New Approach to 2019 Audits and Universes

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Stacey Plizga: Kicking things off for us today by providing an understanding of the changes to 2019 audits and universes, from the Division of Audit Operations...Marie Gutierrez and Doreen Gagliano.

[Applause]

Marie Gutierrez: Good morning, everybody. My name is Marie Gutierrez from the Division of Audit of Operations, and I'm happy to kick off the first presentation today and talk to you about the new approach to 2019 audits and universes. I will go over the overall program package, then hand it over to Doreen Galliano; and she'll discuss the specific changes we made to each program area.

The December 6, 2017 HPMS memo announced the 2018 program audit updates and our intent to redesign our information collection tools to maximize efficiency and reduce burden on the industry. We committed to redesign our audit record layouts, impact analyses, and other data collection templates and submit them to the Office of Management and Budget per Paperwork Reduction Act approval in the second quarter of 2018.

So here we are, and I'm glad to say that we delivered on that commitment. There are definite similarities between how things are now and where we're headed in 2019; but as a direct result of the changes

we've made, the meaning of and the way we use the term "protocols" going forward is changing.

Prior to 2019, our overall audit package included publically-posted protocols which were really, by name and comprehensively, the program area-specific audit process and data request documents. Some of these protocols were also accompanied by questionnaires, and we also had OMB-approved impact analysis and pre-audit issue summary templates. These protocols contained some information about how we conducted audits, while we still maintained internal methods of evaluation that included details of how we sampled and how we assessed compliance.

Starting in 2018, in the spirit of transparency and as a way to streamline the Paperwork Reduction Act process, we separated date our data requests from our audit process. While the data requests and our audit process still work hand in hand, what you will see in 2019 and going forward are, one, data request documents that are subject to public comment through the Paperwork Reduction Act process; and, two, the reformatted audit process documents, which is what protocols will distinctly mean, that will be made public and include our methods of evaluation all the way from verifying universe integrity to sample selection and review.

Data collection tool are posted currently on the CMS PRA website. The URL for that website is identified in the Federal Register notice. The change precipitated from that approach will allow us to distinguish between what data we request and how we use that information during a program audit. Currently available and posted in the Federal Register for your comment are these data collection tools that we will use to request data throughout all phases of the audit. So that's the "what" data we will request, right?

So please note that all of the data collection tools are there: those that we kept as is, like the Pre-Audit Issue Summaries; those that we change, and

I'll talk about those next; and those that are new, like the Independent Audit Validation Work Plan Template, which I'll talk about last.

Then the documents that address *how* we use these data requests will be posted on the CMS website. These are the audit process documents; more specifically, the Program Audit Process Overview document, which contains audit principles that cut across multiple program areas and the program area-specific protocols. The data collection tools are inclusive of all of the information we will be requesting throughout all phases of the audit. These data collection points are the specific data requests; and, as I previously mentioned, we've separated those from the audit process protocol information.

Wherever possible, we simplified data collection by combining record layouts to better reflect plan operations. We adjusted the scope of the data we were collecting based on past audit experience and to ensure we're only collecting the volume of data necessary to conduct our analyses. We removed data points from our collection that created unnecessary burden for sponsoring organizations, and we clarified other data points in response to the questions you sent to our Part C and D audit mailbox, as well as questions and feedback we received from audited sponsors and lessons learned from our own auditors and other stakeholders.

[Pause]

Sorry, I forgot to forward the slide. All right, we're caught up...or you're caught up.

Within the revised data request documents, which are specific to individual program areas, you will find data requests organized by audit phase. For instance, in the audit engagement and universe submission phase, you will see our requests for universes or the applicable universe record layouts, which are descriptive tables that explain the data that is

required in each universe submission and the supplemental documentation that we collect up front to help us understand your operations and allow us to select better samples and better guide you in intravenous preparation.

An example of supplemental documentation that we collect are the questionnaires. During the audit field work phase, auditors may request supporting documentation specific to a failed sample case…like a copy of a decision letter. Auditors may also request root cause analyses, which help you identify the reason for the non-compliance as this is essential for eventual correction and impact analyses.

