a warning sign to us that sponsors are note really clear on what the Medicare requirements are.

Another one would be major breakdowns in certain program areas. This could be all the program areas, or it could just be one or two program areas. We've had sentence where sponsors have been placed under sanction and have done wonderful in formulary, but they had major breakdowns in CDAG or ODAG.

We also look at compliance program failures. Although we don't CMP for compliance program failures, we definitely look at compliance programs to determine whether or not a sponsor should be analyzed for a sanction. If we see some very concerning violations...such as senior leadership not being engaged, the sponsor not conducting proper monitoring or responding to significant issues of non-compliance...that will raise our antenna for a potential sanction.

These signs don't always just come up in compliance program. We talk to the team leads, and we ask the team leads about how the culture was

and how well they interacted with the subject matter experts from the sponsors and whether or not they felt the subject matter experts were well knowledgeable in the material and whether or not the auditors had confidence that the issues could be quickly corrected. It doesn't necessarily mean that that particular issue could be corrected quickly; we also ask auditors if they felt like future issues could come up. That would show us that sponsors are not doing the proactive monitoring and identification of issues that need to be remediated.

I know I've said this many times in other talks, and we've said this in other speeches...that we don't expect sponsors to be perfect, but we cannot stress enough the importance of monitoring and identifying issues quickly, remediating beneficiaries quickly, and putting things in place to ensure future issues don't occur.

We also look at the number of beneficiaries impacted...whether it was a large number of beneficiaries impacted over certain conditions. Then, of course, we also look at IDS conditions...if there are a large number of IDS conditions, it would show that the sponsor was not able to produce the data for the auditors to test. Then, of course, like said...concerns about program knowledge, which we get through various discussions with the team leads.

So once we have all this information, we continue to investigate this organization. We will interview the account managers. We ask the account managers how the organization's rapport is with them and whether or not the organization is transparent with account managers. We also ask if the account manager has seen significant concerns over the past year or so.

We look at compliance notices...a large number of compliance notices, also the types of compliance notices, whether it's warning letters, ad hoc caps, if the compliance notices show any of the same issues that were identified in audit which would show to us that the sponsor continues to have the same issues other and over again.

We also look at complaints. If we see a high number of complaints or a high complaint rate that can indicate to us that Medicare beneficiaries aren't receiving medications or services.

Then finally, we discuss with all other components within CMS about the organization and see if they have any concerns. Another important point that I want sponsors to be aware of is that many times sponsors can find themselves in sanction territory when major issues occur that they weren't prepared for…for example, maybe like a spike in enrollment or a change in the process that would cause an increase in ODAG or CDAG cases. This can often throw sponsors off guard; but it shows to us that maybe the sponsor wasn't necessarily proactive in preparing for the future needs of their organization...which is a major concern of ours.

Once we compile all of the information, we can generally get a good sense of how widespread and systemic these issues are, and whether or not the organization is going to have trouble quickly correcting those issues and therefore putting beneficiaries at risk while they're continuing to operate. And if we feel like that's met and that sanction is necessary, we will move down that path.

Now I'm going to talk about some other referrals for other types of actions. I've spoken mostly about the program audits, but we do get referrals for other types of actions. Here are the most common types of referrals, although we can always receive ad hoc referrals if there has been some major issue; and they can come to us.

The first most common type of referral that we get is our ANOC/EOC referrals, and you'll notice a change in evidence of coverage. CMS requires that sponsors submit their Annual Notice of Change and Evidence of Coverage at certain times each year. We receive referrals at the beginning of the year from our sister division in CM for any late or inaccurate outliers, and we will analyze those cases. We look at the percentage of enrollees that were impacted. We look at how late the

documents were. Also, in the case of an inaccuracy, we look at the type of inaccuracy and where it was located in the document. After we analyze these cases, they may result in a CMP.

The next one is the IRE Auto-Forwards. CMS requires that sponsors send, also known as auto forward, cases to the independent review entity if they're late; and a high number of cases going to the auto forward indicates that sponsors are not making their decisions on time. DCE how receives quarterly referrals from the Medicare Enrollment and Appeals Group on IRE auto-forward outliers, and these may result in a CMP.

In both cases, with ANOC/EOC referrals and with the IRE auto-forward referrals, we will conduct outreach to the sponsor and notify them they've been referred and verify information prior to issuing any kind of CMP.

