TRANSCRIPT
Day 1 04: Program Audits
Holmes, Blanar

I guess it's good afternoon now, everybody, since we're past 12:00 o'clock. We are talking about audits today, and I promise you will get a lunch today. This isn't an actual audit, so you will get to go to lunch. Good afternoon, again. My name is Jonathan Blanar and I'm the deputy division director for the division of compliance and policy operation. And I'm also joined here today by Tawanda Holmes, who you already know.

First off, I'd like to go over what we're going to talk about today. First of all, we'd like to give you a high-level walk through of the audit process. If you were here at the spring conference, we went pretty in detail with the audit process, giving step-by-step examples and timeframes and walking through in a very detailed level the process. So today I'd like to bring it up a little bit, go through it at a higher level for those who weren't here, but we want everybody to understand the process, that way if you are selected for audit, then, you know, you'll know expectations and won't be surprised by anything.

Secondly, we have a new process since the spring conference, and we refer to that as the "Immediate Corrective Action Required process." We also refer to it as the ICAR. And we'd like to spend a little bit of time on that today. It is a new process so we do kind of want to set expectations for that as well. Tawanda will talk about preparation tips for audits. She has some good hints that will help sponsors prepare for their audits. She'll also discuss the HPMS memo that's coming out soon, and it discusses part of what they discussed a little bit ago with the best practices and also some common findings that are being identified in the audits so far in 2012. And we think this memo will help the sponsors -- help improve their internal monitoring, their internal performance, and, ultimately, help beneficiaries receive proper access. And lastly, she'll talk about 2013 planning.

So we're going to talk about the audit process now, and we have an internal diagram that we thought would be helpful to share with everyone to kind of help us walk through the process. You'll notice on the left side, step one is missing. That was intentional, and that's really internal steps that we take to prepare for our audit season. These include things such as the risk assessment, updating our protocols each year, updating our standard operating procedures, et cetera. So I'm going to skip down to step two, and step two is the pre-audit phase. And again, these are kind of the high-level items or key items that we want to talk about. We're not going to get into the details.

So starting with the pre-audit phase, the first thing we do internally at CMS is we create what we call a "due diligence report," and that's where we gather as much information on the sponsor that we're auditing, internal data that's available to us through HPMS, external data that we can gather through Google searches, LexisNexis databases, et cetera. So whatever we can find available out

there on the organization we put into a report, we provide it to the entire audit team so they can familiar themselves with the sponsor that they're auditing.

Some of the information in it includes financial data, geographical information, enrollment numbers, PBM information, their corporation structure, key executives, any legal information that's out there, and again, HPMS data. So we put that report together and we distribute to the audit team so that they can familiarize themselves. That usually happens about two or three weeks before the audit starts.

So moving on, the next thing is we send out an engagement letter. The engagement letter is sent out by the audit lead in our division four weeks before the actual audit begins. A call is made to the compliance officer shortly before the letter is sent just giving them a head's up that it's coming and to be on the lookout for it. The engagement letter includes the areas that are included in scope for audit, and these are your Part D formulary administration, your coverage terminations, appeals and grievances, ODAG, enrollment/disenrollment, compliance program effectiveness, and enrollment. I think I said enrollment.

It includes logistics, so what parts are going to be onsite, what parts are going to be a webinar. The only part onsite right now is compliance program effectiveness piece. Again, we've gotten feedback in the past that we send too many people on site and it's overwhelming for a lot of the sponsors, so we try to be a webinar, and it's worked well. We've implemented that for 2012, and we're getting positive feedback on that.

The engagement letter also includes different requirements as far as the facilities, records, information we need prior to audit, space requirements so a lot of logistical information is laid out in there as well. And it also has -- if you got one, it has lots of attachments that come with it; universe requests for each area, minimum sample documentation that's needed by CMS, and a questionnaire regarding compliance.

