2017 Audit Protocol Updates

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Stacey Plizga: We are delighted to have with us today speakers who will provide us with an understanding of the new design and objectives of the 2017 Compliance Program Effectiveness Audit Protocol. They will also explain the purpose, structure, and content of the 2017 MMP Audit protocols. Please help me welcome Vernisha Robinson-Savoy, Lauren Brandow, and Marla Rothouse.

[Applause]

Vernisha Robinson- Savoy: Hello, everyone. My name is Vernisha Robinson-Savoy, and today I would like to engage you for approximately 20 or 25 minutes before I hand it over to my colleagues to provide some insight on the new redesign of the Compliance Program Effectiveness Audit Protocol.

Just a quick little funny…myself, Marla, and Lauren were joking backstage since all the questions for the conference were discussed in the previous discussion and presentation, we don't expect any.

[Laughter]

Vernisha Robinson- Savoy: So we're hoping that that's the case; if not, please ask your questions. Let's get started.

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Very short agenda for today…my main goal here is to provide some detail on why we have taken a new approach for 2017, as it pertains to how we evaluate the compliance programs of Medicare Advantage organizations and Prescription Drug plans. Many of you I've had the pleasure of working with either through audits, through answering questions sent to our Audit Mailbox, through questions that we receive during the PRA process of clearing the new protocol, and just feedback over the seven years that we've been auditing compliance programs using our outcomes evaluation approach.

I was tasked with redesigning a tool to take our evaluation to the next step. So we're confident through our audit cycles that the majority of our organizations that contract with us for Medicare have the structure and the processes that make up their program that detects, corrects, and prevents non-compliance and fraud, waste, and abuse. Now that we have some confidence that you have the structure in place, we're now taking it to the next level to evaluate, okay, so what happens when those situations occur in your organization.

So that's what I'm going to be focusing on…is the significant changes. Then briefly, there are actually a number of slides that I may not go into in detail, but it's also for your reference of the record layout clarifications, some technical guidance that we are aware of that will help you with your universes.

So just a little feedback…not feedback, just the overview -- over the last six months as many of you may have participated, our audit protocols for 2017 were issued for public comment. Specifically for CPE, which is the Compliance Program Effectiveness – I will be using that acronym often – we received over 150 comments from different organizations, sponsors, advocacy groups, trade organizations…pretty much anyone who had an interest or an investment in the Medicare program.

Some of the major themes that the comments focused on: tracer evaluation; improvements to the audit elements, the record layouts; the on-site interview process when we're on-site with compliance professionals; as well as how we resolve compliance issues while on-site, as well as after the audit is conducted. So just a plethora of changes to consider, and so I honestly believe that we've taken all of that information to make a protocol that will hopefully accomplish our goal of easing the burden on organizations as well as on others.

The objective of the CMS Compliance Program Effectiveness Audit is to evaluate a sponsor's performance with adopting and implementing an effective compliance program to prevent correct Medicare Part C or D program non-compliance and fraud, waste, and abuse in a *timely* and a well-documented manner. Those are two very important factors that are highlighted throughout the protocol.

The review period, which has stayed the same for the last seven years, is one year…so 12 months preceding and including the date of the audit engagement letter. For example, if a sponsor received an engagement letter on May 1, 2017, the audit review period would be May 1, 2016, to May 1, 2017. That's a question that we actually received recently …what protocol do I use if I want to just do a mock audit or such? Is it 2017 or 2016, since the review may be your best benefit for CMS to select three internal auditing tracers versus two?

Then something else is new…another just a check-in with the sponsor. We have a follow-up call about the tracer samples. Once we submit the tracer samples to you, we have a call. We upload them to HPMS, and then we'll schedule a call immediately with the compliance officer -- and you can determine who you would like to have on the call -- to go over the sample requests. So you know exactly what samples we've chosen; where we've selected them from, what universe; and any questions you have about the tracer summaries, how you would like to present those.