The other one that we have been recently getting is 1/3 Financial Audits. Last year we started to get these referrals, and they were started for audits that were conducted on 2015 financial data. We created referral criteria with the Office of Financial Management for the types of cases that would be sent to our division; and these relate to incorrect copays, coinsurance, late enrollment penalty, and troop accumulations.

Again our division is conducting outreach with sponsors that have been referred to better understand the issues that occurred and to understand the adverse impact as a result of these failures. As I mentioned before with the financial impact, in the program audit world if we find that there is a potential that members could have been billed by a non-contract provider...or even a contract provider because we have noticed that there have been situations where contract providers had inappropriately billed beneficiaries...we will consider that to be substantial likelihood of adverse effect. Additionally, we have also seen if beneficiaries had to pay out-of-pocket at the point of sale to receive a medication or services; we will also consider that to be adverse impact.

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We have almost completed our review of the 2015 1/3 financial audits, and we expect to start recovering referrals for the 2016 audits as OFM is now conducting those.

Finally, we have PACE referrals that we're receiving. We're going to start receiving more of these referrals because the PACE audit process has now become more outcome-focused. We have also created a referral criteria based on the certain types of violations that are found during the PACE audits. Violations that show that participants did not receive medically necessary items or services may result in enforcement actions.

So PACE organizations should be aware that CMPs and/or sanctions may increase this year because we're receiving more referrals; however, again, as I stated before related to our outreach, we always conduct outreach with a sponsor when they have been referred; and that doesn't necessarily mean that the sponsor or PACE organization will receive an action. It's just our investigation of the action.

Now I'm going to go on our polling questions. Just a caveat...these are general scenarios. Somebody has got their answer already it looks like. These are general scenarios. Each situation is dependent on other facts of the case. The neat thing about our work is that every situation is different, and it actually makes our work really exciting because we never have a dull, same-old, same-old case. So I'm just putting that caveat out there.

The question is: "DCE receives a referral where the sponsor has misclassified coverage determinations as grievances. There are three cases that failed on audit, and the sponsor submits an IA showing that the number of enrollees either never had a coverage determination started or they never received their requested medication. Sponsor's root cause is they do not accept oral coverage determinations from enrollees. Does DCE: (A) consider this for a CMP; (B) consider this for a sanction; or, (C) decide not to pursue an enforcement action?

It looks like most people have answered the correct one...which is consider this for a CMP...noting that there are three cases that failed and also a potentially large number of enrollees that were impacted, and the root cause is that the policy of not accepting oral coverage determinations from enrollees. That shows us that this issue is systemic and substantial. There is also adverse impact here because the enrollee was either denied a coverage determination or didn't get their medication.

The next question is: "DCE receives a referral where the plan has denied claims from non-contract providers when the beneficiary was referred by the contract provider. Sponsor submits an IA showing that a number of enrollees were filled by the non-contract provider or cannot confirm whether the enrollees received bills from the non-contracted provider. Does DCE: (A) consider this for a CMP, (B) consider this for a sanction, and (C) decide not to pursue any enforcement action?

[Pause for responses]

It looks like most people are showing (A), which is correct...consider this for a CMP. Again, this is one where you have a clear violation. This is plan-directed care. Contract providers when they refer a beneficiary to a non-plan provider is plan-directed care. If we see an IA showing a number of enrollees either were not billed or we cannot confirm whether or not they were billed, we will consider that to be adverse effect or substantial likelihood of adverse effect.

Okay, DCE receives a referral where the plan had a high number of conditions in the area of CDAG, including IDS conditions where the plan couldn't produce universes for the audit team. There were also several concerning conditions in the Compliance Program portion of the audit. Does DCE: (A) consider this for a CMP, (B) consider this for a sanction, or (C) decide not to pursue any enforcement action?

It's leveling out, and the correct answer is (B)...consider this for a sanction. We have concerns here because it looks like there might be a

major breakdown in the CDAG area. There's also IDS conditions, where we can't even test whether or not the sponsor is following our requirements. Then we also have concerning compliance programs. So those things show us that there might be a sanction. Now, considering for a sanction doesn't mean that the sponsor is actually going to get a sanction. Like I said, we do a lot of investigation before we make that determination.