Within the data request document, you will find detailed record layouts that describe each of the data fields we need to collect from you to better understand the scope of the non-compliance. This is one of the bigger changes in 2019.

So if you've been audited before, you're probably familiar with the impact analysis templates in Excel. If you're not familiar with them, that's okay too because we've removed them. But what you will see in the data request document is an Impact Analysis Request in a format that is consistent with the universe record layouts. By getting rid of the Excel templates, we were able to incorporate field descriptions for each of the data points we are collecting; and not only will this change make the impact analyses submissions more consistent amongst audited sponsoring organizations, but it will also make the submissions easier and more efficient.

The new impact analysis record layouts akin to the universe record layouts have a defined review period, which often quantifies the scope of the non-compliance through the date the issue was identified on the audit. It will also include better instructions in the form of inclusion and exclusion language that sponsoring organizations capture the cases that were

affected by the identified non-compliance and exclude any cases that were not related to the non-compliant issue.

But as we moved away from that impact analysis template in Excel, we still needed the root cause analysis tab. That was the other spreadsheet within that old or going-to-be-retired Excel template. So we created a separate root cause analysis template and took the opportunity to improve it by making it a fillable template. The new template is also applicable to all program areas; so you can use it for ODAG, CPE, CDAG, and the other program areas.

It was designed in such a way that sponsoring organizations can hone in on the root cause of the overall issue. As you conduct the root cause analysis and complete the template, you're looking beyond the specific failed sample case. You're determining the reason for the greater or widespread issue of non-compliance, or this beyond-the-case level analysis could provide assurance that the non-compliance is not widespread, or the non-compliance could be limited to a specific segment within your organization.

The root cause analysis will be requested separately from the impact analysis, and auditors will evaluate the root cause statement provided by the sponsoring organization to determine whether the request for a full impact analysis is warranted.

Later this afternoon, Brenda Hudson will be presenting on the details of independent validation audits; but speaking of fillable templates, we created the independent validation audit work plan template for use by sponsoring organizations with their independent validation auditor. The idea of the IVA work plan template was based on our audit validation and closeout document that is accessible on our website right now. It is also based on feedback that we received as a result of our July 2017 Listening Session and the proposals we finalized in the April 2, 2018 Call Letter.

Not only will this new template ensure consistency, it would also increase the likelihood of complete work plan submissions. Please note that the IVA work plan template lists other documents that need to be submitted with the completed work plan; specifically, the validation auditors' résumés and the audit report template will need to be submitted with the completed work plan.

Again, we encourage you to review any and all of these data collection tools that are currently posted in the Federal Register and provide us with your valuable comments.

Now that we've discussed all of the data collection tools that are currently in the Federal Register, we'll turn our attention to the audit process documents. This is the part that completes our overall program audit package. Although not subject to the Paperwork Reduction Act comment process, these documents will be posted on the CMS website for public use; more specifically, the program audit process overview document and the program area-specific protocols will be made available to provide more insight into our audit principles and approach for sampling and evaluation.

The intention is to make it more useful for sponsors to conduct mock audits or for independent validation auditors to conduct validation audits, as these documents address how the data collection is used.

The current program audit process overview document available on our website was designed to provide an executive summary of our audits by phase, as well as a more detailed description of steps within those phases. For 2019, we decided to broaden its purpose. In our new approach to our audit tools, we plan to update the existing program audit process overview document to include...in no particular order...our scoring approach, which remains unchanged; our descriptions of tracer case summaries, which will be applicable to both CPE and SNP-CCQIPE; our methodology for quantifying non-compliance, as collected within our

impact analyses; our application of the pre-audit issue summaries, our application or mitigating factors for non-compliance that was self-disclosed to us prior to the date of the Engagement Letter as we classify our audit conditions; and other audit-related principles that crosscut different program areas, such as integrity testing and invalid data submissions.

The program area-specific protocols are being reformatted for ease of use and updated to provide more transparency in our method of evaluation and sampling approach. The intent behind our redesign efforts is to provide our stakeholders with an audit process document that easily links each data and documentation request to an audited element related to scoring and the compliance standard tied directly to a regulatory and subregulatory guidance.

The program area-specific protocols will provide more details on our approach to integrity testing; that is, verifying that data and documentation requests are accurate and complete and our approach to selecting targeted samples.

