

Centers for Medicare & Medicaid Services  
Special Open Door Forum:  
Part D Appeals Process  
Moderator: Jill Darling  
December 20, 2016  
2:00 p.m. ET

Operator: Good afternoon. I would like to welcome everyone to the Special Open Door Forum - Part D Appeals Process Conference Call. After the speakers' remarks, there will be a question-and-answer session. At that time, you may press "star" followed by the number "one" on your telephone keypad to ask a question.

To withdraw your question, you may press the "pound" key. Thank you. Jill Darling, you may now begin your conference.

Jill Darling: Thank you, (Anne), and -- excuse me -- (Ian). Good morning and good afternoon, everyone. Thank you for joining us today. My name is Jill Darling in the CMS Office of Communications. And welcome to today's Special Open Door Forum - Part D Appeals Process.

Before we get into today's presentation, I just have one brief announcement for you. This Special Open Door Forum is not intended for the press and the remarks are not considered on the record. If you are a member of the press, you may listen in, but please refrain from asking questions during the Q&A portion of the call. If you do have any inquiries, please contact CMS at [press@cms.hhs.gov](mailto:press@cms.hhs.gov). And, also, we do appreciate your patience getting into today's call. So, as always, we thank you. So, I will hand the call off to Staci Paige.

Staci Paige: Hello, good morning and good afternoon, everyone. My name is Staci Paige, and I am joined by my colleague Coretta Edmondson. And we are with the Medicare Enrollment and Appeals Group in the Division of Appeal Policy with CMS. We would like to welcome you all to our call today, and thank you very much for joining us.

The purpose of this Special Open Door Forum is to allow stakeholders to give feedback on the current Part D appeals process. Consistent with Section 704(f)(1) of the Comprehensive Addiction and Recovery Act, or CARA, CMS is seeking input on key aspects of the current Part D appeals process from major stakeholders.

CMS will consider this feedback for potential improvements and future policy changes to make the Part D coverage determination, appeal and grievance processes more understandable and accessible for Medicare beneficiaries. For today's call, we will introduce a topic related to the Part D appeals process, and then open the lines for comments and their recommend improvements.

These topics include the grievance process; initiating a coverage determination including exception requests, redetermination and timeframes for reaching a decision; reopening some notice requirements; overall responsibilities of the beneficiaries and the Part D sponsors; the additional levels of appeals; and, features of the Part C appeal process that work well and can potentially be applied to the Part D appeals process to enhance beneficiary access.

Please be aware this is a listening session where participants will provide comments only. CMS will not be answering questions related to the Part D appeals process. You may send questions and additional comments to our Part D appeals mailbox at [partd\\_appeals@cms.hhs.gov](mailto:partd_appeals@cms.hhs.gov).

Now, I will turn it over to my colleague Coretta Edmondson, and we will start with our first topic.

Coretta Edmondson: Good morning, good afternoon. This is Coretta Edmondson. We will begin the conference discussing the appointment of representation. The first question is, are there any suggestions for improvement related to representatives filing requests on behalf of an enrollee? (Ian), if you could open up the line for comments that would be wonderful.

Operator: At this time, I would like to remind everyone, to ask a question, please press "star" followed by the number "one" on your telephone keypad. Again, to ask

a question, please press “star” followed by the number one on your telephone keypad. There are no questions or comments at this time.

I apologize, one just queued up. So, we now do have a question from the line of (Steven Silvern), who is an attorney representative claimant. And your line is open. Just went away. Hold on just a second. I apologize for the technical difficulty. All right. Please press “star” and the number “one” again and I will open your line up again.

Sorry for the mistake. Again, (Steve Silvern), to queue up again, please press “star” and the number “one.” We had a slight technical difficulty.

Coretta Edmondson: OK. We will go ahead and move on to the next section, which would be grievances. Are there specific concerns or suggestions for improvement related to the grievance process? This would include, but not be limited to, quality of care complaints, timeframes for resolving grievances, as well as guidance on distinguishing grievances from coverage determination. Please open up the line for comments.

Operator: And please press “star” followed by the number “one” to ask your question or make your comment.

And there are no questions or comments now.

Coretta Edmondson: OK. The next section would be coverage determination. Please discuss concerns or suggestions for improvements related to the coverage determination process. This would include adjudication timeframe; exceptions, which would include tolling for the prescriber supporting statement; as well as notice to the enrollees and/or prescribers. Please open up for questions or comments.

Operator: Again, please press “star” followed by the number “one” if you have a question or comment.

And there are no questions or comments.

Coretta Edmondson: OK. I just want to confirm. There are no comments or questions regarding the coverage determination process?

Operator: Again, to ask a question or to make a comment, please press “star” followed by the number “one”. And there are none.

Coretta Edmondson: OK. We will move on to the redetermination process. Are there any specific concerns or suggestions for improvements related to the redetermination process such as the adjudication timeframes or notice to enrollees or prescribers? Please open up the line.

Operator: And, again, if anyone has a question or a comment, please press “star” followed by the number “one” on your telephone keypad.

And there are no questions or comments.

Staci Paige: Hello, again, the purpose of this Special Open Door Forum our stakeholders to give feedback on the current Part D appeals process. So, as the topic comes up, if you have any comments or suggestions regarding our process, please unmute your line and make a comment.

Coretta Edmondson: So, the next topic we will be asking for comments on would be the reopening process. Again, are there specific concerns or suggestions for improvement relating to the current reopening process?

And this would be -- I know we are discussing reopening - but if anyone needs to go back to redeterminations or coverage determinations to make any suggestions or provide any comments. Thank you, we can open up the line.

Operator: Again, please press “star” followed by the number “one” to ask a question or make a comment.

And there are no questions or comments.

(Multiple Speakers)

Coretta Edmondson: Hello, this is Coretta. If anyone is having any difficulties with commenting, please send an e-mail into the address that Staci Paige had provided earlier as well as is in the notification, the HPMS memo that was sent in regarding this meeting. So, it would go to the Part D mailbox, which is [partd\\_appeals@cms.hhs.gov](mailto:partd_appeals@cms.hhs.gov).