DCE receives a referral where the sponsor has failed to cover medications because they were imposing to quantity any limits that were more restrictive than what was approved on its formulary. Most enrollees in the impact analysis receive their medication within the same day. In addition, this issue had been identified by the sponsor quickly; and they had worked to fix the issue as soon as it was discovered. Also, beneficiaries who did not receive their medications were remediated quickly. Does DCE: (A) consider this for a CMP, (B) consider this for a sanction, or (C) decide not to pursue any enforcement action?

[Pause for responses]

The correct answer is (C)...decide not to pursue any enforcement action. Of course I am going to again caveat that this is just a general scenario. So like every situation, we have to look at the facts and circumstances. But in general because the sponsor is showing that they're quickly correcting, they're identifying issues, they're proactive in remediating beneficiaries, we're going to take that into consideration; and we would likely not impose a CMP.

All right, that is all for my presentation. I'm not sure; do we have time for questions?

Stacey Plizga: We sure do.

If anybody in our audience would like to present a question, please step to the microphone in the center aisle. Let us know who you are and where you're from.

[Pause for questions]

Derek Frye: Good morning...Derek Frye from the Bridgefield Group. Can you give us some examples of what you consider to be a high number of conditions and what investigation might look like before you decide if the sanction is needed?

Ann Levinstim: Well, a high number of conditions...there really isn't a specific number; but what we do is we will look at other cases where we've sanctioned organizations and we compare them. A high number of conditions is just one factor. If an organization had a high number of conditions and they were – I mean, we've seen situations where there are a high number of conditions and they're really not egregious violations. It's kind of like a dual thing; it's like the type of violation and also a high number of conditions. We wouldn't just say...this organization had a high number of conditions, the same number of conditions as this organization that was sanctioned.

We've seen situations where there are actually a low number of conditions because maybe the organization had a lot of IDS conditions which then ended up that we couldn't test anything, so there really wasn't a lot of conditions; but that's also a concern for us. It's really more looking at all of the data holistically, and that's really important for our work...taking all of the data, looking at the number of conditions, looking at the types of conditions, the number of beneficiaries impacted, looking at the organization as a whole, getting in contact with people and finding out what the history is like for this organization and then making our decision. So that's the answer I could give you.

Derek Frye: Thank you.

Stacey Plizga: Any other questions from our in-house audience?

[No response]

All right, so we will move to some of the questions we received from our virtual audience. The first one is: "I am curious about the enforcement of Medicare Advantage plans under the 60-day rule and how that is applied to providers."

Ann Levinstim: Yes, this was one of the ones that was received earlier; and this does not really apply to our work.

Stacey Plizga: Okay, the next question that we received: "Long-standing SNF audits have demonstrated sponsor deficiencies that impact very vulnerable beneficiaries, yet there has not been any related enforcement actions so far. Please advise when CMS will include SNF results in enforcement actions."

Ann Levinstim: Thank you, we are looking at that this year. We're going to be taking a look at more of the SNF-MOC conditions and seeing if potential actions could be taken. I do want to make note that if any other condition has impacted a SNF beneficiary, we will take an action; and we have been taking actions on MMPs, which also relate to our dual and vulnerable beneficiaries. Now that there's the audit, SARAG and other auditory program areas related to MMPs, we will be looking at those and taking actions against MMPs for that.

Stacey Plizga: Our next question: "How does CMS determine which beneficiaries to mitigate and which beneficiaries to include an aggravating factor for?"

Ann Levinstim: It depends on the circumstances. I gave an example of the mitigation; and like I said, we've removed the mitigating factor. When we look at mitigating now, we're actually removing the beneficiary...the sponsor getting the medication to that beneficiary on the same day. Another example would be that the misclassification of coverage determinations;

the sponsor misclassified initially, but then started the coverage determination really quickly, or that beneficiary got the medication within one day which they would have gotten anyway if the coverage determination hadn't started.

So we look at all of that when determining which beneficiaries are not impacted or the adverse impact was substantially mitigated.

As for aggravating factors, we have our standard aggravating factors listed out in our CMP methodology, and those are the ones that we use in order to determine which ones are aggravating.

Stacey Plizga: Okay, do we have any additional questions from our in-house audience?

[No response]

If not, I would like to thank Ann for providing an overview of the Analysis of Program Audits.

[Applause]

If you would like to evaluate this session, go ahead take out your cell phones and enter "A" in response to the question, "I would like to evaluate this question," or on your computer, iPad, tablet or smartphone. Go ahead and click that link and follow it.