



Open Q & A Session *All Speakers*

Stacey Plizga: Okay, our next session that we are going to have is the open Q&A session that brings all of our speakers back together one more time, and gives you one last opportunity to ask any questions that you were not able to ask earlier or that you thought of after the speaker had their session. But before we do that, I just want to give you a couple reminders, and those are -- let's see here, to complete the post webcast survey that will be mailed to you after this conference ends. It's only going to take a couple minutes, and it provides CMS with some valuable feedback for ways that we can improve upon future conferences, so please take the time to complete that survey.

Also, after the webcast, an e-mail will be sent to all registrants when the webcast audio and video files, transcripts, presentation slides, and other information are posted, so keep on the lookout for that. That will be e-mailed to you once everything is ready and up there for you. Another thing is, to obtain your CEU credits for today's event, please refer to Page 19 in your conference guide. So if you have any questions about that, please go to the conference guide and look there. All right.

Okay. Now the end of session questions. All of our speakers are back with us today, and we are going to go through, session by session, and ask any outstanding questions of those speakers.

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Session 1: Building Effective Relationships with Your Account Managers

Stacey Plizga: So our first session today was "Building Effective Relationships with Your Account Managers," and we had Judy Flynn and Brenda Suiter. So in the audience, if there is anyone with a question for Judy or Brenda, would you please step up to the mic. And I do not have any questions that came in for Judy or Brenda from our webcast audience. And there's no questions from in-house, so Judy and Brenda, you guys do not need to step. Never mind, you do need to step up.

Kristin Bass: So I'm Kristin Bass with PTMA. We're the trade association for the pharmacy benefit manager. I just wanted to follow up on the "There might not be written guidance or regs." One of the things that is perplexing for those who are trying to follow the regs and the guidances when there are differences among the regions as to what they're recommending that folks do, which is why we rely on the guidance and the regs. So do you have any thoughts on that, because I think it's pretty reasonable to expect that someone would be consistent with guidance and regs? Just saying.

Brenda Suiter: Well it sounds like what the issue is, it's different interpretations; is that correct?

Kristin Bass: Yes.

Brenda Suiter: So if you're hearing different interpretations from your account manager, from a marketing reviewer, please tell them that it's different than what's been told by others. And let the account manager know that. And if you're running into the issue, we'd want to know of, you know, differences in interpretation. So you can always let the association regional administrator know in that regional office. You can let the people know that you work with here in Baltimore. You know, it would be incredibly frustrating to have things interpreted differently, and that's certainly not our intent. So please let us know what the issues are so that we can address them. If we don't know that this is happening, we can't help fix it.

Kristin Bass: Thank you.

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Stacey Plizga: Thank you, Brenda. Okay, for session two, session two --

Christine Johnston: I'm sorry. I have one question.

Stacey Plizga: Oh, okay. Yes.

Christine Johnston: I'm Christine Johnston from IPC/Evergreen. We are a pharmacy consultant, and we assist our plans with their Medicare compliance, and the problem we have with the guidance that you were giving to not ask for guidance is that when we try to work with our PBMs, they want us to document why this is necessary and that the plans word is not often good enough. So I just encourage you -- I guess this is more of a statement to encourage you to help the plans be compliant with the suggestions, because I think I very rarely have come across a plan that doesn't want to do what CMS is suggesting, but often it's getting the operation to understand what's necessary, so just a suggestion.

Brenda Suiter: Thank you very much. We really appreciate and have appreciated the discussion and the questions from earlier this morning as well. Thank you.

Stacey Plizga: Okay, anyone else for Brenda? Okay. I waited. Okay.

Session 2: Encounter Data Update

Stacey Plizga: Our next session, session number two today, was "Encounter Data Update," and that was with Shruti Rajan, and we do have questions for session two that were sent in, so I would like to invite Shruti to come up. And if there's anyone in the audience who has a question, if you would please move to the center microphone.

