Session 3: August 26, 2021

Medicare Part C and Part D Compliance Program Effectiveness (CPE) Program Audit Protocol and Data Request
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Special Needs Plans Care Coordination (SNPCC)
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Matthew Guerand: Good afternoon, everyone. Thank you all for attending the last session of our final MAPD Program Audit Program Protocol User Group Training. Today we will review two program areas. First up is the Part C and Part D Program Compliance Effectiveness Protocol. Following that will be a review of the Special Needs Plans Care Coordination Protocol.

In the previous few sessions, we reviewed ODAG, FA, and CDAG. Thanks again to everyone who joined those sessions. We will post a recording of all sessions to the CTEO Event Archive page with the transcript as soon as they are ready.

The CPE and SNPCC audit protocols reviewed today are included in OMB-approved CMS 10717 and will be used for MAPD audits beginning in 2022. It's our hope this training provides further clarity on our audit protocols and assist stakeholders as they prepare their systems for audits next year.

My name is Matt Guerand. I work in the Division of Audit Operations, which is a component of the Medicare Oversight and Enforcement Group. We are the division responsible for creating and maintaining the final program audit protocols as well as administering program audits.

The CPE Program Protocol is broken down into two sections: The Program Audit Protocol, which includes the audit elements tested and their associated method of evaluation, and the Program Audit Data Requests, which includes the tools and documentation CMS uses to perform its audit activities. You can see on the screen we do have the Table of Contents pulled up to show where the Program Audit Protocols and the Program Audit Data Requests are located.

The goal of today's training is to ensure a uniform understanding of our CPE audit process. For those of you who attended either of the previous trainings, you know that we review each program area beginning with the Program Audit Protocol followed by the Program Audit Data Requests. Today, we will approach this training a little bit differently. In fact, we will review the CPE Protocol in reversed order. We feel this approach is best because it is easier to understand how we review each compliance standard once the information CMS uses to conduct its review is discussed.

So we will begin with review of the Program Audit Data Requests, where we will review the technical specifications of the COA record layouts and the supplemental documentation requests followed by review of the Program Audit Protocol, where we will review each of the compliance standards focusing primarily on our method of evaluation in an effort to help stakeholders gain insight into our CPE process and set expectations for when an audit occurs.

During today's training, we will occasionally pull up the CPE protocol to reference where we are in our review. Also, to avoid any confusion, I'll be using the term "sponsor" to refer to the organizations that participate in the Part C and Part D programs. These are also sometimes referred to as "plans," "sponsoring organizations," "Medicare Advantage organizations," or "prescription drug plans."

Next slide, please. I am on slide 3.

As a note, the data collection specifications and tools described in the Program Audit protocols, including the record layout instructions, are

used for auditing and monitoring activities and by themselves should not be used to interpret policy. Not all data points within each record are used to determine a sponsor's compliance with CMS requirements. Any policy questions regarding compliance program requirements should be directed to the appropriate CMS policy mailbox.

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There are three audit elements tested in CPE that are applicable to each compliance standard. They are Prevention Controls and Activities, Detection Controls and Activities, and Correction Controls and Activities. The purpose of the review is to evaluate performance in the areas outlined in this Program Audit Protocol and Data Requests related to Compliance Program effectiveness.

CMS performs its program audit activities in accordance with the CPE Program Audit Data Requests and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. As described in 42 CFR 422.503(b) and 42 CFR 423.504(b), sponsors must adopt and implement an effective compliance program which must include measures that prevent, detect, and correct non-compliance with CMS program requirements.

To determine a sponsor's compliance with these regulatory requirements, CMS uses a tracer sample audit approach that follows a sponsor through their compliance program for issues that arose during the universe period. All tracer samples have the potential to pass through each of the audit elements during a review. CMS's review assesses the effectiveness of a sponsor's compliance program related to how a sponsor prevented, detected, and corrected non-compliance. Should CMS uncover non-compliance during this CPE review, CMS will determine, based on the finding and the compliance standard under review, which audit element the finding falls under in the audit report.

CMS relies on a variety of resources to conduct the Compliance Program effectiveness review including, but not limited to, tracer case summaries; targeted samples of audit participants and first-tier entities; and

supplemental documentation requests. During audit field work, CMS will review the tracer case summaries in addition to employee samples of audit participants and FTEs selected from attendance logs, supplemental documentation, and/or supporting documentation to determine whether the sponsoring organization is compliant with the general provisions of its Part C and/or Part D contract requirements.

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The CPE Program area has one record layout, the Compliance Oversight Activities record layout, also known as the COA record layout. Sponsors must submit this universe comprehensive of all contracts and plan benefit packages identified in the audit engagement letter in either Microsoft Excel file format with the header row or text file format without a header row. Descriptions and clarifications of what must be included in each submission and data field are outlined in the Universe Record Layout. Characters are required in all requested fields unless otherwise specified, and data must be limited to the requests specified in the record layouts.