We will move on to the next topic, which would be recommendations for enhancing understanding of the appeals process and the overall responsibilities of enrollees, representatives and prescribers in this process. Please open the line up, thank you.

Operator: And please press “star” followed by the number “one” on your telephone keypad to ask a question or make a comment.

Jill Darling: Hi, everyone. This is Jill Darling. We do apologize. There is some technical difficulties. We are getting your e-mails through the Part D appeals inbox. So, (Ian), there are some issues. No one -- they are trying to get a comment in, but it is not working on their end.

Operator: I do apologize. I will make sure to -- make sure this is fixed as soon as possible. Sorry about the technical difficulty here.

Female: Should we wait for them; because otherwise we can't really do anything?

Female: All right, (about how) long does it take?

Female: OK, I don't know.

(Multiple Speakers)

Female: ...separate now. Is that possible?

Female: I don't know (that that will) (Off-Mic)

(Multiple Speakers)

Jill Darling: Again, this is Jill Darling. We do apologize with the technical difficulties. (Ian), if you have a moment, can we go into the post - subconference so we

can discuss the technical difficulties? Again, thanks, everyone, for your patience.

Operator: Thank you. I will bring you to the post conference momentarily and I will put our main conference on music hold. Thank you.

And we are now ready to resume our conference.

Coretta Edmondson: OK. Thanks, everyone, so much for your patience. So, we will start from the beginning as far as the questions and comments are concerned. We will begin again with the appointment of representation. Are there any suggestions for improvement related to the representatives filing request on behalf of the enrollee? Please open up for comments or suggestions, (Ian).

Operator: OK. It is "star" and the number "one" to ask a question. And everyone who has pressed "star" and the number "one" now appears to have on-list. So, there is quite a few -- 48 - in queue. So, let us start with the first one, Deb Pertain from Presbyterian Health. Your line is open, please go ahead.

Deb Pertain: I need some clarification.

Operator: Deb Pertain.

Deb Pertain: Thank you.

Operator: OK. And, next up, we have (Bethany Fitch) from Gateway. Your line is open, please go ahead. (Bethany Fitch) from Gateway, your line is open.

(Bethany Fitch): That was an error.

Operator: No problem. We can move on. (Lauren Bray) from CVS Health, your line is open.

(Lauren Bray): I'm sorry I also hit that in error.

Operator: OK, and next up we have (Steven Silvern). And that was the first one we saw. Your line is open, please go ahead.

(Steven Silvern): My main comment goes to the claims review process. But, there were complications on ending up being able to speak with personnel at Maximus -- directly -- after my wife had sent in, in writing, the request that I would be able to represent her and speak on her behalf.

Apparently, there is a specific form that is required as opposed to a statement, "So and so is my representative, please speak with him" and a signature. That did cause delays and problems. I wonder if the agencies would simply look at the content and the request of the claimants rather than insisting on a specific form.

Coretta Edmondson: Were there any more comments?

Operator: There are several more. I wasn't sure if you were going to give a further response to that. We can move on to the next one if you like. And your next question or comment is from (Joe Tall) from Northern California Department. Please go ahead.

Again, (Joe Tall), your line is open. OK, and we can move on. The next line is from a (Stephanie Erickson) with Cambia Health Solutions. Your line is open.

(Stephanie Erickson): That was -- that was an error as well.

Operator: I do apologize, we will move on then. Our next question is from (Hamera Cambusano) from Humana. Your line is open.

(Hamera Cambusano): Sorry, that was an error as well.

Operator: That was an error, OK, moving on. Our next question or comment is from Jeff Reid with Sharp HealthCare. Your line is open.

Jeff Reid: Yes, I was just curious mainly what audience was contacted for this? It does sound like there is too many comments. So, I was wondering how the information was put out, is it just the Listserv?

Erica Sontag: Hi, this is Erica Sontag from the Division of Appeals Policy. We did send out the Listserv announcement. But, we also sent out memorandums through the Health Plan Management System to all of our stakeholders.

Jeff Reid: OK.

Erica Sontag: And, again, if people were not able to attend the listening session, they have the opportunity to comment through our Part D appeals mailbox.

Jeff Reid: Did it go through the ombudsman programs? (Many here) ombudsman?

Coretta Edmondson: No, we don't believe it did go through the ombudsman program.

Jeff Reid: OK.

Coretta Edmondson: Are there any other specific concerns or questions or suggestions for improvements relating to the appointment of representative form? If not, then we will move to the next area. The next area would be grievances.

Are there specific concerns or suggestions for improvement related to the grievance process including, but not limited to, quality of care complaints, timeframes for resolving grievances, as well as guidance on distinguishing grievances from coverage determinations? We welcome comments at this time.

Operator: And, again, please press "star" followed by the number "one" to add yourself to the question queue. Again, it is "star" followed by the number "one". OK, and I will open the most recent line to make sure that this is one for us. Lisa Hogan, from WellCare Health, your line is open.

Lisa Hogan: (Questions, right). There is a timeframe.

Operator: Lisa Hogan, your line is open.

Lisa Hogan: Yes.

Operator: Did you have a question or comment?



Lisa Hogan: Yes, sir, I do. So, for this particular topic, we were wondering why the -- or we are curious if the grievance timeframe could be expanded to include a stat timeframe and the situations where that might be applicable.

Coretta Edmondson: OK, again, at this time, we are only accepting comments and suggestions. This is a listening session. So, we will not be answering questions at this time. So, if you have suggestions, please provide those suggestions.

Lisa Hogan: Yes. Thank you.

Operator: And the next line up is Christine Peabody from MedImpact Healthcare. Your line is open for your comments or suggestions.

Christine Peabody: Hi, thank you for allowing me to talk. One of the things that we have noticed is that we feel like the definition of a grievance needs to be a little more clear and concise. We find that where a beneficiary will call our contact center or speak to a plan representative, if they even breathe concern, it is deemed as a grievance.

And it is just maybe a lack of information or knowledge. And that is viewed as dissatisfaction with the plan. So, if we could get more information regarding the definition of what a grievance really is, what determines to be a grievance that would be helpful? And if I could, I wasn't able to go back to the AOR.

Regarding the AOR, I know the guidance says that one per grievance coverage determination or appeal is required for each request. It would be helpful, and I think especially more beneficiary-friendly, if the representative doesn't change, if we could continue to use that same signed form.