Okay, our first question that was sent in today, for Shruti is, "Who is the contact person in CMS to address questions regarding the merger of two plans into one plan regarding" -- did we do this one?

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- Shruti Rajan: Yeah, I could answer it again, but yes, there's two mailboxes encounterdata@cms.hhs.gov and risk adjustment, riskadjustment@csm.hhs.gov, so two mailboxes.
- Stacey Plizga: Okay. All right. And then one more question that we received says, "When will user groups start up again?"
- Shruti Rajan: Maybe I can ask people, does anyone remember?
- Unidentified Attendee: June 23rd.
- Stacey Plizga: Yes, that's right. Thank you, Shruti. That was all that we had sent in. It doesn't look like we have anything from the in-house audience, so thank you very much.

Session 3: Reporting of National and Contract Level Quality Scores by Race and Ethnicity

- Stacey Plizga: All right, the next session of the day was "Reporting of National Contract-Level Quality Scores by Race and Ethnicity" with Madeleine Shea. Do we have anyone in the audience with a question for Madeleine Shea today? No? Okay. Because I do not have any questions from our virtual audience, so, Madeleine, you get a pass for this one.

Session 4: PDBM Chapter 6, The Part D Formularies Awaken

- Stacey Plizga: Moving on, the session that was following that was "PDBM Chapter 6, Part D Formularies Awakened." And Bob and Marie, I would like to invite you up, as I do know, we have a number of questions that are still unanswered. And, again, if there's anyone in the audience with a question, please don't hesitate to step up to the microphone. And the first question that we have today is, "Is the application of prior authorization that is resolved at POS actually a coverage determination?"

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Marie Manteuffel: Okay, so thank you for the question. That was something that was addressed during my portion of slides, and, again, when an issue is related to a POS edit that is resolved at the point of sale, so allowing the claim to adjudicate under Part D, the claims transaction does not constitute a coverage determination. In those situations where the patient or the prescriber makes either a verbal written request for coverage of a drug, subject to PA or other utilization management restrictions to the plan sponsor, that is a coverage determination and the plan must process it appropriately.

Stacey Plizga: Thank you. The next question that was sent in, "If the plan chooses to consider all compounds as non-formulary, how does the plan notify CMS of this approach? Is noting this in the EOC to enrollee sufficient?"

LCDR

Marie Manteuffel: That question was also during my section, and, really, a plan wouldn't need to separately notify CMS of that decision. They would just, then, not list those compounds on their formulary that they do submit I would just caution, kind of hearing that question though, that things like home infusion, sterile products, TPNs, those can be considered compounds as well, so just to consider that as well.

Stacey Plizga: Okay, thank you. Another question that we received from our virtual audience, "What are CMS's expectations for determination of whether or not a bene is currently taking a PCD when applying PA-2 edits on PCDs? For example, would a six-month pharmacy claim look back for a continuing bene outside of the transition timeframe be sufficient?"

Robert Dombrowski: Thank you, Stacey. The answer to this question is found in Section 30.4.3 of Chapter 6 of the Prescription Drug Benefit Manual. Yes, six months would be certainly fine. You can choose longer than the guidance that's provided in Chapter 6. But in Chapter 6 it says, "CMS believes a minimum of 108 look back, consistent with other reviews, is typically needed to adequately document ongoing drug therapy." But it can certainly be six months and beyond. Thank you.

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Stacey Plizga: All right. Moving on, same session. Next question, "I would like clarification as it relates to the expiration of an approved exception request. If we clearly state in our coverage determination approval letter the date that coverage will end, is it still a best practice to send another notification to the member within 60 days of the expiration, or are we covered with the initial notification?"

LCDR

Marie Manteuffel: Okay, I think this was in reference to the example we gave of someone getting a letter stating that their prior exception for two tablets of the 10-milligram tablet was approved through December 31st. If that date is in that letter, that's fine, another notification wouldn't be need to be sent. However, we wouldn't tell them that they couldn't. I'm not aware of something prohibiting them from doing that practice.

