Auto-Forwarding Coverage Determination Cases to the Independent Review Entity (IRE AF) – Policy, Monitoring and Compliance Panel

Amber Casserly, CM
Gregory Bottiani, CM
Leila Zaharna, CM

Amber Casserly: Hi, good morning. My name is Amber Casserly. I'm with the Medicare Enrollment Appeals and Group. And today we are going to discuss the current CMS guidelines for timeliness and effectuating cases. And my colleagues on the panel will be discussing the compliance and enforcement actions.

All right. So I'd like to start with our current CMS guidance, and this shouldn't be anything new. So the CMS Part D Effectuation Guidelines were created with input from stakeholders and was made through rulemaking. So for standard coverage determinations for Part D, you have 72 hours to notify the enrollee of the decision upon the receipt of the request, and for expedited the timeframes are shorter. It's about 24 hours to notify the enrollee.

For the next level of appeals for redeterminations, sponsors have no more than seven calendar days to notify the enrollee and no more than 72 hours for the expedited redeterminations.

If the case includes an exception request, the timeframes are those do not begin until the supporting statement is received by the Plan.

Again, these are the citations in the Regulations for this Guidance. And it can also be found in Chapter 18, Prescription Drug Benefit Manual.

So we'll see if this works. Oh good. Okay. So let's do a polling question. So it looks like it's a scenario. So let's say a Plan has missed the timeframe for making a decision and notifying the enrollee. When should the case be auto-forwarded to the IRE? We have A, 72 hours. B, within 24 hours of the expiration. Seven days. Or 14 days.

I don't know if I need to give you more time for that? Okay. All right. So it looks like you are split here, 50/50.

All right. So the correct answer was B. So if a sponsor fails to notify the enrollee of the determination and they fail to process it timely, the case should be auto-forwarded and is considered an adverse decision. This is the same for redeterminations and coverage determinations. It's within 24 hours of the expiration of the timeframe. And, again, the citations in our Regulations.

And another polling question. So here's another scenario. My plan has discovered that a large number of cases were approved. The beneficiaries were notified of the decision, but all the cases are effectuated past the adjudication timeframes. What should we do as a plan? Should you continue processing the cases normally? Should you auto-forward the cases to the IRE? Or should you notify your CMS Account Manager of the cases before sending them?

Give you a little more time here. All right. So it looks like maybe unsure.

So in this case it would be C.

So as a best practice, if your Plan has a large number of cases that you found to be untimely, instead of immediately sending these to the IRE, we ask that you please notify your Account Manager, and they will give you appropriate steps on what to do next.

Okay. So let's go to a Frequently Asked Question. So let's say my Plan has made timely oral notification for an adverse CD, but their written notification was made untimely, so in this case past the three days extension. Are we required to auto- forward this case to the IRE?

And in this case, yes. So even though the oral notification was made in a timely manner, the written notification was still considered untimely. So for this case you should auto-forward it.

All right. So I would like to pass the presentation on to my colleague, who will be discussing CMPs.

Leila Zaharna: Thank you, Amber. My name is Leila Zaharna, and I am a Pharmacist with the Medicare Oversight and Enforcement Group, Division of Compliance Enforcement.

So pursuant to Regulations, CMS has the authority to impose CMPs, or Civil Money Penalties, when a sponsor substantially fails to comply with a requirement related to coverage determinations, appeals, and grievances. CMS has determined that an excessively high Auto Forward rate demonstrates a substantial failure to comply with the requirements in subpart M, which are requirements related to grievances, coverage determinations, redeterminations, and reconsiderations. Therefore CMS is imposing CMPs on Plan sponsors with excessively high Auto Forward rates.

Beginning with data from the first quarter of 2017, CMS will begin issuing CMPs on a quarterly basis to sponsors that fail to meet the established thresholds. Based on the analysis of the previous year's data, CMS has set the 2017 outlier threshold at a rate of 15 or more Auto-Forwards per 10,000 beneficiaries per quarter. Small sponsors with enrollment sizes of less than 800 will be excluded from this analysis as well as those sponsors with fewer than ten IRE cases or appeals per quarter and those with fewer than ten Auto-Forwarded cases.