That would be a little bit more friendly to the member -- to our customers. If a representative changes, then, obviously, we would need a new form. This is particularly helpful in the case of guardianship and power of attorney or conservatorship. So, those are my suggestions and comments. Thank you.

Operator: OK.

Coretta Edmondson: Thank you for those comments.

Operator: And our next line to open for questions, comments or suggestions is Mona Mahmoud from PCMA. Your line is open.

Mona Mahmoud: Hello, this is Mona Mahmoud with the Pharmaceutical Care Management Association, which represents America's pharmacy benefit managers. I appreciate the opportunity to provide our views on the Part D process - for the appeals process in general.

I just want to say that we support the goal of streamlining the Part D appeals processes including aligning the Part D appeals requirements with those in Part C to ensure accurate and complete appeal submission. We do look forward to submitting our comments on the Part D appeals process and opportunities for alignment with Part C and other improvements to simplify and improve the Part D appeals. Thank you.

Jill Darling: Hi, everyone. This is Jill Darling. If you are currently waiting in the queue to make a comment or suggestion or will have comments or suggestions after each topic that is presented, please speak up. And if you are on speakerphone, please take yourself off. Thank you.

Operator: And our next comment or suggestion comes from the line of Stacy Sanders from Medicare Rights Center. Your line is open.

Stacy Sanders: I actually had a comment about future question on coverage determinations. Nothing on grievances.

Operator: OK, moving on. Our next line to check is Luis Cerda from MCS for your comment or suggestion. Your line is open.

Luis Cerda: Hi. Actually, I had one question, but it was about reopenings and notice requirements. I don't know if I have a chance to do that now or shall I wait until we get to that section.

Coretta Edmondson: You may go ahead and ask or make your comment at this time, thank you.

Luis Cerda: Well, actually, we have had like one or two cases that have been reopened. And we believe that we are following the due process when we contact the providers to get all the necessary information that we need in order to make a decision whether to deny or go through with the appeal.

And when we deny, we understand that we have done everything that we possibly could to contact that provider to get all the information that we need. But, sometimes, they just don't do that, they just don't provide that to us. We have had like one or two cases that have been reopened.

And we understand that it is because somehow the information from the provider got through the IRE - and either the provider contact the IRE or the IRE contact the provider - and they gave some information that they did not give to us. And then, we run the risk that that case might be overturned, and it looks like we did not do our due diligence, that we did not provide a service to the member because we did not want to do so when that is not the case.

And we were wondering if there is any way that whenever that happens, the IRE can actually communicate with us and say, "Hey, you know, we received this information from the provider. Have you received this information from the provider? And if you haven't, then here it is. So, maybe you can actually reassess again the case, the appeal, and maybe you will find that you can actually go through with the appeal and you don't have to deny it."

Coretta Edmondson: OK, thank you for that comment. If you do have -- again, if you have suggestions for improvements, you can also send that information to the Part D mailbox.

Luis Cerda: OK, thank you.

Coretta Edmondson: Are there any more comments or suggestions regarding grievances?

Operator: We do have the line open now for Julie Weng from Centene Corporation, please go ahead. Again, Julie Weng, your line is open, Centene Corporation.

Male: We had a question, not a comment, regarding reopened cases and whether or not if a case is originally dismissed that is sent to the IRE but then reopened,

does that case also factor into the timeliness measure or is it only applied to the reviewing appeals measure?

Coretta Edmondson: Thank you so much for that question. At this time, we will not be answering any questions. But, please feel free to submit that question, again, to the Part D mailbox. It is [partd\\_appeals@cms.hhs.gov](mailto:partd_appeals@cms.hhs.gov).

Male: Thank you.

Coretta Edmondson: Again, I just want to stress that this is a listening session and we will not be responding to any questions during the forum. But, please feel free to send those questions to the mailbox. We are accepting recommendations and comments and suggestions for improvements to the Part D appeals process including grievances as well as appointment of representation.

So, at this time, we will go ahead and move forward and start asking for suggestions for coverage determinations. Are there any concerns or suggestions for improvements relating to coverage determination process such as the adjudication timeframe; exceptions, including tolling for the prescriber supporting statement; or notice to the enrollees or the prescribers? And we can open that up for suggestions at this time. Thank you.

Operator: And, first, we have Gil Solomon from Blue Shield of California. Your line is open.

Gil Solomon: Hello. I wanted to reiterate the comment earlier about the reopening or when member beneficiary appeals and gives information that we have not obtained if it looks like we have done our due diligence. On the Part C side, often they will send us an inquiry and ask us to answer questions.

So, I would reiterate that would help us out because we are trying to do a good job. The other comment on this process; we have had reviews come up, particularly when we did sleeping medicines, which we were cautioned about because of our dangerous drugs in the elderly. And we have had some other drugs where it was a safety issue.

And the reviewers seem to be more in the mode of we are denying and they want to approve as opposed to helping us out with some of our safety concerns. And they were, in some cases, allowing prescribers to give doses that were beyond what the FDA approved for some of these dangerous drugs.

So, the comment would be to somehow consider alignment with some of the Medicare dangerous drugs. So, we would have that guidance from Medicare but, then, we would get overturned by our Part D reviewer.

Coretta Edmondson: Thank you for your comment.

Operator: Our next comment comes from the line of (Dawn Mathson) from BCBS Minnesota.

(Dawn Mathson): Hi, thank you. We actually have two comments. One, regarding the auto forward process, we often find that we could resolve a request after the adjudication timeframe has expired, yet before the IRE is able to do so.

Our recommendation would be continued reporting of the untimely cases yet the ability to complete the review of the coverage determination or redetermination to expedite member access to the medication and decrease administrative burden to the plan and the IRE.

The second comment that we want to make is around tolling. And we would recommend expanding the ability to toll a request for both exceptions and non-exceptions cases in order to evaluate all available clinical information. I think we find that in non-exception cases, the physician's statement is equally as important to receive and review against the information for the member's case.

Operator: And our next comment comes from the line of Lisa Hogan with WellCare Health. Your line is open.