So what can you expect to see in each of these program area-specific protocols?

First, you'll see an element that is being tested. For example, in the ODAG protocol, timeliness is one of the elements. Next, you'll see a sub-element, and that sub-element will provide a more detailed description or a breakdown of the element being tested. So in keeping with my example from the ODAG protocol, if the element is timeliness then the sub-element may be timeliness of notification.

Then you'll also see documentation requests. This will identify the source of the data being evaluated, as well as any documentation that may be requested upon identification of non-compliance sample cases. So you can think of the documentation requests information as the crosswalk

between the data request document and the protocol. Again, as an example from the ODAG one that we're building on, the corresponding universe used to measure the timeliness of notification is what would be one of the documentation requests that you'll see.

Next is the Compliance Standard, and this will provide a description of the requirement being tested as quoted from the regulatory and subregulatory guidance. You'll also see the criteria, and this will be the reg or manual reference to the cited compliance standard.

Lastly, the protocols will specify and include our method of evaluation.

The detail of our sampling and evaluation approach, better known as the method of evaluation, was previously kept internal to just CMS...to us. However, in our redesign, we will be sharing this information in keeping with our efforts to remain transparent. The method of evaluation that you'll see in the protocol will include a detailed description of our universe integrity testing information and a description of our sampling approach once the usability of all those universes has been verified.

If you've been audited before, you may recall that auditors conducted integrity testing specifically in the ODAG and CDAG program areas. But starting in 2019, universe integrity testing will be expanded to all program areas. Actually in 2018, we will be piloting integrity testing in the FA program area; and we'll do that in less than nine audits this year.

The purpose is to determine the completeness and accuracy of the universe submission from which samples are selected and compliance is assessed. For starters, the auditors will check that all the contracts are included, all requested dates are represented, and all of the fields in the record layout are complete and that they make sense. The universe integrity testing may necessitate universe resubmissions, which then feeds into the process for determining an invalid data submission

condition. Overall, it's an opportunity to ensure on the front end that the data is good and usable for sampling.

Then as far as sampling is concerned, our intent is to provide enough detail so that a sponsoring organization using our protocols to conduct a mock audit, or an independent validation auditor hired by the sponsoring organization to assess correction from a program audit has the same insight into our targeted sampling approach as our auditors who initially conduct the program audits. That means you may see that we target call logs for cases that appear to have been misclassified grievances or coverage requests, or you'll find details about targeting grievances that appear related to quality of care and really to ensure enrollees were provided with the appropriate contact information for the QIO.

So to recap, the overall program audit package consists of the data collection tools, which are currently posted in the Federal Register for your review and comment; and the audit process protocol documents, which will be posted on the CMS website. We hope you'll see that the new approach to the 29 audits is in keeping with our efforts to continuously improve, reduce burden, and increase transparency.

Thank you for your attention. At this time, I'd like to turn over the presentation to Doreen Galliano.

[Pause]

Doreen Gagliano: Good morning, I'm Doreen Gagliano.

Thank you, Marie, for the first half of our presentation.

I am going to walk through the changes that we have made to each of the audit areas, but first I wanted to summarize some of the high-level changes that we have made and the considerations that we have taken into account for the reasons behind those changes.

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As Marie previously mentioned, in redesigning the data requests for the next audit cycle, we really focused on reducing the burden to sponsors by only collecting the minimal information necessary to conduct one of our thorough audits. We took into account the frequently asked questions that come through our audit mailbox, and we relied on auditors' experience, sponsor experience, and the insight that we have gained from auditing sponsoring organizations in order to propose a more streamlined and meaningful data collection instrument.

Specifically, we consolidated record layouts wherever we could; and we removed unnecessary data points that were no longer meaningful for sampling. Further, we clarified instructions for responding to universe requests, as well as field descriptions to accommodate concerns we have heard in response to current protocols. Along the lines of streamlining our requests, we also reconsidered the use of our questionnaires. We have removed questionnaires that were no longer necessary or that were not being used as we had initially intended, and we added new questionnaires to consistently capture information that was being requested verbally in our audit process; and we reformatted all the questionnaires as fillable forms to reduce burden and to further clarify the information for which we are seeking to collect.