The sponsor has ten days to submit the required universe to CMS, but before that happens -- let me back up. Two days after the engagement letter goes out, CMS conducts a follow-phone call with the sponsor. The phone call is between the audit team, the sponsor's compliance officer, and anyone else the sponsor wants to have on the phone. And the purpose of the follow-up call is to make sure the sponsor clearly understands -- and they talked about this a little bit in the best practice -- was, you know, understand CMS's expectation, so understand the universe request, and that's really the purpose of this call, you know, is to introduce ourselves, introduce yourself, establish points of contact, and then any questions that you have regarding the attachments, ask them. We encourage sponsors to send the questions in before the call. That gives us the opportunity to try to have answers available during the call, but, you know, we encourage questions and we want you to understand the attachments, so that's really the purpose of that call.

So after the two-day call, we had the follow-up call, the sponsor spends their time preparing the universes, and they get submitted ten days after the engagement letter goes out, and they get uploaded to the secure file transfer protocol site, the SFTP, as somebody spoke earlier.

Once CMS gets the universes in, we review them. We review them for completeness, for reasonableness. If we have any questions about data, if any cells are missing, you know, the audit leader will probably reach back out to sponsor requesting universes or additional information on what was missing.

Once universes are deemed reasonable and usable by CMS, we'll go ahead and pull our sample. Somebody spoke earlier about the samples are given the day that the audit begins, so if a CDAG starts on Tuesday, you'll get the CDAG sample right before the audit begins. Enrollment, disenrollment, and agent/broker are given to the sponsor the Thursday before the audit begins. So that's the -- whoops, let me go back first. Well we'll stay on this slide. There we go. Thank you.

So that's a pre-audit phase. We've sent out the engagement letter. We had the follow-up call. We got the universes. We selected our samples. Now we move down to step three and actually start into the audit. Again, it's mostly via a webinar. Part of it is onsite. Our goal onsite is to be 100% transparent. There shouldn't be any surprises at the exit conference. As we go through cases live in your system, we're calling pass or fails after each case. There's times when cases might need to be in a pending status because we need more information. But, you know, we try to be as transparent as possible, so when we get to that exit conference at the end of the audit, the sponsor should already know, you know, what passed, what failed and should already have started correction.

The post-audit process, so the audit results are captured in what we call "work papers." The team leads of each area review the work papers, they approve the work papers. Once they're approved, it's put into a draft report. The draft report is reviewed internally by CMS at a few different levels. It's then released to the sponsor. Our goal is to release reports in 30 days or four weeks. We're trying to meet those timeframes, but sometime it's difficult.

But once the draft report is released, a sponsor will have five days to provide comments on it. Any misrepresentations, inaccuracies, if you disagree with any findings, et cetera, that's your opportunity to respond to the report. We do have a template that we're going to start to implement that everybody can use to make comments to us, that way we get them in one consistent format. It will make it easier for you and easier for us to turn around the final report. Once we do get your comments back, we'll review them. If we agree with the responses, you know, we'll make the changes. If we don't agree, we'll explain why. And, obviously, no changes will be made to the report.

When you receive the final report you'll also receive a link to a questionnaire. We used this in 2011. It was very helpful to us. The questionnaire will go through, you know, what did you think of the pre-audit process? What did you think of the onsite or the webinar process? What did you think of the draft report, the final report process? And that gives you the opportunity to give us feedback so that we can improve our process for 2013 and beyond.

And lastly, moving to step five, the corrective action and validation process, so for 2012 audits, the regional office is taking over the validation -- I'm sorry, for 2011 the regional office is taking over the validation of the deficiencies identified in the audit report. Sponsors will have 90 days to submit their corrective action to CMS, and we're going to get into this a minute, but there's kind of two tracks for corrective action. There's regular corrective action, which is 90 days, and then

there's the immediate corrective action, which I'm going to talk about in a few minutes. It's much more accelerated. But generally, 90 days to submit your corrective action to CMS.

We then validate after those 90 days and you've told us all the deficiencies have been corrected. We will put a team together. We will select new universes. We'll select samples, and we'll kind of do like a mini audit or validation of those deficiencies. We will only be looking at the deficiencies that are in a pending state of the audit report. So it won't be looking at things that have already looked at but will just focusing on the failures in the audit report.

