Independent Validation Audits

Brenda Hudson, CM

Stacey Plizga: Our next session today will summarize the Independent Validation Audit process related to program audits and discuss recent enhancements to the process. Please help me welcome Brenda Hudson from the Division of Audit Operations.

[Applause]

Brenda Hudson: Hello my name is Brenda Hudson and I am with the Division of Audit Operations and I'm happy to speak with you today about independent validation audits. In the next few minutes I will cover the following agenda items. First I will outline the authority under which CMS operates in requiring organizations to undergo independent validation audits or IVAs. Next, I will outline the steps in the IVA and closeout process. Then I will summarize feedback and experience collected from stakeholders that have been involved with audits. I will talk about the listening session that CMS hosted last summer and I will summarize the enhancements to the validation process that were included in the 2019 call letter along with the effective dates for those enhancements. And time permitting we will take questions at the end.

The authority for CMA to require IVAs comes from CMS regulations. Those provisions indicate that CMS may require sponsoring organizations to hire an independent auditor and undergo an independent validation audit to validate whether deficiencies found during the CMS audits have

been corrected. CMS later issues clarifying guidance through an HPMS memo in 2015, that memo outlines steps in the validation process and describes the roles and responsibilities of involved parties. In addition to the guidance provided in the HPMS memo, we have also provided updated details surrounding CMS's expectations for the validation and closeout phase of the audit. This information is available on our Part C and D compliance audit website.

In our guidance document we outline the following sequential phases of the audit validation and closeout process. First, the audit firm selection, development and submission of the IVA work plan, conducting the IVA, submitting the IVA report and audit closeout. I will spend most of our time today talking about the enhancements that were set forth in the 2019 call letter. To help establish context, I will also touch on each of the phases outlined in this slide even though we have not actually made changes to each and every phase. After the requirement for hiring independent auditing firms was implemented in January 2016, stakeholders began to gather experience with the validation process and they shared their feedback with CMS. Feedback centered around a few themes such as the threshold for requiring an independent audit, the burden on sponsoring organizations, selection of an independent auditing firm, the scope and timing of the IVA, the IVA work plan, and the IVA fieldwork and reporting. Organizations also expressed interest in being able to comment further.

In response to requests for the opportunity to further comment, CMS hosted a listening session on July 18, 2017. We had a great turnout, nearly 1400 participants representing sponsoring organizations and independent auditing firms nationwide. Our goal in hosting this session was to gain a better idea of how the IVA process was working and to the greatest extent possible, adopt ideas that would improve the process. During the event we sought comments on the recurring themes that I just mentioned. Afterwards we spent time further considering all of the feedback that was received. In the call letter that was included with the 2019 advance payment notice, we solicited comment on five validation

related enhancements including; the threshold for requiring an IVA, conflict of interest limitations on IVA firms and IVA work plan template, the timeframe for IVA completion and the process for submitting IVA reports to CMS. These were the direct result of feedback that was received during the 2017 listening session. We received comments from a variety of stakeholders all in overall support of the changes. We are proceeding with our enhancements and I will talk through those next.

First we modified the threshold that CMS used in 2017 to determine when an organization must hire an IVA firm. Most commenters supported the removal of CPE conditions from the threshold stating this would reduce burden. Some suggested increasing the threshold further, for example, greater than eight or greater than ten conditions. However, when we updated our estimates with 2017 data we found that the number of organizations that would fall below the threshold of more than five non-CPE conditions and thus would undergo a CMS validation increase to 11% of sponsoring organizations. Under the new threshold, only those organizations with more than five non-CPE conditions cited in their final audit report will be required to hire an IVA firm. We clarified that the CPE conditions will not be excluded from validation itself, it's just that depending on where the organization lands with the threshold will determine who performs the validation. If they fall under the threshold CMS will do the validation; if they fall above the threshold and IVA firm will be required to perform validation.

Earlier I mentioned the phases of audit validation and closeout; the enhancements pertain to the first phase. This is the phase of selecting the auditing firm. We clarified the organizations are not precluded from using the same firm for their annual external CPE and their IVA as long as the firm has not previously provided consultation or assistance with the correction of audit findings. Commenters were supportive, but requested further clarification on terminology, other CMS conflict of interest or COI standards, and the timing for completing the COI assessment. First commenters asked for a definition of management consulting. For the IVA process, we simply defined this term as general consulting services

provided by a firm. We don't consider a firm that has provided the organization with mock audits, as an obvious conflict, unless they also provided consulting services, or helped in correcting the findings identified during the mock audit or any other audit activity. We were also asked whether organizations could follow the COI standards used by selecting a data validation contractor. We chose not to align our standards with those in place for data validation consultants. The standards that are outlined in our audit validation and closeout document provide organizations greater flexibility in selecting a firm. Finally, with respect to the timing for when the COI assessment must be completed we clarified that it must be complete and any conflict taken into account before entering into a contract with the firm.