The program area-specific changes are summarized in the crosswalk that is included in the PRA package on our CMS website. We will now discuss each program area in greater detail, and we will start by looking at special needs.

You will first notice that we changed the name. Instead of referring to Special Needs Plans – Model of Care, or SNP-MOC, we have renamed the program area to better reflect the scope of our review. The program area is now named Special Needs Plans – Care Coordination and Quality Improvement Program Effectiveness or SNP-CCQIPE.

We also redesigned our data collection to collect less data. Previously, we requested 13 months of data. Starting in 2019, the idea is to collect a list of information as of a specific moment in time; namely, a listing of all enrollees and a listing of all models of care at that time of the audit Engagement Letter. From these revised universes, we intend to conduct more of our assessment as it relates to timing of health risk assessments at the universe level; continue assessing care coordination via strategized sampling; and we hope to review an organization's quality improvement process using a tracer methodology similar to that which is used in our review of compliance program effectiveness.

We also added a questionnaire to our data request that collects information that is useful to us in selecting samples that will be reviewed using the methodology that I just described. The questionnaire asks questions that help us understand your organization's operations as they relate to special needs plans and asks questions such as: Has your organization experienced any seamless enrollments, PDP mergers, acquisitions, or planning consolidations; and if so, please describe the circumstance.

In Part D coverage determinations, appeals, and grievances...better known as CDAG...we reduced the number of universe submissions that we require for both program audits and timeliness monitoring project universes. In CDAG, we went from 16 universes in 2018 down to 8 for 2019. That I will outline for you in some upcoming slides.

Although the reduction in universes strikes some as a major change, we want to assure you that the compliance standards remain consistent with our previous protocols. We are still reviewing the same sample cases, similar criteria, within the same elements.

You will also see on the upcoming slides that we have added one new universe in CDAG. This is to evaluate processing and classification of requests. This new universe serves as a catch-all for any unprocessed

cases or cases that are inactive or resulting in something other than an approval or a denial. It will include cases that the sponsor deems to be invalid, unprocessed, dismissed, withdrawn, or canceled.

Additionally, we have removed the CDAG supplemental questionnaire. Instead of asking about your policies up front, we collect and assess any policy-related information as we collect the root cause analyses. We've found that this is a better fit for outcomes-based testing approach.

Finally, we increased the scope of some universe periods...such as grievances and overturn decisions...based on past audit experiences; but we also reduced the scope of some universes, such as the Call Log Universe. This will help reduce burden on sponsors.

We also rephrased our request from monthly to weeks to promote additional consistency in the amounts of data collected from like-sized organizations.

Now I would like to walk you through a crosswalk of the 2018 to 2019 CDAG record layouts.

The left side of this chart shows 2018 record layouts, and the right side of the chart shows the new and equivalent record layouts for 2019. In 2018, Table 1 is Standard Coverage Determinations; and Table 4 is Expedited Coverage Determinations. For 2019, collection of standard and expedited cases will be combined in Universe 1 or record layout Table 1, which is called Standard and Expedited Coverage Determinations.

In 2018, Table 2 is Standard Coverage Determination Exception Requests; and Table 5 is Expedited Coverage Determination Exception Requests. In 2019, both standard and expedited coverage exception requests will be combined, as described in record layout Table 2, Standard and Expedited Coverage Determination Exception Requests.

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In 2018, Table 3 is Direct Member Reimbursement Request Coverage Determinations; and Table 7 is Direct Member Reimbursement Request Redeterminations. In 2019, all DMR requests...whether at the CD or redetermination level... will be included in record layout Table 3, which is called Payment Coverage Determinations and Redeterminations.

In 2018, Table 6 is Standard Redeterminations and Table 8 is Expedited Redeterminations. In 2019, standard and expedited cases are again combined in record layout Table 4, resulting in a combined university of Standard and Expedited Redeterminations.

In 2018, Table 11 is Standard IRE, ALJ, or MAC Determinations; and Table 12 is Direct Member Reimbursement Requests by Other Review Entity; and Table 13 is Expedited IRE, ALJ, or MAC Determinations. In 2019, these three record layouts have been combined into record layout Table 5, Part D Effectuations of Overturned Decisions by IRE, ALJ, or MAC.