Sponsors must provide accurate and timely universe submissions within 15 business days of the audit engagement letter. Submissions that do not strictly adhere to the record layout specifications will be rejected. The COA record layout is a compilation of all compliance oversight activities that occurred during the 26-week period preceding and including the date of the audit engagement letter. It will include all auditing, monitoring, and investigation activities including compliance and fraud, waste, and abuse activities that were initiated, performed, or closed related to the sponsoring organization's Medicare Advantage and/or prescription drug business including auditing, monitoring, and investigations performed on first-tier entities during the universe request period. For data collection purposes, first-tier entities is limited to entities the organization contracts with directly.

We received a question regarding automated data mining activities and whether or not they should be included in the COA record layout. Automated data mining activities should be included in the universe if the organization considers it a monitoring or auditing activity. All compliance

activities should be included if the activity start date, as in Column ID "G," or activity completion date, which is Column ID "H," falls within the universe request period or if the activity is still in progress but the start and completion dates fall outside of the universe period.

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All daily compliance activities should be rolled up into an aggregate time period of one month and included in the universe each time the aggregate time period into which they were rolled occurred. For instance, if a sponsor runs daily monitoring reports of enrollment timeliness for the month of August, roll this up into one line and enter it in the COA record layout as a daily activity in the "Activity Frequency" field. Sponsors must use consistent naming conventions throughout the submitted universe. For instance, when the name of the sponsoring organization's component or department operational area or business unit is requested, a consistent response must be used. For example, please use agent broker or AB or A/B. Whichever method you choose, please use it consistently throughout the record layout.

CMS uses the sponsor's submitted COA universe to select some of its tracer case samples for review during fieldwork.

Next slide, please.

Oops, forgive me. Before you switch...

Sponsors must ensure that all fields are populated. Do not leave any fields blank. For instance, if there are no deficiencies found from a compliance activity, enter zero for the number of deficiencies in Column ID "I" and in Column ID "J," which is subscription of deficiencies, please enter "N/A."

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The documentation listed on this screen must be submitted within 15 business days of the audit engagement letter date. The Compliance Officer Questionnaire, Customized Organizational Structure and

Governance PowerPoint, and FDR Questionnaire will be available in the Submission Materials folder in HPMS. The Compliance Officer Questionnaire will assist CMS with understanding the sponsor's mechanisms for overseeing the performance and effectiveness of the Compliance Program from the compliance officer's perspective.

The FDR Questionnaire helps CMS understand the sponsor's accountabilities and oversight of its delegated entities to ensure compliance with Medicare program requirements. Sponsors should answer all questions thoroughly prior to submission.

The Customized Organizational Structure and Governance PowerPoint Presentation will be used as a central resource for CMS and will be referenced often during the audit. Sponsors are expected to create a customized presentation that includes specific information using the template. Sponsors are not bound by the template and may provide additional information as it sees fit.

The Standards of Conduct/Code of Conduct document, Risk Assessments and Compliance Performance Mechanisms, and Audit and Monitoring Work Plans are sponsor-specific and must be submitted to CMS. Each of these documents must be the most current version available that a sponsor has in place at the time of the engagement letter. CMS may request additional supporting documentation during the audit fieldwork phase if data shown during a tracer case review is not submitted along with the tracer case summary. Sponsors will have two business days to submit the documentation. Auditors have some flexibility to make adjustments to this time frame as needed.

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Moderator: Matt, before we go to the next slide, we have some of these documents available in our Resources pod for downloading; don't we?

Matthew Guerand: We do. Thanks, Kristen.

So those three documents that I mentioned first – the Compliance Officer Questionnaire, the FDR Operations Oversight Questionnaire, and the Customized Organizational Structure and Governance PowerPoint -- are in the Resources pod.

Thanks, Kristen.

Moderator: No problem, slide 8, take it away.

Matthew Guerand: Thank you.

As I mentioned, the COA record layout and all requested supplemental documentation requests must be submitted to CMS within 15 business days of the audit engagement letter. Once received, CMS will conduct an integrity test on the submitted data to ensure it is complete and accurate. For instance, CMS will ensure all questionnaires are complete and other documents – such as the Standards of Conduct/Code of Conduct document – are in effect at any time during the universe period.

Also during integrity testing, CMS will review the COA record layout to ensure it adheres to the inclusion and exclusion language and that descriptions are completed in the correct format. The integrity tests will be conducted using a desk review. Once complete, the CPE team may reach out to the sponsor for clarification on any aspect of the submitted data.

If necessary, the team may host a webinar or host a follow-up call to address any questions uncovered during the desk review. The integrity of the universe and supplemental documents will be questioned if the submissions are incomplete or not prepared in accordance with the Program Audit Data Request instructions or a variance is discovered in oversight activities. Sponsors will have a maximum of three attempts to provide complete and accurate universes. These attempts may occur prior to or after the entrance conference, depending on when the issue is identified.