So that's the process from a much higher level. At least I was hoping it was a higher level. Next, I want to get into the immediate corrective action process. And, again, this is new for 2012. We had some instances in 2011 where we kind of helped develop this process but we really formalized it this year. And the purpose of this is when we identify what we define as significant beneficiary harm systemically across your organization, we feel that immediate corrections are necessary by the sponsor and immediate validation is necessary by CMS to protect our beneficiaries.

The areas that could have an immediate corrective action are Part D formulary administration; Part D coverage determinations, appeals, and grievance; Part C ODAG the compliment of the Part D; and then Part C, access to care, which is also part of the ODAG process. So these are the areas that we feel have the most impact on the beneficiaries as far as access to care and access to drugs. That's why we feel that if there is an immediate need it comes out of these areas.

Okay. So defining what we mean by immediate corrective action or significant beneficiary harm. It exists if the identified deficiency resulted in the plan's failure and systemic failure to provide medical services or prescription drugs, causing financial distress or posing a threat to enrollee health and safety due to non-existent or inadequate policies, procedures, systems, operations, or staffing. These problems that are identified, they're not issues that have been already resolved by the sponsor, but they're current vulnerabilities going forward or that could have the potential to cause significant harm.

And by "immediate," when we say "immediate corrective action" we mean that the sponsor needs to take whatever action is necessary. If that audit is going on in formulary and the team lead identifies an issue that could be significant of any harm, by "immediate," we mean if you need to take manual intervention to stop that harm from occurring, you know, you can take whatever steps are necessary to immediately stop that from happening.

Some examples of deficiencies that would require immediate corrective action, for prescription drug area, disruption of care to beneficiaries in regards to protected class medicines and other critical medications; beneficiary access problems related to the use of clinically inappropriate and unapproved utilization management criteria; and transition issues that would prohibit a beneficiary from receiving a temporary supply of prescribed Part D drugs.

Under the CDAG area, misclassifying coverage determinations or appeals as grievances. This has been a common finding that we're seeing across the sponsors, where if a beneficiary calls in for a request for coverage, the sponsors are processing it as a grievance, which isn't giving the beneficiary their due process rights under the coverage termination rights as far as timeframes

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with standard and expedited requests or giving them their appropriate appeal rights. So that would be an instance under CDAG where that would need immediate attention. Also, failure to audit forward cases to the IRE.

Under Part C organization determinations, failure to follow national and local coverage determinations or other CMS coverage policy, again, misclassifying organizational determinations as grievances, and failure to audit forward reconsiderations. And not on here, but in our process is -- and I mentioned it, but failure to provide the appropriate appeal rights.

So the process works, and we want to explain the process so that if you are audited and you do run into this situation, you'll know how to act when we start to request or send you e-mails to resolve the issue. So while we're onsite the team lead for each area is going to be on the lookout for these types of issues, they're going to identify them, they're going to document them, and if they feel that they're systemic in nature where they're affecting, you know, a large number of beneficiaries or has the potential to affect a large number of beneficiaries, they're immediately informing CMS management, communicating verbally to the sponsoring, and they're probably going to request a beneficiary impact analysis where, Wes, the sponsor, okay, for this issue, how many beneficiaries were affected, what class medication was it, was it a certain drug, whatever data you can gather with that analysis to help us determine the impact of the issue.

While onsite, the PCOG audit lead, that same day, will send an e-mail to the plan's compliance officer detailing the immediate corrective action issue and requesting that the plan fix it immediately. Again, the sponsors are made aware of the seriousness of the issue and our expectations for immediate resolution. And we'll also reiterate them. If there are any, we'll also reiterate them at the exit conference.

So post-audit, we continue to follow through on these. So within a few days of the exit, CMS is going to send the sponsor an e-mail indicating all the immediate corrective actions and deficiencies that were identified for each area, so it will be broken down by formulary, by CDAG, and ODAG. The sponsor will reply -- has 72 hours to reply to CMS how they corrected the problem, both in the short term, whatever the manual intervention was, or, you know, if it was a system fix to a PBM system, or whatever it is in the short term, and then the long-term plan for corrective action, whether it's additional staff training, whether it's hiring more staff, et cetera.