In 2019, we have also combined Standard and Expedited Grievances in record layout Table 6, which were previously collected separately in 2018 per record layout Tables 14 and 15.

On this slide, you can see where we have introduced a new record layout, Table 7, to collect a universe of Unprocessed Cases. As I mentioned earlier, this universe serves as a catchall for unprocessed cases, or cases that are inactive or resulting in something other than an approval or a denial. It will include cases that the sponsor deems to be invalid, unprocessed, dismissed, withdrawn, or canceled.

In 2018, Table 8 should look pretty familiar, as it is equivalent to the record layout Table 16 for 2018, which is currently called Part D Call Logs.

Finally, you may have noticed that there are two existing record layouts in 2018 that are going away. In 2018, we will no longer collect universes for standard and expedited cases that were auto-forwarded to the IRE. We removed these record layouts, as they are often duplicative of other cases that we are already looking at in earlier universe record layouts.

Now moving on to ODAG, I will walk you through the changes made that should sound very familiar to the changes that we just discussed in CDAG. Once again, we consolidated collection of standard and expedited cases to reduce the number of universes for submission in our program audits and our timeliness monitoring projects. We also kept the Compliance Standards relatively stable except for where there were changes in policy. W removed the supplemental questionnaire also.

So let's take a look at a crosswalk of the revised universe record layouts.

By consolidating similar cases, we were able to reduce the number of ODAG universes collected for both program audits and timeliness monitoring projects from seven down to three, as shown on this slide.

In 2018, Table 1 is Standard Pre-Service Organization Determinations; and Table 2 is Expedited Pre-Service Organization Determinations. In 2019, Table 1 will be Standard and Expedited Pre-service Organization Determinations.

In 2018, Table 5 is Standard Pre-Service Reconsiderations; and Table 6 is Expedited Pre-Service Reconsiderations. In 2019, Table 2 will be Standard and Expedited Pre-service Reconsiderations.

In 2018, Table 3 is Requests for Payment Organization Determinations; Table 4 is Direct Member Reimbursements; and Table 7 is Requests for Payment Reconsiderations; and Table 9 is IRE Payment Cases Requiring Effectuation. In 2019, Table 3 will be Payment Organization Determinations and Reconsiderations.

In 2018, Table 8 is Pre-Service IRE Cases Requiring Effectuation; Table 9 is IRE Payment Cases Requiring Effectuation; and Table 10 is All Part C ALJ/MAC Cases requiring Effectuation. In 2019, Table 4 will be Part C Effectuations of Overturned Decisions by the IRE, ALJ, or MAC.

In 2018, Table 11 is Part C Oral and Written Grievances; Table 12 is Part C Oral and Written Expedited Grievances. In 2019, Table 5 will be Standard and Expedited Grievances.

In 2018, Table 13 is Dismissals; and in 2019, Table 6 will be Dismissals.

In 2018, Table 14 is Call Logs Part C; in 2019, Table 7 will be Part C Call Logs.

To wrap up the changes we have made to ODAG and CDAG and before we move on to discuss changes that we have made in compliance program effectiveness, I wanted to revisit one of my earlier points related to keeping the Compliance Standards the same. By keeping Compliance Standards relatively stable between 2018 and 2019 for CDAG and ODAG...again, except for changes to guidance or policy...we were also able to keep the program elements the same. Any changes to elements for CDAG and ODAG are by name only, as shown on the slides:

Timeliness in 2018 is still called Timeliness in 2019.

Appropriateness of Clinical Decision-Making and Compliance with Processing Requirements in 2018 has been renamed to Processing of Coverage Requests.

Grievances and Misclassifications of Requests in 2018 has been renamed to Classification of Requests for 2019.

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For compliance program effectiveness, we will review the same three elements as we have done in previous years which include: prevention, detection, and correction controls and activities. We will use the same method of evaluation, which includes tracer summaries and employee samples to review the following items: oversight activities of first-year entities, employees who are responsible for oversight of your Medicare program, and your auditing and monitoring of internal operations.