However, three attempts may not always be feasible depending on when the data issues are identified and the impact that the universe resubmission request could have on the audit schedule or the integrity of

the audit findings. When multiple attempts are made, CMS will only use the last version submitted. If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report.

After the third failed attempt or when the sponsor determines after fewer attempts that it is unable to provide an accurate universe within the time frame specified during the audit, the sponsor will be cited an invalid data submission condition relative to each element that cannot be tested grouped by the type of case. This information can be found in the Annual Program Audit Process Overview document located on the Program Audit's website,

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Once integrity testing is complete, CMS will select six tracer samples primarily from the COA record layout that represents compliance risk to a sponsor's operations and enrollees with the likelihood of touching multiple elements of a compliance program, including intelligence obtained from documentation received within the universe. Tracer sample selections will be sent to the sponsor two weeks prior to the entrance conference and are due at the start of the entrance conference. However, if a universe requires resubmissions, it could adversely affect our ability to select samples in time to complete those tracers before submission.

When available, CMS will choose from the following activities of tracer samples:

Compliance oversight activities related to a sponsor's pharmacy benefit management

Appeals and grievances, including oversight of call routing process

FTE performing a delegated function

Quality improvement programs, if applicable

Network management

Enrollment and disenrollment

Agent/broker misrepresentation

Quality of care, including issues reported through compliance mechanisms

Customer member services or compliance actions, such as notices of non-compliance warning letters, relative to the audit review period

CMS may also select tracer samples from other information available to CMS and therefore not requested from the sponsoring organizations, such as compliance actions; enforcement actions; or memos issued via the Health Plan Management System. In response to each tracer case summary requested, sponsors must prepare and submit written documents that provide specific facts, rationales, and decisions around how suspected, detected, or reported compliance issues are investigated and resolved by the sponsor.

CMS will also select targeted samples of 20 audit participants and two first-tier entities from attendance logs and impacted individuals and entities from tracers, supporting documentation, and/or supplemental documentation. These samples will be provided on the first day of the CPE audit.

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In response to each tracer case summary requested, sponsors must prepare and submit a written document in either Microsoft Word, Excel, or PowerPoint, or Adobe portable document file of a storyboard or dashboard prior to the entrance conference. The summary document must provide the specific facts, rationales, and decisions around how suspected, detected, or reported compliance issues are investigated and resolved by the sponsor. Each summary document must include the following information in chronological order:

An overview of the issue or activity

The compliance and business operations units that were involved in detecting and correcting the issue

A detailed explanation of the issue or activity, for example, what the sponsor found; when the sponsor first learned about the issue; and who or which personnel or operational areas were involved

A root cause analysis that determined what caused or allowed the compliance issue, problem, or deficiency to occur

The specific actions take in response to the detected issue or activity

The processes and procedures that were affected by the issue or activity and those that were revised in response to becoming aware of the issue or activity

Next slide, please.

Continuing on, the tracers must include:

The steps take to correct the issue or the deficiency at the sponsor or FDR level, including a timeline indicating the corrective actions implemented or, if not implemented, when the sponsor expects the corrective action to be completed

How the issue was escalated – for example, to senior management, compliance oversight committees, or the governing body

All relevant communications within the sponsor and within FDRs regarding the issue

Finally, each prevention, control, and safeguard implemented in response to the issue or activity

CMS will review each tracer case summary submission in preparation for the tracer review during Week 3. Questions pertaining to each summary will be discussed during the tracer session.

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CMS will conduct at least two interviews, sometimes three depending on how an organization is structured, during its CPE review. The three interviews will be with a sponsor's compliance officer; individuals responsible for special investigations and fraud, waste, and abuse oversight; and finally, individuals responsible for first-tier downstream and related entity oversight. In some circumstances, an organization is structured in a manner where the SIU/FWA team is part of the compliance team. In these instances, CMS will host one interview with both teams simultaneously.

The intent of the interviews is to open a dialog with the sponsor. They are an opportunity for a sponsor to explain firsthand how the organization's compliance program operates on a day-to-day basis and how it effectively responds to compliance issues. CMS may ask the compliance officer or the individuals responsible for SIU, FWA, or FDR oversight about any potential compliance issues that were uncovered during Week 1 of an audit to see how the organization has responded or if they were aware of the non-compliance prior to the audit. CMS may also follow up with the sponsor about responses submitted in the questionnaires.

Next slide, please.

Okay, that concludes our review of the Program Audit Data Requests. Next, we'll move to the Program Audit Protocols. For those who are not in the webinar, we are on slide 13 in the CPE slide deck.

Next slide, please.

You can see on the screen that we've just pulled up where we are in the CPE protocol itself. We are reviewing Compliance Standard 1.1.

CMS will evaluate Compliance Standard 1.1 by assessing the sponsor's written compliance policies, procedures, and standards of conduct to ensure they:

Articulate the sponsor's commitment to comply with all applicable Federal and State standards

Describe compliance expectations as embodied in the Standards of Conduct

Implement the operation of the program

Provide guidance on potential compliance issues

Identify how to communicate compliance issues to the compliance personnel

Describe how these issues are investigated and resolved and include a policy of non-intimidation or retaliation for good faith participation in the Compliance program

Next slide.