(Ron Patel): Hi. This is (Ron Patel) from WellCare Health Plans. Thank you for taking this call and having this forum. We actually have three comments as well. Our three comments -- and I wanted to agree on that last comment about expanding the tolling process to non-exceptions.

The standard 24-hour to 72-hour timeframe does make it difficult to obtain the required medical documentation. And we have recently seen the outreach attempt guidance that CMS has given as well for best practice. And expanding that tolling would allow us to better serve our members in that regard.

Additionally, the second comment we have is to help us better define the -- and it is a recommendation -- but, better define the exception process. So, how to identify an exception versus an issue. I think a little bit more black and white would be helpful in that regard to avoid having misclassifications and avoid mistolling any cases where they should truly be issued.

And then, finally, I believe the last comment we have here is postmarking of member notification correspondence or letters within the 24-hour and 72-hour compliance timeframe. It does make that very difficult to accomplish. We do carry out our outbound notification phone call to expand that timeframe to three days.

But, the expectations to have a letter extracted, sent to a print vendor and put into the mail stream within a 24-hour stat timeframe does make it difficult to meet that. And, so, we are obligated to make that call to expand the timeframe. So, we would recommend finding an improved process for that as well, if not to expand it to three days regardless. Thank you for the time.

Operator: And there are no further questions or comments at this time.

Coretta Edmondson: OK, thank you. We will go on and move to redeterminations. Are there specific concerns or suggestions for improvement related to the redetermination process, again, such as adjudication timeframes or notice to the enrollee and/or prescriber?

Operator: (Chad Dober) from ETNA -- or Aetna, your line is now open.

(Chad Dober): Thank you. This one is actually applied to both C.D. and R.D. and is a little more global. But, I am thinking around Chapter Six, Medically Accepted

Indications. There are essentially two drug decks in HFS. And they really haven't been updated since Part D's inception.

And I am -- the comment that I would have would be to consider expanding or to consider medically accepted indications for Part D drugs as well as potentially consider some patient members that are in life-and-death situation, last ditch efforts for treatment that off-label use may be practical but is not approved because of compendia and medically accepted indication not supporting it.

And so, sometimes, those patients don't get the drugs that might help them in an off-label indication. So, just some things to consider related to that piece.

Operator: Our next comment comes from the line of (Elisa Palefsky) from Priority Health.

(Michael Wan): Yes, this is (Michael Wan) with Priority Health, apologies. I was trying to get in for the coverage determination section. I wanted to echo a couple of the comments that were made by previous plans regarding the physician outreach. Having to reach that office three times, especially in a 24-hour review, can be difficult.

And that gets compounded, especially over weekends and holidays when offices are not open, with the guidance that was just issued this fall dictating that a clinical reviewer, whether that'd be a plan physician or other qualified professional, making that third phone call.

We have discovered that - or found this process to be quite burdensome administratively. Additionally, it has been very low value add. I think that the success rate of getting that information with the clinical reviewer calling is less than 10 percent.

And then, even, like I said, on weekends making a third phone call - when we already know that the office or provider is unavailable or closed - and we basically just now delayed providing the member with either appeal rights or some other decision before getting there.

And then, lastly, the last comment that was made in regard to medically accepted indications -- I wanted to bring up the issue of potentially using immunosuppressants for members that only qualify under Part D because of when their transplant was done, not all immunosuppressants are medically accepted in all organ transplants.

Specifically, I want to highlight lung transplants. We've had several members that were -- based on the way the medically accepted indication regulations are written, we were unable to provide coverage for the medication they had already been stable on. Thank you.

Operator: Our next comment comes from the line of (Chris McClure) with Blue Cross Blue Shield.

(Chris McClure): Hi, I was actually to get in during the coverage determination portion. However, my sentiment was the same as some previous commenters around the tolling, especially over weekends and holidays where we receive the request right before the close of business hours.

And then, essentially, you have to make three attempts that we know we are not going to be able to reach anyone. So, if there was a possibility to adjust those tollings for the non-exceptions especially over the weekends and certain holidays, it would be beneficial and better use of not only the plan's time but potentially more in favor of the beneficiary.

Operator: And our next comment comes from the line of Georgia Burke at Justice in Aging. Your line is open.

Georgia Burke: Yes, thank you. I wanted to talk about beneficiary notification and, particularly, issues of concern for limited English proficient beneficiaries. Both the notice at the pharmacy -- I think, currently, it is only available in English and Spanish, and it would be very helpful to have it available (and to have a model notice) in other languages as well.

And just more generally, for coverage determination notices at all of the plan levels, if we look at the 1557 regulations that HHS put out and also at the



general requirements under Title VI, these are critical documents. They are complex. They relate to beneficiary rights.

And looking at the reasoning on what documents are appropriate for translations that were laid down in the 1557 regs and commentary, it seems to us that these are the kinds of documents that should be translated for individuals who are limited English proficient. And I'd also like to make one other point on the language access, which is that for all of these notices as well, there should be the multi-language insert that is required under 1557.

And, I think, it would be very helpful for CMS to clarify to the plans that that insert should be included, again, because these are definitely significant documents since they affect beneficiary rights. So, that's the issue I wanted to talk about, thank you.

Operator: Our next comment comes from the line of Heather Carper from Geisinger Health Plan. Your line is open.

Heather Carper: Hi, thank you. Yes, this is Geisinger Health Plan. And we would definitely like to provide some comments about the coverage determination and redetermination process. We would like to concur with the other plans that have provided some comments about the expedited coverage determination timeliness standard.

And we also agree that the 24-hour turnaround time is -- does create some barriers for our ability to obtain the needed clinical to make effective decisions. So, we would like to agree with those comments. As well, we'd also like to speak about the redetermination process.

And we have a couple of comments about the external review process, which is the Maximus Part D QIC process and the fact that it is much different than the current Part C process; the way the external review process is completed. For the Part C process, as many of you know, it is a continuous appeal decision-making process.

So, the members -- the beneficiaries do not typically have to get involved in that. We are required to send those cases external. And, conversely, for Part

D, those cases are requested randomly. So, it is very challenging for the health plan to be able to identify any opportunities or areas for improvement or to change our policies to create more clinical effectiveness on the Part D side because those requests are so random in nature.