Stacey Plizga: Okay, thank you, Marie. And I think that does it for our questions for the PDBM Chapter 6 presenters. Is there anyone in the audience that would like to ask a question? No? Okay, well thank you very much. All right.

Session 5: Effective Strategies for Addressing Overutilization and Abuse of Prescription Drugs in Medicare Part D

Stacey Plizga: Our next session, "Effective Strategies for Addressing Overutilization and Abuse of Prescription Drugs in Medicare Part D." Do we have anyone in the in-house audience who has questions for our speakers? No? Quiet group today. Okay. I don't have any questions for you. Did you receive some questions?

Okay, we do have a few questions here, which is awesome. Question number one, "Is there further guidance on how safety should be managed for members who have been approved for high-dose MEQD for that hard edit?"

Anna Polk: Thank you. So we believe this question is asking about those beneficiaries who are identified through level-three retrospective DUR as

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an over-utilizer, and after case management whose use is determined to be appropriate. So what happens to these folks if they subsequently bump up against the cumulative MED opioid POS edit? And as we talked about during the session, exclusions can and should be applied to the cumulative MED edit. This would include those beneficiaries who have already undergone a determination of medical necessity, which could have come about as a result of level-three case management. If this was not the intent of the question and the questioner is still listening, please do submit additional details to the Part D formularies or the OM mailboxes.

Stacey Plizga: All right, we do have two more questions for Anna and Diane. The second question is, "If a MED or med hard edits is implemented by the sponsor at POS, can the sponsor perform a coverage review to assess medical necessity? If so, does the policy criteria used to assess medical necessity need to be approved by CMS, and what is the process for policy criteria review considering not all opioids are on the formulary?"

Anna Polk: And so, again, I'm not a hundred-percent sure we understand the intent. So if we miss it, please e-mail us. But I believe this question refers to the cumulative MED opioid POS edit. And to answer the first part of the question, yes, if the sponsor is using a hard edit, the beneficiary or prescriber may be required to request a coverage determination. To answer the second part of the question, no, the criteria surrounding how medical necessity will be determined does not need to be submitted to CMS. Sponsors are expected to submit details around the cumulative MED opioid edit itself; however, these details are expected to be applied across the entire opioid class, and so it's assumed that non-formulary opioids will also be included.

Stacey Plizga: Okay, thank you, Anna. And the last question that we for this group, "This question involves the abuse of a protected class, in this case HIV/AIDS drugs. If we find that a member has a persistent pattern of overutilizing such drugs, is a plan permitted to place POS controls or limits on that member?"

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Diane McNally: My question. So right now CMS does not have specific guidance for non-opioid drugs. But in the original supplemental guidance that was put out back in 2012, we did talk about other drugs, and what we said was we would expect plans to perform the same due diligence in determining medical necessity as you do for opioids. And later, we did have an HPMS memo that was put out. And if a plan does decide to put beneficiary specific limits on a beneficiary, or POS edit limit on a beneficiary, that communication, that copy of that notification letter should be sent to the Part D OM mailbox.

Stacey Plizga: Thank you. Okay, so if there are no further questions from our audience, then I would like to thank Diane and Anna for participating in our Q&A Session. Thank you so much.

Session 6: PBM Migration: Lessons Learned in Part D

Stacey Plizga: Okay, moving on, our next session is "PBM Migration: Lessons Learned in Part D." Okay. Anyone in our audience have a question? No? Okay. This was our WellCare group, but, also, we had a couple individuals who are participating from CMS. And the question that we did receive is directed toward the CMS individual, and that question is, "Have you ever seen such a level of coordination with CMS and internally among the company on a PBM transition?"