Furthermore, for Compliance Standard 1.1, CMS will evaluate the 20 audit participant samples either by live presentation or a review of the sponsor's submitted evidence to ensure a sponsor's compliance policies and procedures and standards of conduct are accessible to employees.

Additionally, for the two FTE samples selected, CMS will request sponsors demonstrate accessibility of a sponsor's policies and procedures and standards of conduct. As an example, sponsors may share attestations of receipt from the FTEs or other documentation demonstrating distribution of these materials to the FTE. CMS does not assess an annual timeliness standard to this distribution.

Next slide, please.

For Compliance Standard 1.2, CMS will evaluate the six tracer samples with the sponsor via webinar, including interviews with the compliance officer and individuals responsible for SIU, FWA, and FDR oversight as applicable to assess whether the sponsor designated an employee of the organization, parent organization, or corporate affiliate as the compliance officer.

CMS will also determine if the compliance officer and compliance committee demonstrated accountability and reporting of Medicare

compliance issues to appropriate senior management and governing body and, finally, determine if the governing body exercised oversight of the Medicare Compliance program.

Next slide, please. We are on slide 17.

CMS will use the same 20 samples selected from the attendee logs earlier to evaluate Compliance Standard 1.3. Here, CMS will assess whether compliance training was provided annually to the compliance officer and organization employees; the sponsoring organization's chief executive; and other senior administrators, managers, and governing body members. To determine this, sponsors may provide training attendance logs, training certificates, employee attestation of receipt of compliance policies and procedures, and standards of conduct as evidence training was provided.

Compliance Standard 1.3 does not test for FTEs.

Next slide, please.

For Compliance Standard 1.4, CMS will assess whether sponsors established effective lines of communication between the compliance officer; members of the Compliance Committee; employees; managers and governing body, and FDRs; and implemented a reporting system that is accessible to all and allowed a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified. To determine this, CMS will rely on the six tracer samples selected for review along with interviews with compliance officers and individuals responsible for SIU, FWA, and FDR oversight as applicable.

Sponsors may submit evidence of communication to the affected or involved business areas regarding compliance issues; evidence of oversight activities that occurred as a result of the detected issues; description of the enrollee and/or sponsoring organizations impacted as a result of the detected compliance issues; contemporaneous meeting minutes/agendas, letters, and correspondence to support statements within the tracer case summaries that effective lines of communication have been established.

Next slide, please.

For Compliance Standard 1.5, CMS will ensure sponsors have well-publicized disciplinary standards through implementation of procedures which encourage good faith participation in the Compliance program by all affected individuals. These standards must include policies that:

Articulate expectations for reporting compliance issues and assist in their resolution

Identify non-compliance or unethical behavior

And provide for timely, consistent, and effective enforcement of the standards when non-compliance or unethical behavior is determined

Next slide, please. We are on slide 20.

For Compliance Standard 1.6, CMS will review the six tracer case summaries via live presentation by the sponsoring organization, including interviews with the compliance officer and individuals responsible for SIU, FWA, and FDR oversight, as applicable, to assess whether the sponsor established and implemented an effective system for routine monitoring and identification of compliance risk, including internal monitoring and audits of its internal operations and FTEs to evaluate compliance with CMS requirements and the overall effectiveness of the Compliance program.

CMS will ensure the internal monitoring and evaluate the sponsor's compliance with CMS requirements and the overall effectiveness.

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Finally, for Compliance Standard 1.7, CMS will assess whether sponsors properly responded to compliance issues; investigated potential compliance problems identified; or corrected such compliance problems promptly and thoroughly to reduce potential for returns and ensure ongoing compliance with CMS requirements. CMS will evaluate the six tracer case summaries via live presentation by the sponsor including

interviews with the compliance officer and individuals responsible for SIU, FWA, and FDR oversight, as applicable, during review of the standard.

Sponsors may provide evidence to support statements within the tracer case summaries that reflect how they promptly responded to compliance issues, including:

Procedures reviewed and revised in response to detecting and correcting compliance issues

Training provided in response to identifying and correcting compliance issues

Evidence of oversight activities that occurred as a result of the detected issues

Evidence of accountability and oversight by the sponsoring organization when issues are detected at the FDR level, including response and correction procedures; communication; educational requirements; and engagement with the compliance department

Operational areas and oversight entities

Description of the enrollee and/or sponsoring organization impact as a result of the detected compliance issues

Meeting minutes and agendas, letters, and correspondence to support statements within the tracer case summaries.

Next slide, please.

This concludes our Part C and Part D Compliance Program Effectiveness section of the final MAPD Program Audit Protocol Training. We aimed to address all of the CPE topics that were submitted in advance of today's training. If you have additional program audit process related questions following today's presentation, please send them to the e-mail box listed on this slide which is: part_c_part_d_audit@cms.hhs.gov. As noted previously, policy questions should be directed to the appropriate CMS policy mailbox.