And we'd also like to provide an additional comment about the Maximus decision-making process. It doesn't seem to be very consistent. It is actually inconsistent in how they make their decisions, and we were hoping that maybe CMS would be able to provide some additional guidance for the Maximus decision-making process right now.

There is really no set standards for Maximus to follow, and we are hoping in the future that we would see some guidance come out. Thank you.

Operator: Our next comment comes from the line of (Giavolo Ocarii) from Highmark. Your line is open.

(Giavolo Ocarii): Yes, my question is related to some of the questions asked earlier related to tolling. And we would like CMS to be a little bit clearer with the definition of tolling and, also, the universe of the situation where tolling could be used. It is clearly stated that you could use it if you are requesting information from the prescriber.

But, could that process be also used for other situations where we are requesting information from the authorized representative members and other situations that might warrant additional information? Thank you.

Operator: And our next comment comes from the line of Stacy Sanders with Medicare Rights Center. Your line is open.

Stacy Sanders: Thank you. And thanks so much for the opportunity to participate in this listening session. I actually also had comment about the coverage determination process. So, I will go back to that and, then, I can move on to some additional comments.

But, as Medicare Rights Center fields somewhere around 20,000 questions every year on its national help line, and among those calls the most persistent

trend involves calls from people with Medicare who are attempting to manage some type of denial of coverage - and most often, that is under Medicare Advantage and Part D.

And consistently, year after year, our most common call in that area of denials and appeals comes from a beneficiary who has left the pharmacy counter empty handed and is struggling to understand how to navigate the coverage determination process. The most common call to our help line is from an individual who does not know why they have been denied.

Typically, we have to work with the beneficiary, give them direction in terms of calling their plan to assess the reason for that turning away at the pharmacy counter and to help them through the process of requesting a coverage determination. Followed by just sort of a basic lack of knowledge about the reason that they have been turned away at the pharmacy, the most common call is from an individual who has been denied or has been turned away because the prescription drug is off-formulary.

Our general sense is that people with Medicare would be much better served if they were provided more information sooner. So, if there was a way to communicate at the point of sale about why it is that the individual has been turned away, whether it is off-formulary or due to some other type of utilization control.

And, we continue to feel like efforts to improve the pharmacy counter notices, and particularly any efforts that could provide more specific details to beneficiaries, would help them navigate the coverage determination process more easily. That lack of knowledge really does lead to situations where beneficiaries go without their medication entirely; pay the full cost out of pocket.

And that just generally leads to -- in our experience -- a lack of adherence with needed medications. So, we'd encourage CMS to continue its ongoing exploration of ways to improve the process at the point of sale when the beneficiary has presented the prescription.

And, lastly, just along those same lines, continue to hope that CMS can explore ways to streamline the process so that the beneficiary is not in a position where they do have to formally request coverage after having been turned away at the pharmacy counter. We often find, particularly in the Part D context, that the beneficiary really has to serve as the referee between their plan and their provider in terms of submitting the correct information to the plan.

To make that coverage determination request, it requires a lot of fact-finding and a number of phone calls on the part of the beneficiary. And it is a difficult process to manage sort of serving in that referee role. We often have to support people throughout that process so that they collect the appropriate information and can make that coverage determination request if that is the best option for them.

So, to the extent that we can explore ways to streamline that process and really lift some of that burden from beneficiaries, we think they would be much better served through the coverage determination process.

Operator: And our next comment comes from the line of Anthony Hansen with Providence Health. Your line is open.

Anthony Hansen: Yes, we have a couple of comments and like to -- again, on the coverage determination front, I just want to reiterate some comments that have already been stated. Again, we want to reiterate that tolling of all cases seems important. We do issue quite a few denials on standard cases based solely on timeframes.

We have cases from holidays or weekends in which the -- or, say, come in late on Friday and then are denied on Monday without giving the provider ample time to provide information to us, especially when a member calls in requesting an oral coverage determination without the provider's knowledge.

I also want to comment on the medically accepted indication that has been brought up a couple of times. We also see -- I wouldn't say frequently -- but, we do see times in which a medication is definitely appropriate for a

beneficiary. However, we issue a denial based solely on the Chapter Six regulation of not being in a compendia or FDA-labeled.

In which case, we'd recommend that regs are updated to reflect Chapter 15 of the benefit manual with said third party literature or primary literature could be used in accepted standards of care to make -- guide coverage determinations. And that is all we have.

Operator: And our next comment comes from the line of Chris Casella with Health Partners Plans. Your line is open.

Chris Casella: Hey, thanks a lot. Good afternoon. I just want to reiterate the comments that they said earlier about expanding the tolling to coverage determinations. And I also want to make a comment about expanding the definition of when coverage determinations become exceptions.

It is pretty much the same thing as expanding our tolling definition. I think that language would help out and eliminate some judgment calls. That is it. Thank you.

Operator: And we will be checking again just momentarily here to see which other comments are ready. And we do now have a question from (Jennifer Palmer) from Freedom Health. Your line is now open.

(Jennifer Palmer): Hello. I'd like to have some examples provided of excluded drug requests that are received where the requester is also asking for tier exception along with the coverage. We would like to know if the denial for the notice of inquiry should include verbiage about tier exception also not being included or if this is a situation where a case should be split and a member would get a coverage determination on a tier exception and, also, the notice of inquiry letter. Thank you.

Coretta Edmondson: Thank you. I believe that was a question. So, once again, please feel free to direct your question to the Part D mailbox. If you have any specific questions or comments, you can send those to the Part D mailbox. Thank you.

Operator: And for our next comment, we have Sue Greeno from the Center for Medicare. Your line is open.

Sue Greeno: Yes, Sue Greeno from the Center for Medicare Advocacy. I'd first like to reiterate what Stacy from the Medicare Rights Center said regarding beneficiaries getting bounced around between calls back and forth and not knowing how to navigate the system of appeals and grievances.

And that is a very common call at our center. In addition, I'd also like to second and third - several callers have mentioned that they'd like to see parity between the Part D and the Part B appeals process.

Currently in Part B, in addition to the compendium, the medically -- I'm sorry -- peer-reviewed literature is accepted for Part B appeals and making the case for obtaining coverage whereas in Part D, only the compendiums are acceptable and the peer-reviewed literature is not considered.