In this slide I've included examples of what would and what would not be considered conflicts of interest. The most important question to consider is whether the firm has provided consultation or assistance with the correction of audit findings. If they have, we would consider the relationship to be a conflict of interest. Organizations are encouraged to discuss individual questions about potential conflicts with their CMS validation lead.

The enhancement listed here pertains to the second phase of the audit validation and closeout process, developing and submitting the IVA work plan. This is the most significant of the five enhancements and it pertains to the creation and use of an IVA work plan template. Commenters identified expected benefits such as improved consistency, efficiency, and stabilization of cost and resource estimates from the audit firms. Commenters requested that CMS be as specific as possible when defining the template fields. They supported clarifications for requirements pertaining to auditors with clinical experience and the number of auditors. Commenters concluded by expressing interest in commenting on the draft template. Based on the supportive comments that we received, we included the draft template in the PRA package that is currently available for public comment, this was discussed earlier in the first session. The template would capture certain key elements. First, a

summary of any prior Medicare work that the firm has provided to the organization. It would also capture details regarding the audit team's experience and credentials. CMS is looking for two auditors per program area. A minimum of two is required to satisfy the requirement for a complete and full independent review.

To further clarify expectations for staffing and credentials we are interested in assurances that the auditors have sufficient clinical experience. For example, an FA or CDAG clinical auditor would need to have expertise in the formulary administration, transition and processing of coverage request requirements. A pharmacist would be a logical choice. Also for CDAG, ODAG or MMP-SARAG a clinical auditor would need to have expertise in processing coverage request requirements, a physician would be a logical choice. An MMP-SARAG clinical auditor would need to have expertise in evaluating the level of care and social supports necessary for the provision of long-term services and supports for the duel-eligible population, a social worker would be a logical choice. A SNP-CCQIPE or MMP-CCQIPE clinical auditor would need to have expertise in care coordination and quality improvement program effectiveness requirements; including model of care processes, health risk assessments, interdisciplinary care teams, care coordination and care planning, a nurse would be a logical choice. If an auditor does not have the suggested clinical credential listed CMS would expect a summary of what qualifies them for the respective area, such as prior audit experience under the direction of a registered clinician.

The template would also capture universe periods. We are looking for a period that is consistent with what CMS evaluates on a program audit, unless there is a good reason for a variance. The template would also collect information on the case sampling methodology to test universe integrity and case sample compliance. For timeliness and IRE forwarding related conditions case sampling does not apply because the entire universe must be evaluated. Finally, although we do not intend to create an audit report template, the independent auditing firm should include the template that they abide by when submitting the validation report to the

sponsor. The template would be reviewed and approved by CMS at the time that the template is reviewed and approved. So it's basically the submission of the work plan and then the sponsor's report template, those would be reviewed and approved. In conclusion regarding the validation work plan template, please refer to the PRA package that is currently available for public comment and share your input.

Next I thought that it would be helpful to touch on the timing for CMS's approval of an IVA work plan. A standardized template not only improves consistency across audits but it should expedite the CMS review and approval window. By using the standardized template CMS hopes to reduce its time to review the work plan and provide feedback to the organization, in most cases within one to two weeks of receipt of the work plan. The CMS validation lead will usually schedule a follow-up call with the organization and the auditing firm to discuss comments. After the discussion the auditing firm will make any required updates to the work plan. CMS will review the updates and determine whether additional updates and discussions are required. This proves will continue until CMS determines that the work plan is sufficient. CMS's goal is to finalize the work plan no later than three weeks after receipt of the draft – of the first draft.

In the next enhancement we also based the determination to make changes on stakeholder experience. We increased the timeframe to complete the IVA and submit the report from 150 to 180 days. We believe that it is important to allow the organization sufficient time to fully correct conditions, accumulate a sufficient clean period, to test corrections, and then to allow the validation auditor to carry out the audit. Commenters supported this extension noting that the additional time will facilitate the ability to remediate deficiencies that were identified during the program audit. Some commenters suggested that CMS extend the timeframe beyond 180 days. While we declined this suggestion, we clarified that organizations may submit requests for an extension to their CMS validation lead. And these requests will be evaluated on a case by case basis. This extension is effective starting in 2018. So what that means is

that any organization that's undergoing a program audit in 2018 that results in a need for a validation audit will have 180 days to complete the IVA audit and submit the firms report to CMS.