It's just, again, a Q&A session just to ensure that we're both on the same page.

Then we have something else new for 2017. In previous years, we've selected a number between 5 and 20 employee records that we evaluate to test for compliance with submission that the organization has provided the code of conduct, certain policies and procedures as it relates to compliance, as well as OIG and GSA exclusion checks. For 2017, we are conducting this specific test on site. So on the first day, unlike the other samples, you will be provided 20 employees as well as Board member names; and you will be expected to provide the OIG exclusions, checks or evidence that you've performed those checks, as well as evidence that receipt of code of conduct and any other requirements that are outlined in Chapters 9 and 21, the Compliance Program Guidelines.

During the sample follow-up call, if there are any issues with you have with an external vendor for your OIG GSA screenings and you may need some additional time, that is definitely where that discussion needs to take place so that we're aware of how we may need to maneuver to make sure that both parties are in agreement with how we will proceed. So we're going to select 20 employees and Board members; it's a combination, but only 20 records.

For the on-site…after Week 1 or the program activities for CDAG, ODAG, SNP-MOC, and/or Formulary Administration, the small CPE team arrives on-site at your organization. We have restructured…in a way, we've streamlined…Week 2, which is referred to as a CPE on-site audit. And then hopefully it's more transparent, as well as it allows organizations to decide what resources are needed where.

So Day 1, we have a walkthrough. After the welcome, we set up, and all that good stuff. We have a walkthrough of your compliance program. That's really in prior years where we covered the seven elements. This is where we will go over your presentation of the organization: your

structure, who's who, your risk assessment. Any questions that we have about the documentation we reviewed prior to arriving on-site that is where we will discuss those issues.

Also on Day 1, we will complete all of the compliance interviews. We have an hour interview with the leader of the SIU Division; or, if you don't have an SIU, the function that performs those fraud, waste, and abuse prevention, detection, and correction processes. As well as we have an hour interview scheduled with the compliance officer, and an hour interview with the party or parties that manage the delegation oversight within the organization for Medicare operations. So that's a full day. Then we usually have a wrap-up after each day just for 15 minutes with the compliance officer to go over the document request list and just preview what will be covered for the next day.

Day 2 is the focus all on tracer samples. A tracer sample can range from one to three hours. It really depends heavily on how detailed the tracer summary is. Again, if you have any questions about how do I organize my thoughts because I can see, now that we don't provide a template how challenging that can be, please reach out to your audit lead or your CPE audit lead, once that person has been designated, to get some insight on how you can proceed with that because if it's detailed, we can get through that tracer.

On Day 2, we would like to, if possible, between Days 2 and 3, review those employee records to assure compliance with the exclusion checks. One of the questions that we received often recently is: How many months should I be prepared to provide for the ECT review? It's the 12 months, so just keep that in mind…that it's the audit period that you want to provide.

A huge significant change that we've had is the audit elements -- traditionally, the seven elements that are listed to the left – and now we are focused on the three core actions of the Compliance Program. This is

to show the question that I received (inaudible) processes. Where do these three core functions come from? Well, this is what a Compliance Program is supposed to do or what it was designed to do. You will see in the protocol how we correlate that to the seven elements; I mean, it's all embedded within each other. And the tracers, the way that they're designed to tell the story in chronological order, the core elements of a Compliance Program will play out. So we're confident of that.

For prevention, this particular element evaluates the sponsor's internal controls to reduce the number of potential non-compliance and fraud, waste, and abuse and regulatory violations from occurring within all Medicare business operational areas by employees and delegated entities. These compliance controls provided the framework for which the company and its employees operate, convey compliance expectations, prevent repeated issues from recurring, and deter minor issues from becoming significant problems with adverse impact to the sponsor's operation and Medicare beneficiaries.