After the e-mail is sent to the sponsor, the audit lead will also have a phone call right afterwards to go through the e-mail, to go through each issue to ensure that the sponsor fully understands the issue, and, again, a sponsor has 72 hours to reply to CMS that it corrected the issue. Once we receive the response, it can either be accepted or denied by CMS. It's accepted if it's reasonable and is measurable; it's specific if detailed and includes timeframes; it includes how the sponsor is going to monitor the progress. It's not accepted if it's vague. There's no timeframes. The issues aren't addressed. So we want that to be accepted the first time in, so please keep that in mind. The audit lead will let the sponsor know whether or not the submission was accepted.

So validation: So we talked about validation in 90 days for the regular findings in the audit report. Now we have the immediate validation that happens very, very aggressively. So the sponsor submits it within 72 hours, and for formulary administration and ODAG and CDAG it's a little bit

different on how the validation works. But for formulary, immediately after that is received then the sponsor says that, you know, they corrected the issues, we go ahead and we start validation immediately. We ask for a three-day universal rejected claims, and then we'll go ahead and review those and work with a sponsor to come to a determination as to whether or not the issue has been corrected.

For ODAG and CDAG we allow 30 days to pass by. We then ask for a universe consisting of 30 days after the corrections were made. And then we go ahead and we validate that as well using our protocols. And we're only validating the issues that were in the e-mail as the immediate need issues, so we're not looking at other areas. But if we do find new type of deficiencies as part of this validation, we will make the sponsor aware of those as well. So that's all.

We also work hand in hand with DCE for the immediate need items for division of compliance enforcement. If we need to consider other routes because things aren't getting fixed, it could be civil money penalties, sanctions, et cetera. So we just ask that you work with us if these are identified and work quickly to get them resolved. So thank you, and I'm going to turn over to Tawanda.

Thank you. So technologically challenged. So it's about 12 minutes left, so I'm going to try to run through these as fast as possible because I know we're embarking on lunchtime. So preparation tips for the audit is I thought that the five-star sponsors did an excellent job with preparing tips, and I just want to add onto that. So even before you receive your start notice, we're asking that everyone just take a look at the memo, the HPMS memo, the audit protocols and all of the attachments that was dated May 11th that was released in HPMS, become familiar with those protocols and templates, become intimate with those protocols and templates.

We're asking everyone to conduct internal audits. Use those protocols to do your monitoring. Use those protocols to do your risk assessment. After you receive your audit start notice, we're asking that you kind of do a huddle with all your internal folks, with your PDMs, your FDRs, anyone who touches these operational areas, you may want to have a huddle with them. Compile your questions about the universe and the expectations and things that are required. Sometimes the universe templates -- things that we refer to in the universe templates and certain headers could be called different things in your organization, so we need to hear about that and have those things cleared up.

During the follow-up call we ask that sponsors ask questions. That's your opportunity to find out from the audit lead any clarifications that's needed about the universes, the templates, and the process. That's the opportunity for the team leads to ask questions about how the universes will come in, how you load your formularies, and things like that.

One of the things that sponsors often have challenges with is realizing that all of the reviews are done simultaneously. And what we'd like to explain to sponsors is that when we're doing formulary we're doing CDAG at the same time, and that's important to know because oftentimes sponsors are unable accommodate both. The team that they have for formulary is the same team members that they may need for CDAG, so we need to hear about those types of logistical issues, because with the

audit lead they can have the formulary review conducted on a Monday/Tuesday, and then we can wait for CDAG to be done Wednesday or Thursday.

We also ask that as soon as you get your SFTP account, please do a test file right away. Oftentimes, not a lot, but there are times that sponsors experience difficulties uploading the files. When you upload your file there's typically two folders. Sometimes sponsors will put it in their own personal file. The way this account is set up, you'll have your personal file and then you'll have another folder -- you'll have your personal folder -- I'm sorry -- and then there's another folder where CMS will be able to pull your universe. And sometimes sponsors get it confused and they'll put their file in their personal folder, and we can't get to it.

Contact your audit lead if universes is going to be delayed or, if you have any further clarifications, the audit lead wants to hear from you and want to be flexible and receiving your universes. The enrollment, disenrollment, LAP, agent/broker areas, as Jonathan pointed out, we typically will send those samples out the Thursday before the audit, and then that Monday morning is when you'll receive the rest of the samples.