We'll take a brief moment and then switch to the SNPCC Care Coordination review.

[Pause]

Kristen, I think I might be having a bandwidth issue again. Just let me know if the SNPCC presentation is pulled up.

Moderator: Yes, the slides are up.

You should be seeing the cover slide for "Special Needs Plans Care Coordination (SNPCC).

Matthew Guerand: Okay, well, I don't see that. I hope everyone else can. So we'll go ahead and jump into the SNPCC training. Kristen, you can move to slide 2.

Okay.

So now we will review the Special Needs Plans Care Coordination Program Audit Protocol and Data Request that is part of OMB-approved CMS 10717 that will be used for Medicare Part C and Part D program audits beginning in 2022.

As you might guess, the SNPCC protocol is broken down into two sections, the Program Audit Protocol and the Program Audit Data Request.

The Program Audit Protocol section includes the method of evaluation CMS uses to assess a plan's compliance with CMS requirements. The Program Audit Data Request section includes the tools CMS uses to perform its audit activities. The goal of today's training is to ensure a uniform understanding of our SNPCC audit process.

To begin, we will review the compliance standards included in the Program Audit Protocol, focusing primarily on our method of evaluation in an effort to help stakeholders gain insight into our SNPCC process and set expectations for when an audit occurs. Afterward, we will review the Program Audit Data Request, focusing on the technical specifications for many of the fields in the SNPE record layout. We will not review every

field in all of the record layouts. We aim to address all of the SNPCC topics that were submitted in advance of today's presentation, as well as topics we know have caused misunderstandings among stakeholders in the past.

If a specific field is not covered during today's presentation, stakeholders may submit questions to our audit mailbox at: part_c_part_d_audit@cms.hhs.gov. I will share this e-mail again on the last slide of the presentation.

Also, I will continue to use the term "sponsor" to refer to the organizations that participate in the Part C and Part D programs. These are also sometimes referred to as "plans," "sponsoring organizations," "Medicare Advantage organizations," and "prescription drug plans."

Finally, for those who are unfamiliar, when I refer to a "MOC," I am referring to a model of care.

Next slide, please. We should be on slide 3.

The data collection specifications and tools described in the Program Audit Protocols, including the record layout instructions, are used for auditing and monitoring activities and by themselves should not be used to interpret policy. Not all data points within each record are used to determine a sponsor's compliance with CMS time frames.

Next slide, please.

The SNPCC Protocol is limited to the Care Coordination audit elements only. You can see this pulled up on the screen now. The purpose of this review is to evaluate sponsors' implementation of its model of care as approved by MCQA.

The MOC is an integral component for ensure that the unique needs of each enrollee are identified by the SNPCC and addressed through the plan's care management practices. For purposes of evaluating care coordination, the SNPCC protocol will be limited to collecting and evaluating the special needs plans enrollees, record layout, and its

associated impact analyses, which are the care coordination impact analyses, record layouts, and the health risk assessment timeliness impact analysis record layouts.

The 13 compliance standards that make up this element ensure the SNP is meeting the needs of each of its enrollees using the MOC as its framework. CMS performs its program audit activities in accordance with the SNPCC Program Audit Data Request and applying the compliance standards outlined in the protocols and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed within the protocol, taking into account the approved MOC and the regulations cited for each compliance standard. CMS may review factors not specifically addressed if it is determined that there are other related SNP requirements not being met.

Next slide, please. We should be on slide 5.

The SNPCC program area will undergo universe integrity testing in 2022. The universe integrity tests will operate similarly to other program areas. The SNPE universe must be submitted to CMS within 15 business days of the audit engagement letter. Once received, CMS will do an initial check on the universe to identify potential discrepancies. For example, CMS will look to make sure there are no blank fields within a universe; that all contracts are accounted for; and that the universes were populated according to the appropriate universe time frame.

Once complete, CMS will conduct the integrity test to verify the accuracy of data within the universe submission. The timing of integrity testing typically takes three to five business days after CMS receives all universes from a sponsor and prior to fieldwork beginning. CMS will select 10 samples from the sponsor's submitted SNPE universe for review. Sample selection for integrity testing purposes is not specific to certain criteria. Rather, CMS will objectively review the SNPE universe and select samples that may not align with the data request instructions to ensure the universe is populated accordingly.

At a minimum, CMS will verify the dates provided in the SNPE universe during integrity testing and retain the right to review any and all fields within the universe submission. Sponsors will have a maximum of three attempts to provide a complete and accurate SNPE universe. These attempts may occur prior to or after the entrance conference, depending on when the issue is identified. However, three attempts may not always be feasible depending on when the data issues are identified and the impact that the universe resubmission request could have on the audit schedule and/or the integrity of the audited findings.