So you will see here, these are what we consider preventative controls that we will evaluate during the CPE audit. Again, if you want to think of it in the core element perspective of a compliance program, you will see Elements 1, 2, and 3. Now, I do want to note that the elements or the compliance standards that preventative measures could be detection, depending on how the tracer – the issue is handled. So we do take that into consideration during the audit.

And just one quick thing about detection that I want to highlight is while this is the second audit element, this element tests the effectiveness of the sponsor's internal controls that should have detected the issue of non-compliance. So the auditors will continually ask you that question during the tracers is, okay, you became aware of this issue for detection; so why did you pursue this way, and what guarantees you or provides assurances – that's a better word – that you were able to identify it within

a timely manner? And "timely," again, is based on your operating procedures. So that's for that.

For correction, correction is pretty straightforward. This audit element evaluates the sponsor's escalation process. So, again, we will be asking – that is critical for us to understand because we understand that not all issues go to a Board. Not all issues go to the compliance officer. You may have within your organization a compliance officer for business areas versus just a Medicare compliance officer. So *our* job, our job is to understand your business processes and then to follow and to assure that issues are processed in the way that you have structured within compliance with CMS requirements. I hope that makes sense, but it's really our job is to understand your business.

So while the third element is correction, it's really focused on testing the effectiveness of your responsiveness. So we're looking at timelines here…your approach to the issue of non-compliance or fraud, waste, and abuse. So the question here is: Was there an appropriate plan of action for correction? And I understand that "appropriate" is subjective; but that is why we test – while it's a small number of tracers, it is very comprehensive. So the tracers typically can be an appeals and grievance audit, a monitoring of your SNP-MOC process – I'm just thinking of some tracers – an audit of your PBM specifically for data that they submitted on your behalf to CMS that was incorrect.

So asking that question, "Was there an appropriate plan of action for correction," it depends on the situation; so that is your job to tell us.

Okay, and I'm almost done. This is record layouts; I'm not going to read this to you. This is for your information; and for those that are joining us on the webcast, it's just some clarification for each record layout that we received recently that we would like to provide as information to you.

I'm going to forward it over in the interest of time. If you have any questions, you can definitely – any audit-related questions to the audit mailbox. CPE, specifically policy for regulations or the Compliance Program Guidelines, please submit it to the box. Myself, as well as my colleague – we monitor that and answer those questions as immediately as we can. And here's a website for where all of the audit information is available to you.

I will turn this over to Marla and Lauren.

Marla Rothouse: Thank you very much, Vernisha.

We're going to change gears a little bit and focus in now on the Medicare and Medicaid plans, and how they fit into the overall CM Program audits. I'll be honest, not knowing the audience out there, we're going to provide a little bit of background on the financial alignment initiative and how Medicare and Medicaid plans came to be. Then we'll talk about how they fit into the 2016 program audits last year and now what we're doing for the program audits in 2017.

Just by, again, way of background on the financial alignment initiative and Medicare and Medicaid plans in general, back in 2011, CMS announced new models that would work to integrate the service delivery and financing of both Medicare and Medicaid through federal/state partnerships. We wanted to create access to quality, while providing integrated services to these beneficiaries.

Through that, we've created two major initiatives. One is a nursing facility initiative that I don't have on these slides, but I welcome you to go to our MMCO website and learn more about.

Then we have our Financial Alignment initiative, which hopefully will be known to more of you. Under the Financial Alignment initiative, we have

three models. We have a fee-for-service model, which is when CMS is entering into an agreement with the states, under which the states are eligible to benefit from savings resulting from initiatives they take that reduce costs in both Medicaid and Medicare. We have our Capitated Financial initiative, which is our big one that you all may be familiar with, which is where we enter into three-way contacts with states and health plans to provide comprehensive, coordinated care and integrated benefit of both Medicare and Medicaid through managed care. Then we have a third alternative model that's actually leveraging the Medicaid Advantage Dual Special Needs Plans to do some administrative alignments that we can do through an MOU.