CMS will continue to analyze the Auto-Forward data, and may modify this threshold as needed on an annual basis to address changes in industry performance.

For any sponsor that meets the threshold criteria rate of 15 or more Auto-Forwards per 10,000 beneficiaries per quarter will receive a CMP. The first time a sponsor's contract meets the criteria and they receive a CMP, they get one consecutive quarter to improve their performance before being considered for another CMP. After that subsequent quarter, if they ever meet the criteria again, they will receive another CMP.

In addition, as Greg will be talking about in a few minutes, organizations may receive compliance notices for meeting different threshold criteria. The escalating level of compliance letters will continue for each consecutive quarter of noncompliance with the analysis beginning in the fourth quarter of 2016. Going through the compliance continuum can also lead to an enforcement referral for a CMP.

CMP notices will be posted on CMS's enforcement website. Sponsors have the right to a hearing with the Departmental Appeals Board Office listed in the CMP notice. The CMP notice provides an explanation of the appeals process and how to submit a request, which is due sixty days from the date of the notice.

CMS may impose a CMP up to $37,396.00 per enrollee adversely affected or with the substantial likelihood of being adversely affected. However, CMS expects to issue per-enrollee CMPs based on standard penalties that align with the public methodology that will be discussed in the CMP session tomorrow afternoon during the Audit and Enforcement Conference.

CMP considers excessive Part D IRE Auto-Forwarding to be a serious beneficiary access problem. If sponsors had processed and notified enrollees of decisions within the required timeframes, beneficiaries would not experience delays or denials of medications or financial harm for paying out of pocket for medications. Part D plan sponsors are expected to devote sufficient resources to internal or external processes that ensure coverage determinations and redeterminations are processed timely before receiving a compliance or enforcement action from CMS. Each sponsor should develop and implement processes that will help it make decisions timely and avoid high levels of cases that need to be Auto-Forwarded to the IRE. For example, sponsors should also anticipate the increased volume of requests at the beginning of each year and ensure that the appropriate number of staff are available to process the requests.

Next Greg will be discussing compliance actions for untimely cases.

Gregory Bottiani: Thank you, and good morning everybody. My name is Greg Bottiani, and I work in the Division of Benefits Purchasing and Monitoring within the Medicare Drug Benefit and C and D Data Group. Our division works with other CMS components on Part D compliance-related compliance matters among other things.

Now before getting into the specifics of IRE Auto-Forward compliance, I would like to take a minute to discuss compliance actions generally. The purpose of a compliance action ranges from making a sponsor aware of its noncompliance to something more immediate, such as requesting a corrective action plan. In the most urgent of circumstances, cases are referred to the Oversight and Enforcement Group for sanctions or enforcement actions. The hierarchy of compliance actions begin with a notice of noncompliance, followed by a warning letter, then a warning letter with a request for a business plan, and finally a corrective action plan request.

That's the order of issuance for some of our regular monitoring efforts, but we may escalate when necessary. For example, when a sponsor is so far an outlier when compared to other sponsors that an escalated level of compliance is warranted. Also, in order to avoid penalizing a sponsor twice for a single instance of noncompliance, as a general rule, a compliance action is not issued when there is a sanction or enforcement action for the same issue during the same time period.

I would now like to explain the compliance protocol for excessive Auto-Forwards.

In the 2017 Call Letter, CMS announced that it would be taking compliance actions against sponsors with an inordinate rate of IRE Auto-Forwards. So in addition to the automatic CMPs, CMS has and will continue to issue compliance notices to sponsors whose Auto-Forward rates are excessive but do not warrant an automatic CMP. In other words, for these sponsors, there is still an opportunity to take corrective action prior to a CMP referral.