For example, sponsors will not be allowed to resubmit universes after CMS has shared timeliness results with the sponsor. When multiple attempts are made, CMS will only use the last universe submitted. If a sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's Program Audit report. After the third failed attempt or when the sponsor determines after fewer attempts that it is unable to provide an accurate universe within the time frame specified during the audit, the sponsor will be cited an invalid data submission condition relative to each element that cannot be tested grouped by the types of case.

This information can be found in the Annual Program Audit Process Overview document located on the Program Audit's website. This process of validating universe submissions has proven useful in determining the quality of data received in order to accurately and successfully conduct program audits. Samples selected during integrity testing does not preclude CMS from selecting the same samples for review during the fieldwork portion of the audit.

Once integrity testing is complete and all universes have been accepted, CMS will conduct timeliness tests to determine a sponsor's compliance with CMS regulations.

Next slide, please.

For Compliance Standard 1.1, CMS will conduct a timeliness test at the universe level on enrollees who have been continuously enrolled in the

organization's SNP for at least 90 days. While the SNPE record layout asks for all current enrollees as of the date of the audit engagement letter, CMS will run this test on only those enrollees who have an effective date within 12 months of the audit engagement letter and have been continuously enrolled for 90 days to ensure these enrollees received an initial health risk assessment.

For instance, if an engagement letter is issued on July 1, 2021, CMS will include all enrollees with effective dates of July 1, 2020, and have been continuously enrolled for 90 days under the assessment. Using this example, enrollees with an effective date of June 1, 2021, would not be included in the assessment since at the time that the engagement letter is issued the enrollee would not have been continuously enrolled for 90 days; and the organization would still have time to complete an IHRA if it has not already done so.

CMS will consider a plan compliant with initial health risk assessment timeliness requirements when they have completed initial HRAs within 90 days before or after the enrollee's effective date with the SNP. If non-compliance is found or CMS identifies enrollees where an initial HRA was not completed within 90 days of the enrollment effective date, CMS may request an impact analysis – specifically, Table 2IA: HRA Timeliness Impact Analysis. I said CMS may require the impact analysis because CMS uses an internal threshold to determine if collecting the additional information in the format of an impact analysis to quantify outreach attempts or other possible mitigating factors is necessary.

If determined to be necessary, the IA review period is limited to the 12-month period prior to the date of the engagement letter. As I mentioned, CMS will request this IA, inclusive of a root cause analysis, to ensure organizations attempted to contact enrollees who are identified as not having completed an IHRA in the timeliness assessment or to understand why outreach may not have occurred in accordance with the approved MOC.

Next slide, please. We are now on slide 7.

For Compliance Standard 1.2 – again, once universe integrity testing is complete, CMS will conduct a timeliness test on members who have been continuously enrolled in the organization's SNP for 365 days or more or new enrollees who failed to complete an initial HRA to determine whether the sponsoring organization conducted timely annual health reassessments.

CMS will consider a plan compliant with annual health risk assessment timeliness requirements when they have completed annual HRAs within 365 days of the previous HRA. For example, for enrollees who completed an IHRA or an AHRA on July 1, 2020, CMS would ensure they had a subsequent HRA completed by at least June 30, 2021.

Similar to the previous compliance standards, CMS may request an impact analysis – again, Table2IA, for all enrollees identified as not having a timely AHRA completed. The IA review period is limited to the 12-month period prior to the date of the engagement letter. CMS will request this IA to ensure organization's attempts to contact enrollees who were identified as not having received an AHRA in the timeliness assessment.

Next slide, please.

For Compliance Standard 1.3, CMS will select 30 samples from the SNPE universe that reflect the general composition of membership in each plan type; for instance, a D-SNP, C-SNP, or I-SNP. At a minimum, CMS will select five enrollees from each plan type – again, a D-SNP, C-SNP, or I-SNP offered by the organization. The remaining samples will be selected from the plan type with the greatest representation in the universe.

Samples will be provided to the organization on the Thursday prior to the start of audit fieldwork via HPMS as an organizational sample file. During the audit, CMS will review the 30 samples to ensure the completed HRA included a comprehensive initial assessment and reassessment of the needs of the enrollees including medical, psychological, cognitive, functional, and mental health needs.

Next slide, please. We are now on slide 9.

CMS will assess Compliance Standard 1.4 by reviewing the evolution of an enrollee's ICP up through the date of the engagement letter. It may include multiple iterations of an enrollee's ICP as the specific health needs of an enrollee change over time. Auditors will seek to ensure ICPs are designed to address the needs identified in the HRA consistent with the approved MOC.

CMS will determine if the ICP included measurable outcomes inclusive of a time frame for completion or evaluation if the outcome was not met in accordance with the MOC. CMS will consider if the ICP includes the following -- again, in accordance with the MOC:

The enrollee's self-management goals and objectives

The enrollee's personal healthcare preferences

A description of services specifically tailored to the enrollee's needs, and

The identification of goals.

Next slide, please.