My next slide just gives you a picture of the map of where we have the different models in play right now. So the fee-for-service demonstrations are happening in Washington and Colorado. Our Administrative Alternative demonstration is happening in Minnesota with the DSNPs there. Then we have 10 states participating in the capitated demonstration. I can tell you New York, though, has two different demonstrations; so we have 11 demonstrations in 10 states happening right now.

Once these capitated demonstrations really became operational, CMS wanted to make sure that we were capturing their performance in the overall Medicare Program audits. We wanted to make sure the MMP lines of business were being looked at. To that end, we began including the MMPs in the parent organization audits last year. Overall, CMS did a lot of audits last year. There were 37 parent orgs that covered 168 contracts; and if you break that down, there were 8 parent organizations that operated 19 Medicare/Medicaid plans across 7 of our demonstrations that were captured in the program audits last year.

Let me just say, for everyone's peace of mind, the MMP-specific findings that happened last year were documented in the final audit reports as observations. They were not counted in the overall parent org audit score

in their audit reports. That's not to say that some of the observations did not include corrective actions for our MMP-specific findings, but they were really just observations in the final report and weren't counted towards that overall score.

But what we saw very quickly as the audits were progressing throughout the year is because the MMPs were operating under three-way contracts, there were differences between Medicare Advantage and the requirements outlined for the plans in the three-way contracts. Some of the biggest areas were in appeals and grievances or timelines to complete health risk assessments; the membership of your ICT, the care teams; and some of the covered services. One of the biggest differences between Medicare Advantage and our MMPs is the covered services include long-term supports and services. So it's just looking at a different scope of services than in a Medicare Advantage audit.

It became – at least on the audit I attended – I would say the proverbial square peg/round hole…trying to make the MMP line of business fit into the Medicare Advantage protocol. For 2017, we wanted to do better than that square peg/round hole; so that is why we worked to develop some MMP protocols this year. We released them for a comment back in February, and we had a lot of comments. MMPs, DSNPs, industry, advocates – we heard from everybody. We have recently released the final protocols on April 28th; so fairly new and not sure everyone's gotten them yet, but they're out there. They are called the MMP Service Authorization Requests, Appeals and Grievances, or SARAG protocol, and the MMP Care Coordination and Quality Improvement Program Effectiveness Protocol. I'm not going to say the acronym; there's debate internally at CMS of how you pronounce that, so I'm just staying clear of it.

I just want to do some major highlights of the feedback we got from all of you in your comments and how we changed the draft protocols to what

we released in April. Lauren will get into more of the technical aspects for us.

First and foremost, these will be pilot protocols for the 2017 contract year. So any parent organizations that have MMPs that get audited this year, these two protocols will be pilot. And we really tried, as much as possible, to leverage the existing Medicare Advantage ODAG and SNP-MOC protocols where we could. We tried to keep terminology the same, even if we had originally done it differently in the draft. We're trying to really standardize them as much as we could, respecting the fact that the three-way contracts sometimes have much more specificity; and we're really trying to audit the organization against the requirements in the three-way contract.

So you will see at the beginning of each of these two protocols a definition section. I would say that's very much for the ease of reading the protocol that we've included those in the protocols, but you should always refer back to how terms are defined in your three-way contract. That would be what the auditors are going to be looking at when they audit.

We also took your feedback about the amount of data elements we were collecting for the universes; and we've certainly scaled that back significantly, especially in terms of claims and call logs. I think you'll see a great difference from the draft protocol to now the final pilot protocols. Most importantly, I also want to clarify how the pilot protocols will work into scoring…which is to say, they will *not* be part of your parent org overall audit score in 2017, just like 2016. Except this year, they won't be considered observations if they're MMP-specific findings. There would be CARs, things like that. If there's corrective action, we are looking for validation for the audits.

But these pilot protocols will *not* count towards the parent org scores, so it *will not* impact STAR ratings for our parent organizations. I just want to emphasize that for everybody's peace of mind, but want you to know that

we are going to be including them in the final report. They won't be in the Executive Summary in the MMP-specific findings, but they'll be in the actual body of the report.