In a December 16, 2016 HPMS memo, compliance thresholds were announced. We also stated that if modified for 2017, it would be based on

an analysis of the data from the previous year and that moving forward the compliance thresholds may be modified annually based on an analysis from the data of the previous year in order to address changes in industry performance.

The thresholds for 2016 were ten or more appeals, ten or more Auto-Forwards, and an Auto-Forward rate of ten or more per 10,000 beneficiaries. Understanding that we had not provided notice of the thresholds for which we were issuing compliance notices in 2016, we decided to modify our typical compliance escalation continuum. We looked at data by contract by quarter and issued a single notice of noncompliance to any sponsor that exceeded the threshold in any of the first three quarters of 2016.

Then, when fourth quarter data became available early in 2017, we issued a notice of noncompliance to any sponsor that exceeded the threshold in that quarter. We did not escalate the level of compliance action at this point.

So after reviewing the 2016 data, we decided to use the same compliance criteria for 2017. We basically had three options, and we went with the third. First, if we had lowered the number of Auto-Forwards or the Auto-Forward rate, it would capture contracts that had relatively few Auto-Forwards and thus discourage sponsors from utilizing this important beneficiary protection.

Second, if we raised the number or rate of Auto-Forwards, we would bump up against the criteria for an automatic CMP, and thus there wouldn't be much difference between a sponsor that received a notice of noncompliance and one that incurred a CMP.

The third option was to retain the 2016 criteria, with which we had already seen improvement in the number of cases being Auto-Forwarded. So we will continue with a quarterly analysis and retain the 2016 thresholds. However, escalating actions will begin with the first quarter analysis. So a sponsor that was noncompliant in the fourth quarter of 2016 and is again noncompliant in the first quarter of 2017 will receive a warning letter for that first quarter of 2017 noncompliance.

The next two slides repeat and build on what Leila discussed a few minutes ago. In any given quarter, a sponsor with ten or more appeals, ten or more Auto-Forwards, and an Auto-Forward rate of 15 or more per 10,000 beneficiaries, will receive an automatic CMP. That sponsor will have one quarter to improve their performance before receiving another CMP.

The other way to receive a CMP is through the compliance escalation process, and the CMP is the next step after receiving a corrective action plan request.

Here you see the different types of compliance actions and when they would be issued. Again, the criteria for receiving a compliance action are ten or more appeals, ten or more Auto-Forwards, and an Auto-Forward rate of at least ten but fewer than 15 per 10,000 beneficiaries.

Escalation is based on a compliance action in either of those previous two quarters. So, for example, a sponsor that received a notice of noncompliance for the first quarter of 2017, is compliant in the second quarter, and again noncompliant in the third quarter would receive a warning letter for that third quarter noncompliance.

If that same sponsor were compliant in the second and third quarters and again noncompliant in the fourth quarter, they would receive a notice of

noncompliance for the fourth quarter. And I would like to note that as far as I am aware there has only been one instance of a sponsor actually moving through the escalation process for a referral to a CMP in the history of the Part D program. So it is an extremely rare occurrence, and we don't expect to see that happen.

Here we have a polling question. A sponsor that has a rate of ten Auto-Forwards per 10,000 enrollees for four consecutive quarters and does not meet any of the exclusion criteria will be issued an enforcement action in the fifth quarter if the rate is eight Auto-Forwards per 10,000 enrollees. A for true or B for false.

I think you guys have this. Yes, that's the correct answer. The sponsor is now compliant because their rate was eight per 10,000 beneficiaries.

Now in order to avoid a CMP referral, they would also need to be compliant in the following quarter, so the sixth consecutive quarter.

There we go.

So we have some good news for everybody. Since we initially raised the issue in the 2017 Call Letter, the trend is toward fewer Auto-Forward cases, which means that sponsors are meeting the adjudication timelines and beneficiaries have the information needed to move forward with their health care.

I would again like to reiterate the conclusion that Leila stated earlier that CMS considers excessive Part D IRE Auto-Forwarding to be a serious beneficiary access issue and that Plan sponsors are expected to devote sufficient resources to internal or external processes to ensure coverage determinations and redeterminations are processed timely before receiving compliance or enforcement actions from CMS.