So, I'd like to ask CMS to consider expanding to include the peer-reviewed literature. Thank you very much.

Operator: And our next comment comes from the line of Cortney Resto with EmblemHealth. Your line is open.

Cortney Resto: Hi, I just want to follow up on someone's comment before about the requirement to auto forward redeterminations within 24 hours of exceeding the adjudication timeframe. I agree with the earlier comments that, I think, we could enhance the member's access to the drug if we are allowed more than 24 hours to do that.

My suggestion would be to change the regulation to require 24 hours from the identification of an appeal that exceeded the timeframe as, often, they are identified longer than the initial 24 hours from the original expiration timeframe. Thanks.

Operator: And for our next comment, the line of (Joanna Poach) from IHP is now open. Please go ahead.

(Joanna Poach): Hello, I apologize, I was trying to get in to discuss the AOR topic but, for some reason, I wasn't able to get in. I am hoping that I could still ask the question in regards to that - or it's more of a comment.

Coretta Edmondson: Sure. Go ahead.

(Joanna Poach): OK.

Coretta Edmondson: You can make a comment.

(Johanna Poach): Sure, it is more just requesting like clarification in regards to redeterminations, specifically expedited redeterminations and also standard where we don't receive an AOR form received by -- when someone's trying to (present) an enrollee, and more specifically, to the timeframe of when a case should be dismissed if no AOR is received.

Coretta Edmondson: Again, if you have specific questions, please forward those questions to the Part D appeals mailbox at [partd\\_appeals@cms.hhs.gov](mailto:partd_appeals@cms.hhs.gov). Thank you for your question. OK. At this time, we will go ahead and move to another area for comments and suggestions.

And if we have additional time at the end, we will come back to coverage determinations and redetermination. So, we want to go to reopenings once again. Are there any specific concerns or suggestions for improvements relating to the current reopening process?

Operator: And our next comment or suggestion comes from Tiffany Cunningham with Anthem Inc. Your line is open.

Tiffany Cunningham: I apologize, that was a mistake.

Operator: Moving on, our next comment or suggestion comes from Justin Cook with HealthFirst Healthcare.

Justin Cook: Yes, thank you for taking my call. I just wanted to add to the redetermination. I feel there should be a post-service timeframe for Part D redeterminations. Currently, there is only the seven-day timeframe on appeal. But, if someone

is appealing a reimbursement that is tough to get that done in seven days on top of all the pre-service cases.

And we would like clarification when someone makes an invalid - or a type of appeal that is strictly stated in the evidence that covers that they can't do like appealing a denial of (adhering) exception for -- we have already made a formulary exception to. If states are not allowed to ask that, I sure there was clarification about the process in there.

And in the reopenings, if there was just more leeway in the guidelines as far as allowing reopenings not strictly for errors that the plan made but if new information is given, it is just the interpretation can be looked as very narrow to where our -- the initial review cannot be reopened if new information is given. And that is all I had. Thank you.

Operator: And our next comment or suggestion comes from the line of Laurie Delgado with Anthem Healthcare. Your line is open.

Laurie Delgado: Thank you. There is a delay when it comes to the request to speak, just so you know. Most of my issues have been addressed. I just wanted to echo that the post-service claims appeal and the seven-day timeframe when processing these appeals of the member reimbursement denials.

We often have to outreach to the member for a copy of their receipt or their documents that contain the NCD number and the diagnosis, which then they -- that they did not include when making their request for reimbursement.

And that seven-day timeframe for the payment appeal decision isn't sufficient for treating additional information from the member when they didn't already give us the needed documentation. So, I just wanted to underscore that. Thank you.

Operator: And for our next comment, the line of (Dawn Becker) with Blue Shield of California is now open. Please go ahead.

OK, it appears that line is no longer there. Gil Solomon with Blue Shield of California, your line is open.



Gil Solomon: Yes. I wanted to reiterate the off-label that has been mentioned and if the health plans are telling you that it might mean something. The other thing that I want to reiterate is the consistency on reopening. Some of the reviewers do not give a real clear explanation, and some reviewers have actually quoted only a portion of the compendia to support the paragraph.

And then, when we try and reopen, what tends to happen is they are dismissed very easily by saying that, "Well, that was the reviewer's opinion and it is -- they decide it was medically appropriate." So, I think that some kind of audit when reviews are reopened to look at how the reviewers are doing and if they are doing a reasonable job to give a good interpretation of the compendia.

Because, most of the time, they are very good, but sometimes we are finding that it is just a two-line summary and it doesn't really quote the compendia or anything. So, I think that would be something to be looked at. I don't know how much reviewer audit or supervision is done for them.

Operator: And our next comment comes from the line of David Griffith with Geisinger Health Plan. Your line is open.

(David Griffith): Hi, yes, we already gave our comments regarding coverage determinations. Yes, we have been trying pretty much since the beginning to get on. Just to expand a little bit about our comments on the coverage determination, we really see issues with when we get verbal requests, especially from members close to the weekend.

And our suggestion would be to -- if -- for requests, if it is urgent and it is not received via fax, that the urgent request should be at least 72 hours for turnaround time. But, if you expand the tolling to include these, then that would kind of take care of that as well. We also see issues with getting the request from the member when they call in.

And we spend a great amount of time trying to track down who the prescriber is and get their information so that we can actually start the request and have it reviewed. To ask them to get the information from the prescriber, we...

Coretta Edmondson: I'm sorry. Caller, I'm so sorry, I don't mean to cut you off.

(David Griffith): That's OK.

Coretta Edmondson: We can barely hear you. So, if you could speak a little louder. And if you could start from the beginning, that would be very helpful. My apologies.

(David Griffith): That is OK. Is this better?

Coretta Edmondson: No, it is not.

(David Griffith): OK.

Coretta Edmondson: Are you on a...

(David Griffith): Let me try -- I am on a headset -- let me try...

Coretta Edmondson: OK.

(David Griffith): OK. Does this work better?

Coretta Edmondson: Much better.