For Compliance Standard 1.5, CMS will assess how the organization reviewed an enrollee's ICP and, if necessary, revised an enrollee's ICP based on the beneficiary's health status and in accordance with the SNP's MOC. CMS will work with an organization to understand the decision-making process that is undertaken when they learn of a change to an enrollee's health status and determine whether or not to update an ICP.

Next slide, please. I am now on slide 11.

For Compliance Standard 1.6, CMS will review with the organization any and all evidence the sponsor can provide that demonstrates the organization implemented the ICP in accordance with its MOC. Organizations can show, for example, case management notes; ICT documentation; claims data; and prescription drug event records in an

effort to demonstrate implementation of the ICT. CMS expects the organization to be able to access all appropriate systems and have the necessary personnel involved to demonstrate or support implementation of the ICP for sampled enrollees during the audit.

Next slide, please.

CMS will assess Compliance Standard 1.7 by reviewing documentation that reflects the organization's facilitated beneficiaries and/or caregiver participation when developing the beneficiary's ICP. Organizations may provide ICP notes, communications such as those between the ICP members and enrollees and caregivers, documented verbal outreach, or written communications to demonstrate involvement.

Next slide, please.

CMS will assess Compliance Standard 1.8 by reviewing documentation that shows how the organization coordinated communication amongst its personnel, providers, and enrollees to enhance the delivery of care. CMS will rely on documented phone calls, letters to and from providers regarding member care, and any additional material provided by the organization to support coordinated communication.

Next slide, please.

For Compliance Standard 1.9, CMS will assess this compliance standard by reviewing documentation that shows an organization's interdisciplinary care team comprised of clinical disciplines according to the SNP's MOC contributed to the care management of each individual enrolled in the SNP. Organizations may again show evidence of meeting minutes, written communications, or documented phone calls that reflect how the ICT contributed to improving a beneficiary's health.

Additionally, CMS will ensure an enrollee's primary care provider was involved in the coordination of care. Sponsors may show meeting attendee lists or other documentation that shows PCP involvement. CMS will rely on an organization's MOC to understand when and how PCPs

are involved with the ICT on member care if not all of the time and hold the organization accountable to the MOC.

Next slide, please.

CMS will assess Compliance Standard 1.10 by reviewing documentation that shows how an organization implemented its transition procedures in an effort to maintain continuity of care for SNP beneficiaries according to its MOC when a member has either planned or unplanned transitions between healthcare sets.

Organizations may show what occurs once a case manager learns that a member was transferred to a higher level of care. This would include how the case manager participants in the daily activities of the member while hospitalized, including how they coordinate with the utilization management; how the care management team communicates with a member of the family and PCP regarding transition process; how the care management team transmits pertinent health information to treating physicians at the hospital; and finally, how the care management team and hospital team develop a safe discharge plan for the enrollee.

Organizations will also be expected to demonstrate how the care plan is made available to the ICT and the PCP.

Next slide, please.

For Compliance Standard 1.11, CMS will ensure the staff involvement in the development of enrollee ICTs sets professional requirements, including credentials, as described in the MOC.

Next slide, please.

For Compliance Standard 1.12, sponsors must demonstrate to CMS how each member of an enrollee's ICT received training at the organization's MOC.

Next slide, please. I am now on slide 18.

For Compliance Standard 1.13, CMS will ask organizations to demonstrate all care providers who treat an organization's SNP enrollees, whether it is an I-SNP, C-SNP, or D-SNP member who received training on the MOC. During an audit, CMS may request evidence that all providers who routinely provide services to SNP members of an organization have received training on the MOC, including non-contract providers. Organizations are responsible for making providers of all updates made to the MOC, whether on or off cycle.

In the event an organization is unable to demonstrate that a provider received training, CMS will ask the organization to provide evidence that outreach was conducted or that training materials were made available to the providers in an effort to ensure the training was completed.

Next slide, please.

That concludes our review of the Program Audit Protocol. We will now move to the Program Audit Data Request. So if you're following at home, we are on slide 19; and on the screen now is where we are within the protocol itself.

Next slide – we should be on slide 20. I still can't see the slides, so hopefully we are.

All sponsors must submit the SNPE record layout comprehensive of all contracts and plan benefit packages identified in the audit engagement letter. All universes must be submitted in either Microsoft Excel format with a header row or Text file format without a header row. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual's universe record layout. Characters are required in all requested fields unless otherwise specified, and data must be limited to the request specified in the record layout.

Sponsors must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

The instructions for the SNPE record layout are straightforward:

List all current SNP enrollees as of the date of the engagement letter.

List each enrollee only once.

Include enrollees with disenrollment effective dates at the end of the month in which the audit engagement letter is received.

Exclude enrollments received before the date of the audit engagement letter that are not effective until the first day of the month following the engagement letter date.

Next slide, please. We should be on slide 21.

For the Enrollment Effective Date field, enter the effective date of the enrollee's most current effective date with the organization, assuming there has been no break in coverage. For example, if an enrollee initially enrolled in PBP001 on June 1, 2015, but was moved to PBP015 in 2019, either due to a member-initiated request or a sponsor-initiated request, the sponsor should enter January 1, 2015, in this field.