This slide shows a list of contacts. If you have questions about compliance or enforcement actions, you can reach out to the PartD_monitoring mailbox for questions about Part D timeliness, and Auto-Forward policy questions you can reach out to the Appeals mailbox, and for questions related to CMPs you can reach out to the Parts C and D CP Guidelines mailbox.

And with that we'd be happy to take any questions you might have.

Stacey Plizga: Okay, if anybody from our in-house audience has a question, please step to one of the microphones in the center aisle. Introduce yourself, tell us where you're from, and then go ahead with your question.

Derek Frye Hey, Derek Frye from the Burchfield Group. I just had a question. In your analysis you looked at for Q1 2017 approximately how many sponsors would have fallen in the threshold that they would have received either a warning or –

Gregory Bottiani: We don't want to get into the numbers of how many sponsors fell into – or were above the threshold, so that's something that we're not inclined to discuss today. I hope you understand that, but (inaudible).

Derek Frye: Sure.

Babette Edgar: Hi. Babette Edgar from Blue Peak Advisors. Amber, you had a Frequently Asked Question that even if a plan did oral notification timely, yet their written notification was late, that those cases need to be Auto-Forwarded to the IRE. What if those cases are all approvals and it does not fall within the 24-hour period?

Amber Casserly: If it does not fall within the 24-hour period, so we do have an exception in our manual guidance for cases that are approvals that have missed the effectuation timeframes. These are for fully-approved cases, though. So if it is not an approval and it has missed the adjudication timeframes, is that what you are saying?

Babette Edgar: If it is an approval –

Amber Casserly: It is an approval.

Babette Edgar: It missed the written notification, the three days after the oral.

Amber Casserly: Right.

Babette Edgar: And it is not within 24 hours.

Amber Casserly: Right. So I would refer you to 30.1 in the Chapter 18 Manual, and we ask plans to use this sparingly. They are to not forward it to the IRE. They can go ahead and approve it, but not Auto-Forward it. But, again, this is a sparingly-used exception.

Babette Edgar: And that is even if it is outside of the 24 hours?

Amber Casserly: So we do offer a timeframe of 24 hours in the Guidance. If it is an approval, I would say reach out to your Account Manager and ask them for what steps to take. You know, if it's not super far out of the timeframes, they may tell you to go ahead and approve it.

Babette Edgar: Okay. Thank you.

Travis Sutphin: Hi. Travis Sutphin from Emerald Health. Does CMS have a position on what is "sparingly," like the percentage?

Amber Casserly: Right. So, again, based on facts and circumstances of the cases, we don't have a definitive definition for "sparingly." And, again, it would be a case-by-case basis.

Audrey Mahoney: Hi, Amber, it's Audrey Mahoney from Aetna. One of your FAQs indicates that in cases where the Plan makes timely oral notification but the letter is issued after the timeframe, those cases should be Auto-Forwarded. However, we understood that in the case of successful oral notification, that we had three calendar days. Is that accurate?

Amber Casserly: That's correct. In the FAQ, that would be for an adverse decision.

Audrey Mahoney: Oh. I thought that we had three calendar days for both favorable and adverse.

Amber Casserly: Oh, no, I'm sorry. For the Auto-Forward, the FAQ for Auto-Forwarding –

Audrey Mahoney: Okay.

Amber Casserly: The example is for an adverse.

Audrey Mahoney: Okay. All right. Thank you.

Amber Casserly: Yes.

Stacey Plizga: Okay, any other questions from our in-house audience?

Okay. I do have a couple questions here that we received from our virtual audience, so I will go ahead with those. The first one, should Plan sponsors Auto-Forward coverage determination cases to the IRE when the member notification was timely but the provider notification was not?

Amber Casserly: Okay, so in these cases, our Guidance, they should not forward these cases to the IRE.