(David Griffith): OK, sorry, my headset must not be working. So, I just wanted to expand upon what we had already said from Geisinger. The first is expanding when we get a verbal request -- expanding -- when they ask for it to be urgent, we have trouble getting that completed in the 24 hours and getting the information from the prescriber.

We end up denying a lot of those for lack of information. And, then, it is overpopulating our denials and the appeals. So, expanding the timeframe for urgent verbal requests to at least 72 hours would be good. So, obviously, if you expand the tolling criteria and it included those, we would have that taken care of.

And, then, the other thing is that we spend a lot of time trying to get the information from the prescriber before the review is even done when a member is the one initiating the coverage determination. So, our suggestion is

to either expand that timeframe as well just for member-initiated requests or make it so that the prescriber has to be the one to actually initiate it so that the member can ask us to start it.

But, then, we try to get the information from the prescriber. And it doesn't start until we actually get in contact with them. Our issues are around trying to actually talk to them and get the right prescriber the right strength so that we can review the proper medication because a lot of times we have members call in that say they want a drug and they don't know the strength and they give us a doctor.

And we spend a lot of time trying to track that doctor down. And it is worse on Fridays, weekends, holidays where we end up denying them just because we can't get in contact with them. Thank you.

Operator: And our next comment comes from the line of (Garima Agarwall) with Health Alliance Plan. Your line is open.

(Garima Agarwall): Thank you. We had a couple of comments regarding the redetermination process. First of all, the Part D QIC drug appeals case file transmittal and the case narrative form -- both the forms we find are not user-friendly. Users are not able to put all of the information in the form due to the character limitation in the form fields. The members are -- the providers are unable to input all of the information that is pertinent to the review of the appeal.

Secondly, we would allow -- we would like to see how plans can actually make a determination of a request for an expedited review. Some of our providers meets the criteria for expedited review instead of automatically expediting based on the provider's request for a fast appeal.

The other thing I'd like to highlight was just reiterate one of the comments made earlier from -- I believe it was Geisinger Health Plan -- around the inconsistencies from the IRE decision-making process. We have seen this both on the Part C and the Part D side. So, hopefully, CMS will look into streamlining that process. That is all I have. Thank you.

Coretta Edmondson: Thank you so much for those comments. OK, we want to move along. And, now, we are asking for recommended improvements or changes to the appeals process at the IRE, ALJ or the Medicare Appeals Council levels.

Operator: And for our next comment or suggestion, we have Leslie Fried from the National Council on Aging. Your line is open. Again, Leslie Fried, National Council on Aging, your line is open. OK, and moving on. Again, it is “star” and the number “one” for any comments for suggestions.

And Stacy Sanders from the Medicare Rights Center, your line is open.

Stacy Sanders: Hi, thank you again. I wanted to follow up -- I have two comments, one related to redeterminations and the next to this question about the reconsideration in IRE level. First, I just -- and I think this is actually somewhat responsive to some of the concerns that have been raised about beneficiaries including appropriate information in the request to health plans.

But, our general experience with initial denial notices, which beneficiaries receive ahead of requesting a redetermination if that is what is appropriate for them is that those notices could be significantly improved. We think that they could be written in a more plain -- in more plain language terms and more clearly spell out what the next steps are for the beneficiary.

We also think it would be incredibly helpful if specific notices were tailored to specific types of denials because, for instance, what a beneficiary may need to provide with respect to prior authorization might be different than if a prescription drug is off-formulary.

The paths for the beneficiary are slightly different depending on the reason for the denial. And in instances around tiering exceptions, the information that needs to be provided, the sort of path forward, is also quite different than in a case where a prescription drug has been denied.

So, we do hope that CMS will think about ways to really tailor those notices to the reason for the denial in order to make it clear to the beneficiary what needs to be submitted, what supporting information they need from their

provider. And then, hopefully, that will help the plan more successfully manage and process the beneficiary's request.

So, we would, again, just really encourage a fresh look at some of those denial notices. And then, second, around the reconsiderations, we have been supportive of proposals to bring a practice that exists in Medicare Advantage to Part D, which is the auto-forwarding of an unfavorable redetermination.

So, if the plan has denied the appeal, auto-forwarding to the IRE would diminish the burden on the beneficiary in terms of making that request to the IRE. And that does exist in Medicare Advantage. And, so, we would like CMS to explore allowing that auto-forwarding in the Part D context as well. Thank you.

Operator: And, again, it is "star" and the number "one" if anyone else would like to ask a question.

And we do have -- I'm sorry -- not ask a question but make a comment or suggestion.

And we have Anthony Hansen from Providence Health. Your line is open.

Anthony Hansen: Hi, I just want to offer some more comments on the IRE process. I would like to reiterate a comment that was previously stated earlier about a suggestion to report untimely cases to CMS but not automatically auto-forward if a case is approvable. We have had situations in which a case is, yes, untimely and then we are required to forward it to the IRE and delaying medically appropriate treatment.

For instance, we had a case that took the IRE 93 days to get back to us, in which case the member was out of medically appropriate medication in which our hands, as the plan sponsor, were tied waiting for that response from the IRE meanwhile for 93 days with the beneficiary without medication that we really couldn't do anything for her.

Another instance with the IRE is -- I would agree with another comment -- is we have had issues with inconsistent reviews. We recently had a case that

was overturned, the IRE physician reviewer that deemed a medication was in the compendia for a listed indication.

However, the medication was a class three support that was not recommended by the compendia, but it was included since there were studies on it. And from a plan, it was really -- it's really difficult from a plan to have an open line of communication with the IRE outside of facsimile.

It would be very beneficial to have open phone lines for plan sponsors to get in contact and either have an open discussion about questionable case overturns and whatever recourse is from that standpoint. Thank you.

Operator: And our next comment or suggestion comes from the line, again of Leslie Fried, National Council on Aging. Your line is open.

Leslie Fried: Hi. Can you hear me now? Hello.

Coretta Edmondson: Yes, we can.

Leslie Fried: Good, because I tried before. Actually, I was in line a long ways back. So, I just have two quick comments. One has to do with the notices of denials. We hear a lot - and submitted previous comments about - how specificity is really important for those beneficiaries who do end up submitting and requesting a coverage determination.