It may be helpful to share with you our experience concerning the timing of the formal validation audit itself. After the work plan is approved it generally takes three to four months to conduct the audit and submit the report to CMS. These are the activities that are happening during that timeframe. The organization provides the firm with the documentation. The firm conducts the audit. The firm drafts the report that contains at a minimum the name of the firm that conducted the audit; all audit conditions that were included in the testing; the outcome of the transactions or sample cases tested for each condition; a description of the criteria, cause and effect of any non-compliance found, this includes references to failed case samples, impact analyses, universe results, and other information that supports the non-compliance. And once the IVA report is complete, the organization submits it to CMS by day 180.

For our last enhancement we clarified the way in which IVA reports should be submitted to CMS. Organizations will submit the report unaltered to CMS and copy their independent auditor on the submission. We received a few comments on this clarification all in support, indicating that copying the firm helps ensure that the report remains intact. This enhancement is not required practice until audit year 2019. However, if the organization chooses to copy the firm on the email submission to CMS in 2018 that would be acceptable. Once the organization submits the audit report, CMS will review it along with any supporting documentation and rebuttals. CMS will determine whether additional follow-up is required. If necessary, CMS will schedule a follow-up call with the organization and the firm. The estimated timing for a CMS final determination is three weeks from the receipt of the report. CMS will formally close the audit once we determine that all conditions identified in the final CMS program audit report have been sufficiently corrected. Once this occurs CMS will send the organization's CEO a formal letter through email and close the audit in HPMS. If not all conditions are sufficiently

corrected additional follow-up may be required such as ongoing monitoring by the account manager. If significant deficiencies remain CMS will not close the audit and will require a revalidation audit. This notification would be sent to the CEO through email. CMS will usually schedule a call with the organization to discuss the status of remaining deficiencies and a need for revalidation prior to sending the email to the CEO. The revalidation process mirrors the validation process.

Here we have summarized the effective dates for our enhancements. The first two are effective for program audits conducted in 2018; these would apply for validation audits occurring as a result of program audits conducted in 2018. So first it would be the conflict of interest clarification, and second the extended timeframe by which an organization must undergo a validation audit and submit their firm's report to CMS. Next there are two enhancements that will become effective for program audits conducted in 2019 and beyond. These would apply for validation audits occurring as a result of program audits conducted in 2019. First the threshold modification for determining when and independent validation audit is required; and second the IVA report submission clarification. The effective date for the use of an IVA work plan template has not been established. That template is subject to public comment and OMB approval under the PRA process. Ideally a work plan template will be available for use in audit year 2019. If you have questions about this topic after today's event, you may send them to the CMS mailbox listed on this slide. However, if you are in the midst of an active validation audit, we do ask that you direct your audit specific questions to your CMS validation lead.

Kaye Rabel: So at this time we do have time for some questions. If there are any questions from our in-house participants, please come to the center mic and state your name and let us know where you're from.

Babette Edgar Hi, I'm Babette Edgar, I'm from Blue Peak Advisors. Thank you Brenda for your presentation and we appreciate the clarifications from an independent validation auditor standpoint. I do have two questions for you

to clarify the audit team staffing and credentials. You mentioned that there would be two auditors required per area and we appreciate you listing out the different potential folks that could be working on that from a clinical perspective. Are you anticipating that both of those auditors have to have those clinical designations? Or is it sufficient for one of them, let's say, to be a physician?

Brenda Hudson: Yeah, that's a good question. And I think the intent there is that we want the clinical expertise. But it's always good to have someone that supports for the documentation. So it's really just the representation in the program area.

Babette Edgar: Great, thank you so much. And then my second question was related to ODAG and MMP-SARAG. Would a nurse be sufficient for those two program areas, for the clinical expertise?

Brenda Hudson: Yeah, it's sort of individualized. So what we would probably do when we got the work plan is we would take a look at the conditions and the types of analyses that would be required, and we would compare it with the description of the credentials for the auditors and see if it matched up. We did include a little bit of flexibility talking about like if the person didn't have the particular credential but they had expertise and you could describe that. So hopefully that's helpful. But yeah, it's really on a case by case basis we would look at your plan and then also the credentials of the people involved.

Babette Edgar: Great, thank you so much.

Brenda Hudsoon: Sure.

Derek Frye: Hi Brenda. Derek with Bridgefield.

Brenda Hudson: Hello.

Derek Frye: So I appreciate the PRA release that you guys have submitted. One question there is on the work plan template. Are you planning to release that in a word format rather than just PDF?

Brenda Hudson: Yeah, that's a good question. So it's really in a fillable format, which hopefully makes it a little bit easier. For PRA purposes I think we have limitations on how it's presented so it shows up in PDF format. But it would be fillable once it's live and ready for use.

Derek Frye: Okay, thank you.

Kaye Rabel: Okay that concludes our time for questions today. Thank you Brenda for sharing information on the program audits.

[Applause]

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