The good thing about the enrollment/disenrollment, LAP, agent/broker, we want to give sponsors an opportunity to prepare the documentation and upload all of those cases ready to go on Monday. We believe that those areas require the most documentation, so it would not be efficient to go through those areas, go through those cases with all of the documentation via webinar. We really like it when you kind of highlight how you are compliant, having dates highlighted and things for us that will make the review go much smoother and quickly. Samples are provided during the entrance conference. I mentioned that.

During the webinar, be prepared to discuss why the samples are compliant. If you don't have the right folks in the room, the audit lead or the team lead will go to the next case until you get someone in the room, or if we feed to wait a day, we can defer a day as well. Feel free to ask questions if you still aren't clear as to why a sample failed. The team leads, as they're going through, beneficiary case one, and they're asking to see different things, they're asking to see documentation, they're asking to see dates that something was paid, they want to see actual claims were paid. And if it's still feeling like it's a fail or if you're still not understanding why it's a fail, please ask.

All screenshots, although we're going through your systems live with you, there are oftentimes that the team lead will actually have the screenshots of what they actually saw, have that captured, copied, and pasted and upload to the SFTP. Please label that screen shot. It's coverage determination appeals grievances. It relates to the effectuation timeliness area, and it's case number, too, is very helpful. And please try to upload those daily for us.

Provide your audit team with items requested within the deadlines provided. Again, we want to give sponsors ample amount of time to provide us all documentation, even during the daily uploads. If you're still experiences difficulties, please contact the team lead and let them know when they expect to receive the documents.

Immediate issues should be addressed as directed by CMS. I thought Jonathan did a good job talking about immediate corrective action process. We're asking that you track your fail samples to

assist in planning correcting action right away. One of the things that I heard one of the sponsors, at the end of every evening, they kind of do a huddle and they touch base about things that they failed. And right away, that said to me they're already starting to think of corrective action. During the exit conference, ask many questions, that's what we're there for. Develop your corrective action plan. I have here "in anticipation of the final audit report, but as I just mentioned, I think you should be preparing for corrective actions right away.

The post-audit, review the draft report, provide the comments timely. Upon receiving the final report, prepare your corrective action plan for CMS. And one of the things that Jonathan pointed out, we want to let sponsors know that the regional office will be responsible for the validation of corrective action starting in 2011 and going forward. We're asking that everyone respond to our audit questionnaire. Upon receiving your final report, we're sending you an e-mail with your final report with a link to our audit process questionnaire. This is a tool that we will use to improve our process.

So the next slide is a slide, kind of a placeholder for our 2012 best practices and common findings HPMS memo. It was right there. We were all ready to push send but it didn't quite go, so I just want to highlight a few things. That memo should be released either later this week or early next week. Right now senor leadership is still reviewing it. It's going through our clearance process. And as soon as they're done then you all will have it. But I actually have a copy, and it's 14 pages long. And I just want to kind of share just a little bit, tease just a little bit before you get that grand meal later this week or early next week. Just a few things like letterman has his top ten, I have some things on here that I want to share that I thought was really good if you don't mind.

So for formulary administration, a best practice, routine review or rejected claims reports by sponsor and the PBM. The PBMs do their own rejected claim reviews, the sponsors do their own claim review, and they kind of get together and they talk about it. And they talk about unexpected findings, and they communicate how they plan to correct, just absolutely love that. Who enjoys having that call with Cynthia to talk about rejected claims? Nobody wants that call; right? So I think that that was -- someone pointed that out as a best practice. That an awesome practice.

Common findings; transition field, we're still seeing that sponsors are still struggling a little bit with the transition field for both new and continuing enrollees, so we we're asking that everyone kind of pay attention for that. So for CDAG Part D coverage determination appeals and grievances and Part C compliment of that, things were pretty similar. So best practices; timeliness, sponsors ensuring timeliness in their decision making by tracking and overseeing their coverage determination appeals and grievances, and that notifications to pharmacies of coverage determination decision and appeals decisions within one hour of a decision. I just think that's absolutely amazing to me.