We get notices back that are very vague and it is really unclear the reason for the denial. So, it is really important -- I think it would benefit everyone, including the plans - that the folks understand with specificity the reason that they walked away from the pharmacy counter without their drugs.

And, second, way back to the authorization of the authorized representative pieces - which I tried to get in then. Many state laws -- in fact, most state laws -- have surrogate decision-making laws which allows someone to represent a family member, et cetera, who does not necessarily have capacity anymore.

You don't need a guardianship, since states have surrogate decision-making laws. And there needs to be a process for folks who are representatives under

state laws to actually be recognized by the Part D plans for appeal process.  
Thank you.

Operator: And our next comment or suggestion comes from (Sefanit Goshu) with Memorial Hermann Texas Medical Center. Your line is open.

(Sefanit Goshu): Hi. I guess, my suggestion is extending the tolling time until we are...

Coretta Edmondson: I'm sorry. Caller, could you speak up because we cannot hear you?  
Thank you.

(Sefanit Goshu): Can you hear me now?

Coretta Edmondson: A little louder.

(Sefanit Goshu): OK. Can you hear me now?

Coretta Edmondson: Yes.

(Sefanit Goshu): OK, my comment is about expanding the timeline as far as tolling until we receive a medically necessary information from the doctor's office. That is the one comment that I have. Thank you.

Coretta Edmondson: OK, thank you for that comment. OK, we would like to move on. At this time, we would like to callers to discuss any features of the Part D appeals process that you believe works well at this time.

Operator: And, again, it is "star" and the number "one" to queue up to give your comment or suggestion. "Star" and the number "one". And we do have (Steve Silvern) from -- who's an attorney for representative claimant. And your line is open.

(Stephen Silvern): Hi. Thank you for taking my call. I actually have been trying to get in to comment on the level two and three appeals processes and substance. The more important comment is -- I conversed with officials at Maximus, up to and including -- with some difficulty reaching them -- the project manager for Medicare D.

I learned that at the level two, at least with Maximus, they do not do a Tangney versus Burwell analysis. They simply look to see if the diagnosis is listed as a medically acceptable use in the compendia for off-label drugs.

Obviously, the Tangney versus Burwell case, which was decided back in May by the U.S. District Court in Massachusetts expands the analysis to include a look at the claimant's symptoms. I was surprised that the project manager for Maximus, which makes the level two determinations, had never heard of the Tangney versus Burwell case.

And he confirmed to me that all Maximus does at level two is look at whether the specific diagnosis is listed. That is the beginning of the analysis under Tangney, not the end. Secondly, to the extent that the reviewers require to limit themselves to the compendia, the compendia turns out not even to be purchasable in the case of drug decks by the claimant or the claimant's representative. They won't sell it to me.

I think that Maximus and any other reviewer who denies a claimant needing treatment ought to be required to send along the entire compendia immediately with the adverse decision. I was told by Maximus initially that they would wait 60 days to send me materials including the compendia comments and reference on the medication involved.

By being aggressive and threatening immediate District Court litigation, the project manager, I understand, has sent for (four inches roughly of) materials to my office in Colorado. So, procedurally, the compendia references to the medication ought to be sent immediately to the claimant. And, secondly, a Tangney analysis should be part of the level two process and, indeed, the level one process. That is my comment.

Coretta Edmondson: OK. Thank you so much for your comment. The last area that we would be asking for comments or suggestions on is to please discuss features of the Part C appeals process that work well and could potentially be applied to the Part D appeals process.



And we already have heard several comments about the adverse decisions and those cases being forward to the IRE. So, if there any additional comments or suggestions, please provide those at this time.

Operator: Again, it is “star” and the number “one” to ask your -- sorry -- to make your comment. And we have one comment from the line of Stacy Sanders from the Medicare Rights Center. Your line is open.

Stacy Sanders: Hi, thank you. Yes, I actually just wanted to respond to the prior question about what is working well in the Part D appeals process. And, for my organization, we certainly oversample for challenges and the beneficiaries who call us are people who are struggling to navigate the process and, as I said, have typically left the pharmacy counter sort of flummoxed by what to do next and what their next steps are.

But, I think, what does work really well is when the beneficiary has someone knowledgeable who is working on their behalf, whether that is a counselor from our help line or someone from a state health insurance assistance program or otherwise - potentially even someone from the health plan - who is walking them through the process.

So, someone who is knowledgeable of the jargon that is just inherent to this process, someone who knows the steps, someone who can help beneficiaries identify when a request for a coverage determination and when a redetermination is appropriate or when it is appropriate to work with the healthcare provider to identify some type of alternative medication.

For instance, in an off-formulary situation, there may be a medication on formulary that would work perfectly well for the beneficiary and would help them avoid the coverage determination and redetermination process and so forth.

So, our general sense is that this process works best when there is a knowledgeable individual who can really help guide the beneficiary through the process because so many people who are using their Part D benefits are just not as familiar with this process as those of us who work on it day to day and the folks at the health plans or the PBMs or otherwise.

So, I think, the instances where it has worked well are those where the beneficiary is fully supported navigating the process. And related to that, I do think there are specific challenges in Part D where you have standalone plans that may not have as strong a relationships with health care providers as is the case in Medicare Advantage where you do have a plan that has a network and relationships with those providers.

So, we do hear -- and this is just anecdotally -- that the Medicare Advantage process can be streamline somewhat because of some of those existing relationships. So, in the Part D context where we can strengthen communication between the plan and the providers so that the beneficiary is not stuck in the middle, I think that that would go a long way towards making the process work better. Thank you.

Operator: And, again, it is “star” and the number “one” for any further comments or suggestions.

Jill Darling: And if there are any more further comments, we will just take one more, please.

Operator: And there are none.

Coretta Edmondson: OK, great, thanks so much to everyone who participated in the call. Once again, we apologize for the technical difficulties earlier today. Later on, if anyone on the call or anyone wasn’t able to participate has any additional recommendations for improvements or enhancements, please feel free to send those comments or suggestions to the Part D appeals mailbox and please in the subject line enter Open Door Forum. That mailbox will be open with those suggestions until December 27. Thank you.

Operator: And this concludes today’s conference call. Presenters, please stand by. And participants who have dialed in, you may now disconnect.

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