[Pause]

I'm thinking about that for a second. I think I meant to say June 1, 2015, in this field.

Next slide, please.

For the Most Recent Plan Change Effective Date, plans must enter the most recent date of the last plan change within the organization in this field. For example, if a member changes from PBP001 to PBP002 after the date they initially enrolled with the organization, sponsors will enter the effective date of the enrollee's movement to PBP002.

Next slide, please.

For the Date of the Most Recent HRA, enter the date of the enrollee's most recent HRA. If only the initial HRA was completed, enter the date of the initial HRA. Enter "None" if no HRA was completed. This includes

instances where the enrollee refused to complete the HRA or was unable to be reached.

Next slide, please.

For the Date of Previous HRA, enter the date of the enrollee's previously-completed HRA. If an enrollee is new to the organization or has been continuously enrolled but switched PBPs within an organization, this date may be the same as the date of the initial health risk assessment, as identified in Column "K."

Next slide, please. We are now on slide 25.

For the Date the Initial HRA was Completed field, enter the date the SNP received the HRA from the enrollee or the enrollee's rep. This might be the date of a verbal HRA if completed telephonically or the date a paper or electronic HRA is received by the organization.

Sponsors should enter "EXC-10" if the initial HRA date occurred more than 10 years prior to the engagement letter date. Sponsors should also use "EXC-10" if the first HRA was more than 10 years prior. This would occur if the organization was unable to contact the enrollee or if the enrollee refused the IHRA within the first 90 days before or after the enrollment effective date and the first HRA was not the IHRA.

Sponsors should enter "None" if IHRA was completed outside the 90-day time frame.

Next slide, please.

Sponsoring organizations should populate the Enrollee Risk Stratification Level at time of Audit Engagement Letter field according to their internal acuity scoring system that assesses an enrollee's severity of illness or intensity of service. Question No. 4 in the SNPCC Supplemental Questionnaire asks sponsors to describe their stratification level and their process of assigning enrollees to each risk stratification level. Sponsors should populate this field according to the response given in Question No. 4.

Next slide, please. We are on slide 27.

For the Date of Most Recent Individualized Care Plan field, enter the date of the most recent ICP. For continuous ICPs, enter the date of the most recent update. When no care plan was developed, enter "None."

Next slide, please.

We will now quickly go over the Impact Analysis Requests.

SNPCC has two impact analyses, the Care Coordination Impact Analysis Record Layout and the HRA Timeliness Impact Analysis Record Layout.

Table 1IA, which is the Care Coordination Impact Analysis, is used to quantify non-compliance identified during an audit. Sponsors must populate this table as directed by the CMS SNP Team Lead with all enrollees impacted in the 26-week period preceding the date of the audit engagement letter through the date the issue was identified on the audit. Sponsors will not be required to complete all fields in Table 1IA if non-compliance is uncovered. Rather, the SNP Team Lead will clearly relay to the sponsor which fields must be populated depending on which requirements were not met based on the sample cases reviewed.

For instance, if a sponsor did not review or revise individualized care plans consistent with this level of care or is warranted by changes in the health status or care transitions of enrollees, the CMS Team Lead may ask the sponsor to complete fields "A" through "F," which will typically always be required when this IA is requested, and fields "K" through "R" only. These fields are applicable to that specific example of non-compliance.

Conversely, Table 21A is collected to potentially mitigate non-compliance. Upon request, sponsors must populate this table with all enrollees impacted in the 12-month period prior to the date of the engagement letter. CMS will use this information to determine if appropriate outreach was made to the enrollee to complete the IHRA or the annual HRA, depending on the compliance standard being tested. Sponsoring organizations conducting more than one HRA event within the 12-month

period on a single enrollee should populate both instances of the HRA event that occurred during the applicable time frame.

Next slide, please. We are now on slide 29.

I'll briefly discuss the SNPCC Supplemental Questionnaire, which is also located in the Resources pod.

This questionnaire is designed and collected to assist CMS in understanding the unique qualities of your organization's SNP program operations. This questionnaire is located in the "Submission Materials" folder of HPMS and is due within five business days after the engagement letter is issued. Separate questionnaires may be provided for each entity and operating system showing the CMS contracts that are applicable to each completed questionnaire. If multiple questionnaires are completed, they must be zipped together and uploaded to HPMS as a single file.

Last slide, please.

This concludes our final MAPD Program Audit Protocol training. We aimed to address all of the topics that were submitted in advance of today's presentation and hope you all found this training useful. If you have any additional Program Audit process related questions following today's presentation, please send them to the e-mail address listed on the slide on your screen.

As noted previously, any policy-related questions should be directed to the appropriate CMS policy mailbox.

Thank you all for attending and have a great rest of the day.

Moderator: Thank you so much, Matt.

At this time, a new browser window will open and take you directly to the Participant Survey. Thank you for taking the time to join us today. This concludes today's webinar. Thank you.