Placing an interactive voice response message phone call to inform beneficiaries of their decision of their pending coverage determination appeals, and they don't do this just for the expedited. This is standard requests also. Now I know some of this may be just practice business as usual but this is just absolutely amazing to me. Effective communication was one. Effective communication coordination among all parties associated with sponsors on coverage determination and appeals and grievances, and I think one of the five-star sponsors, one of the ladies mentioned how they actually do a trending analysis.

This other one, utilizing a five-point contact, when the letters are sent to the prescriber they also send a letter to the patient, they also make phone calls to the patient, to the prescriber, and to the pharmacist. This approach is more expansive than the requirement to solicit necessary information from the prescriber.

A common finding, expedited coverage request were inappropriately downgraded to standard coverage requests to meet CMS timeline requirements. Another common finding is insufficient outreach to prescribers or beneficiaries to obtain additional information to make appropriate clinical decisions. Compliance: this is a good one. Best practice, tracking and monitoring systems. We found that some sponsors have a really robust monitoring system. They're able to integrate what they're externally reporting a hotline. They allow potential for fraud, waste, and abuse tips to be uploaded into their tracking system. They control rights to the system to ensure cases are handled properly by the appropriate person. They establish protocols to close audit deficiencies that are found. And they allow for corresponding caps, kind of similar to our audit process. Both compliance and operational staff monitor progress towards established goals.

A common finding is the opposite, a lack of an effective system for monitoring and auditing or identifying compliance risk. A best practice for training of agent brokers, that the brokers go through a really robust training and testing exercise where the training score is typically 85% or higher. Some sponsors require a 90% pass rate. Another one is a comprehensive training program including a ride-along process between a compliance manager and new agent brokers.

A common finding: in the complaint department we found that sponsors do incomplete investigations when allegations are made against agent/broker. Part C and D enrollment, timeliness. For best practice there are some sponsors that review enrollment with missing information on a daily basis. A common finding: incorrect denial of enrollment and disenrollment requests and incorrect enrollment of a beneficiary into a plan for which they were not eligible. And lastly, for LAP, timeliness is a best practice. Working diligently sponsors can enable the Part D LAP hour rate independent review entity decision to be effectuated within four days or less.

A common finding: failure to supply the beneficiary with the LAP assessment and his or her appeals rights within ten days of receipt of Part D LAP amounts from CMS. So that is the best practice and common findings, and I'm just going to rattle through what's going on for 2013. We'll take question. We go to lunch, and we out of here.

So 2013 audit plan, first I want to acknowledge, have to acknowledge my team who worked hard and they're dedicated and they're passionate about their goals. And, of course, we wouldn't be able to accomplish this if we didn't have a successful leadership, so we want to give all kudos to that. I feel if the five-star plans can do it, I can do it too, acknowledge my team members and my leadership as well. We also want to acknowledge, we couldn't do any of this without our regional office colleagues, as well as the folks in central office, our colleagues as well.

So in 2013, finalizing the audit strategy, we plan to go to Chicago this year to meet with our audit committee, and these are arrays and branch managers in the regional office. Last year they came to us on my birthday in November to do the 2012 audit strategy, so we're going to take a trip to

Chicago next month, and we're starting early this year. The next one is we want to release the 2012 audit lessons learned December of 2012. That will be the August to December lessons learned. We plan to release these twice a year. So the first HPMS memo that you will get, that will come late next week, early next week, and then we'll do another one later in the year.

The 2013 protocols will be released January 2013. HPMS, if everything goes right, our new audit module HPMS will go live in 2013. All of the audit start notices in the universe requests that come to you via e-mail, we're going to have an audit module in HPMS to be able to do that audit. It will be automated in HPMS. 2013 audits will begin late January, early February 2013. And lastly, we're developing a PCOG webpage. This webpage is scheduled to go live, if not next week, the following week. This webpage will have all of our audit protocols, our sister division who does division of compliance, division of compliance and enforcement. She does the compliance policy. She does the enforcement action. Miss Trish Axt.

All of her information will be there as well. And that's all we have today. Thank you so much for your time and your attention.