Linda Anders: I would hate to ever disrespect any previous PBM transitions that have occurred. This was a lessons learned opportunity. We built off of the fall presentation and were able to work really closely with our colleagues at Aetna, and WellCare's transition happened to come right on the heels of that. And we were able to, almost in real time, apply the lessons that we were learning. So we were better prepared to assist with this transition than I think we had been previously and had already, you know, implemented all-hands-on-deck approach, and they were able to, I think, benefit from that.

Arianne is our specialist on PBM issues in general. When there is something going on with a PBM, she is the one that will reach out and

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contact the PBM and see how broad spread the issue is. And she may have things to add to that conversation.

Arianne Spaccarelli Right. As Linda said, it was just on the heels of another big transition, where there were submissions were working very closely with. And the other factor in why we work so closely with, obviously it was a very large transition. It was 3.5 million members, so any time that happens, we're concerned about disruption on a larger scale than we might see typically.

Stacey Plizga: Okay. Any other questions for this group? No? Okay. Well thank you to Linda, Arianne, Michael, Laura, and Lee.

Session 7: Combatting Fraud, Waste and Abuse in Medicare Parts C and D

Stacey Plizga: And then our last session of the day is "Combating Fraud, Waste and Abuse in Medicare Part C and D." And I do not believe we have any questions from our viewers. We asked a great deal of questions during the presentation. Is there anybody in our viewing audience in-house with a question? No? Okay.

Rehabilitation Act, Section 504 – Randy Brauer, Office of Hearings and Inquiries, CMS

Stacey Plizga: Well, then, at this time, we do have a presenter who is joining us to help close things out today. So with that, I would like to introduce to you Randy Brauer.

Randy Brauer. Wow, so many of you hung in there until the last minute. I am impressed. It's nice to see so many folks. I haven't talked to our plan community in a long time, but I'm back, and I'm sure you all thrilled about that, and you'll be even more thrilled when you hear what I am here to talk to you about, and that is compliance with Section 504 of the Rehabilitation Act of 1973. If this is something that doesn't sound familiar to you, it should, and you should go back to your respective organizations and ask around about this.

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So, in summary, Section 504 of the Rehab Act requires that all of us, you, me, CMS, government agencies, anyone that receives some kind of financial assistance from the federal government, ensures that no one is discriminated against or is prevented or prohibited from receiving services or benefits because they can't have information that they need in a format that is accessible to them. So what I'm talking about, of course, is accessibility, information accessibility in person, telephonic, and written materials being made available to individuals in formats that are acceptable and usable by them, such as Braille, large print, audio CDs of your written documentation, qualified readers, and that sort of thing.

So, there was a memo they came out from HPMS back in September of 2014 that outlined CMS's expectations and your responsibilities in this area, and my office now, I am the director of the Offices of Hearings and Inquiries, and we have taken on the responsibility for 504 compliance across the enterprise for CMS, so for all of our products, Medicare, Marketplace, and Medicaid. And since you all are a group of folks who have been doing business with us for a really long time, we want to ensure that we're working with you right from the get-go to make sure that everybody who does business in the Medicare space ensures that our beneficiaries are protected and have access to the information that they need and that we don't, even inadvertently, discriminate against someone by not making those things available in those formats.

That's really all I wanted to say today, a little public service announcement, and also let you know that we'll be coming back, joining our CM colleagues again in June at the compliance conference to provide a little bit more information about how we're going to work with you to ensure that we're all doing the right thing for all of our beneficiaries, making sure that they can get what they need. And we'll be providing information and updates along the way. But if you have questions about 504, you can send them on in to me in the Office of Hearings and Inquiries, and we'll take it from there. So that was it, my little public service announcement. Good to see so many of you. I think you have a few closing remarks, so I will stop here and say thank you.

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Stacey Plizga: Okay, we are going to jump back one, and I'm going to ask you one last time to evaluate the Open Q&A Session. So if you could take out those cell phones or link up to pollev for the last time and complete the survey on the Open Q&A Session, we would surely appreciate it. Great.