Stacey Plizga: Okay. The next question that we received, if a determination was made within the required timeframes but oral notification was not possible and the written notice was not mailed within the timeframe, is it correct that these cases should be Auto-Forwarded to the IRE regardless that our determination was made within the required timeframe?

Amber Casserly: If a Plan makes a fully favorable decision within the 24-hour timeframe after the adjudications timeframes have expired, then the case does not need to be forwarded to the IRE.

Stacey Plizga: Okay. The next question I have, for standard redeterminations, can you please clarify if a Plan has seven or eight days from the Received Date to process? Our interpretation of the Chapter 18 Guidance has been that the Day One is the day the request is received and we have six days from the Received Date to process this request. We have heard that during a program audit, the auditors considered the day the request was received as Day Zero, then the Plan had seven days from the Receive Date to process the request. Which is correct?

Gregory Bottiani: So for a standard redetermination Part D, you have seven days from the date of receipt to issue a decision that is to notify the enrollee of the decision. The request is deemed received as soon as your organization gets the request and the clock starts. However, for purposes of calculating timeliness for counting days, the first day is not counted until a full day has passed. Therefore, if you receive the request on January 1st at 2:00 p.m., you would count January 2nd as Day One. Seven days past January 1st would therefore be January 8th, at which point your redetermination timeframe would be over.

Stacey Plizga: Okay. Thank you. The next question that I have here, related to 2016 compliance activities, based on current availability dates for 2016, CMS issued compliance notices to sponsors that had ten or more IRE cases appeals, ten or more Auto-Forward cases, and an Auto-Forward rate of ten or higher per 10,000 members during any quarter in 2016. Please confirm that the phrase "ten or more IRE cases appeals" does not refer to upheld appeals sent to the IRE per CMS Guidance outlined in Section 80.3 of Chapter 13 of the Medicare Managed Care Manual. We do not believe CMS intends to penalize Plans for following the Guidelines to forward timely uphold decisions to the IRE.

Gregory Bottiani: That is correct. Chapter 13 does not apply.

Stacey Plizga: That wasn't fair because the question was really long and your answer was really short!

Gregory Bottiani: That's what I'm known for.

Stacey Plizga: All right. And I have one last question here. Does the analysis exclude cases that a member requests to go to the IRE?

Gregory Bottiani: It does.

Stacey Plizga: I think I'm going to lose this one.

Okay, any additional questions from our in-house audience? Op, we have one more. Please, come up to the microphone.

Britton Whitbeck: Sorry. Britton Whitbeck from Lumeris. So I wanted to follow up. There was a question about attempts to make oral notification unsuccessful.

Stacey Plizga: Yes. I'm sorry. Could you lift the microphone, because you're rather tall. So we can hear you. Thank you.

Britton Whitbeck: Britton Whitbeck from Lumeris. So there was a question about unsuccessful attempts for oral notification. I just wanted to confirm that three good-faith efforts satisfies the oral notification as long as you issue the written notification within three calendar days? Is that correct?

Amber Casserly: Yes. And can you also just send that question in writing to the Part D Appeals mailbox?

Britton Whitbeck: Yeah.

Amber Casserly: Thank you.

Britton Whitbeck: Okay.

Thank you.

Stacey Plizga: Thank you for your question.

Okay, if that is it from our audience, then I would like to thank Amber, Gregory, and Leila for providing an understanding of CMS's Auto-Forward policy for untimely cases.

Okay. It is time for our first session evaluation. So please take out your phones and text your response or go to the Poll EV link on your Smartphone, tablet or computer. Enter A for you would like to evaluate the session and then follow the prompts to start the survey. Go to the next one, and finally indicate when you are finished.

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CMS has made several changes to the Summary of Benefits since CY2015. Our next presenter will provide a high-level overview of the gradual changes that have occurred and will cover the requirements of the current Summary of Benefits and note any upcoming changes for CY2018. From the Division of Surveillance, Compliance, and Marketing, please help me welcome Elizabeth Jacobs.