The following things have changed:

We removed the self-assessment questionnaire to reduce program audit burden. But don't worry, we now know that sponsoring organizations use this document to help in their operations as they prepare for CMS program audits. So this particular document is still available on our website for you to use. It is just no longer part of the data requests that we will use for program audits.

We combined the internal auditing and internal monitoring universes, or record layouts; and we streamlined data collection for oversights of FDRs. For instance, one of the more notable changes is the removal of one of the most burdensome data points related to how long an entity has contracted with the sponsoring organization being audited.

We are collecting less data points for the ECT universe because there was a lot of burden associated with this.

We also changed the names of the record layouts, but these changes really were minimal.

Finally, the existing questionnaires were made into fillable forms as Marie did describe earlier in our presentation.

Last but not least is formulary administration. We decided to end with this program area, as it has experienced the least number of changes for 2019:

Overall, we are collecting pretty much the same fields; we just consolidated record layouts for rejected claims, and we clarified a few field descriptions.

We also amended our record layouts in FA to account for the transition from the HICN to the Medicare Beneficiary Identifier.

To assist with sampling, we did add a supplemental questionnaire that asks sponsoring organizations about their operation, to include items such as...if you utilize prior claims history for purposes of transition for existing enrollees having a planned benefits change, if you have a specific prior authorization form, if you have employer group waiver plans which submitted claim fields you use to determine if an enrollee is subject to long-term-care requirements if you or one of your delegated entities will be walking auditors through the various screens within the applicable platforms reviewed during the audit, and finally, if you utilize any methods other than claims history to ascertain new versus ongoing therapy for enrollees.

This questionnaire will be due within five business days of receiving your audit Engagement Letter. Auditors will use this document to guide the conversations when they meet with the audited organization prior to universe submission.

Finally, the last update I wanted to mention relative to FA is more closely related to the protocol as opposed to our data requests; but it's important, and it may be of interest to our audience today. Although there were minimal burdens associated with the website review element in our actual program audits, we have suspended this element due to its overlap with other ongoing monitoring projects conducted within CMS.

This concludes our presentation on our overall audit approach to program audits and universe collections starting in 2019. We've walked you through what our PRA package will look like, as well as described for you some enhancements you can look forward to in our audit process documents.

If you have specific questions about this presentation, please e-mail them to our audit mailbox shown on the screen and in your slides, paying close attention to the underscores.

For questions or of you are interested in providing comments on our actual data collection tools for 2019, you can follow the instructions in the 60- and 30-day Federal Register Notice. Keep in mind that the comment process is different for each.

To find the notice, you can search the Federal Register for package ID number CMS10191. Again, that's CMS10191. You should use the same number for finding the PRA package that is posted to our CMS website.

Finally, just a reminder that the changes are subject to OMB approval under the PRA process; and, as such, the changes are not yet improved by OMB so you should not take any action until the time of OMB approval.

Thank you very much.

[Applause]

Kaye Rabel: At this time, we are out of time for questions for our in-house participants. Please feel free to save your questions and ask them during our open Q&A session this afternoon; and our webcast participants, please feel free to submit your questions with the SurveyMonkey link.

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Thank you, Doreen and Marie, for the update on the 2019 Audit and Universes.

It is now time for our first session evaluation. Please take out your phones. If you will text your response or go to the poll EB link on your smartphone, tablet, or computer. If you would like to evaluate this session...and we encourage everyone to do so…and you're participating via your cell phone, go ahead and enter "A" in response to the question, "I would like to evaluate this session," and send your response.

You will receive a text message with the following message: "Hello, please evaluate this session with this link." Select the link, and you will be taken to the Poll Everywhere site. Chose "Start," and you will be presented with the evaluation questions one at a time. Select your answer and click "Next" to advance to each question, and then go ahead and submit your response by choosing "Finish."

If you are participating via the Internet, when prompted by the moderator, choose "Yes" in response to the question, "I would like to evaluate this session," and you will be presented with the link to evaluate the session. The link appears quickly at the top of the screen in green, so click on that link. When the next screen appears, choose "Start." You will be presented with the evaluation questions one at a time. Select your answer and click "Next" to advance to each question and then submit responses by choosing "Finish."