With that, I'm going to turn it over to Lauren to speak to you in more detail about universes, data elements, and the technical aspects of the two pilot protocols. Thank you.

Lauren Brandow: Thank you, Marla.

Let's discuss the MMP audit process, including what changes sponsors with MMP and MA products can expect.

MMPs can expect to receive notice that they've been selected for audit six weeks prior to the fieldwork via the engagement letter. For sponsors with MA and MMP products, your program audit engagement letter will also include information about the MMP review. As Angelique mentioned in the previous session, the program audit will be extended by one week for a total of three weeks. The SARAG and CCQIPE reviews will take place during Week 2 of the audit; and Compliance Program Effectiveness, or CPE, will take place during Week 3.

Both the SARAG and CCQIPE reviews will be conducted over webinar with no on-site presence. Sponsors with both MA and MMP products would submit all program audit universes, including ODAG, in addition to SARAG and CCQIPE universes. The sponsor would populate ODAG universes with MA cases only and populate SARAG universes with MMP cases only. No other program areas will be impacted by the addition of the SARAG and CCQIPE audit protocols. Further instructions regarding universe submissions would be provided during the follow-up call after receipt of the engagement letter.

Lastly, for sponsor with both MA and MMP products, MMP contracts may be cited in the final audit report in program areas other than SARAG and

CCQIPE if MMP members were affected by an issue of non-compliance identified in other programs areas. For example, it is possible that an MMP contract might be cited in an ODAG clinical decision-making related impact analysis, if there is overlap in the sponsor's MMP and MA clinical decision-making process.

Now I'm going to discuss the new MMP audit protocols individually. We'll start with SARAG.

SARAG tests three elements: timeliness, appropriateness of clinical decision-making, and grievances and misclassifications. For timeliness, although MMP timeliness requirements can be consistent with MA processing time frames -- for example, Part D coverage determinations and appeals – they frequently diverge from MA requirements, which is why MMP timeliness will be evaluated separately from the MA contracts for medical requests. Timeliness related to claims payment requests from providers and state fair hearings overturns will not be evaluated.

In regard to the second element, appropriateness of clinical decision-making and compliance with SARA processing requirements, for sponsors that have previously undergone an ODAG review, note that the SARAG review includes new MMP-specific requirements, such as aid pending appeal and the appropriateness of clinical decision-making and notification for cases the State Fair Hearing Office overturns.

Additionally, the appropriateness of the clinical decision-making element will include the review of service authorization requests and appeals for behavioral health, substance use, and long-term services and supports or LTSS. CMS will sample 40 cases for this element, regardless of the number of MMP contracts reviewed for one sponsor. We will evaluate each case selected based on the applicable contract-specific requirements.

For grievances and misclassification of requests, the documentation universes and compliance standards are almost identical to ODAG. There is one difference in the standard grievance record layout in which CMS asks MMPs to identify whether the grievance involves behavioral health, substance use, or LTSS services.

The SARAG review includes 12 universes. As Marla mentioned, there is a significant amount of overlap between SARAG and ODAG record layouts. Note that there are no SARAG universes equivalent to the ODAG universes for direct member reimbursements, payment reconsideration requests, or dismissals. Additionally, since New York MMPs external appeals are subject to review by the Integrated Administrative Hearing Office, or IAHO, not the independent review entity, or IRE, IAHO cases will be part of the State Fair Hearings decisions universe; and New York MMPs would not submit data for the other IRE-related universes.

The SARAG universes have some new data fields. For example, the field issue description and type of service has been separated into two data columns for the new record layouts. This was done for sampling purposes. Fields pertaining to aid pending appeal have been added as well, and you'll notice a few fields that are relevant to MMPs contracting with a particular state; but these are minimal.

Some response options for familiar fields have been altered. For example, in acknowledgement of the role of the service coordinator and what they do in terms of submitting service authorization requests on behalf of members, we are asking MMPs to identify whether a request was submitted by the service coordinator if that information is tracked by the MMP.

For the Call Log Record Layout, that has been altered to identify optional data fields. This is in line with the ODAG and CDAG Call Log record layout and was changed to reduce MMP burden. As stated in the

protocol, MMPs can submit this data in their preferred format, as long as it includes the minimum data that CMS is requesting.

Some of the comments that we received on the draft protocols related to SARAG touched upon these themes. Commenters wanted to know if Part B point-of-sale drugs should be included in the universes and whether to include Part D drugs. As stated in the universe preparation and submission section of the protocols, SARAG universes should include prescription drugs that would be processed under Medicare Part B but would exclude all other prescription drugs. Therefore, sponsors would not include Medicaid-only prescription drugs or Part D drugs in the SARAG universes. This would include the exclusion of grievances and calls related to Part D drugs.

Also in response to commenters, CMS will permit MMPs to exclude concurrent review for inpatient hospital and skilled nursing facility services, post-service reviews, notifications of admission from the universes. If the MMP has already programmed its system to include these requests in its universes, we will accept the universe submission.

Note that requests for extensions of previously-approved services have *not* been excluded, although they can be excluded from the ODAG universes. I just want to point out that difference.

Now let's talk about CCQIPE. As Marla noted, the CCQIPE protocol closely resembles the SNP-MOC protocol. One of the major differences between the protocols is that CMS will evaluate MMPs against the specific requirements for the three-way contract rather than the MOC, the model of care. However, CMS has asked MMPs to submit their model of care at the time of their universe submissions.

Also in contrast to the SNP-MOC protocol, the CCQIPE protocol does not have an enrollment verification element. Care coordination will address the timeliness and administration of the health risk assessment; the

individual care plan appropriateness and implementation; and the interdisciplinary care team composition, qualifications, and functioning. We'll also look at the coordination of member transition across care settings.

Unlike SARAG, the CCQIPE review *would* include Part D drugs. Part D drug claims should be accounted for in the Medicare/Medicaid Plan Members universe; and CMS may review care and case management documents, such as prescription drug events that would include these claims.

Quality Improvement Program Effectiveness will review the performance of the MMPs Quality Improvement Project to determine whether the MMP has collected data on performance measures, analyzed the results, and has taken appropriate action when a performance goal is not met.

For both Care Coordination and Quality Improvement Program Effectiveness, CMS will evaluate how the plan has integrated member and/or member representative participation.

The Medicare/Medicaid Plan Members record layout is the universe from which CMS will select 30 members for the Care Coordination review. All of the sponsors' MMP contracts will be represented in the review. In response to commenters, CMS has removed fields in the Medicare/Medicaid Plan members' record layout that require breakouts of approved and denied claims, payment numbers, and amounts for behavioral health and substance use and LTSS services. These fields were removed to reduce MMP burden. Now, only requests for cumulative totals remain.

Additionally, due to the nuances of the setting or method by which the Health Risk Assessment could be conducted, CMS removed the field requesting this data; but we will look at it on a case-by-case basis during the actual review.

If you have any questions about the audit process or MMP contract requirements, you can e-mail the Audit Mailbox or the Coordination Office at the following e-mail addresses; and this concludes our presentation. Thank you.

[Applause]

Stacey Plizga: If you have questions, would you please hold them until the afternoon session when we do the Q&A session as we are out of time right now.

I would like to thank Vernisha, Lauren, and Marla for sharing the information on program audits.

We will be evaluating this session. If you would like to evaluate this session, go ahead and select "A,", follow the link, and answer the questions.

We will be taking a 60-minute lunch break and will begin the afternoon session promptly at 12:30 p.m. For our in-person guests, there is a cafeteria downstairs. For those who preordered your lunch, you can pick that up at the Jazzman Café.

Thank you very much…enjoy your lunch!