Session 2: August 24, 2021

Part D Formulary Administration (FA)
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Part D Coverage Determinations, Appeals, and Grievances (CDAG)
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Matthew Guerand: Good afternoon, everyone. Thank you all for joining today's session of the final Medicare Advantage Program Audit Protocol User Group Training. 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.

Today is the second part of our user group training series. We will review two program areas. First, I will review the Part D Formulary and Benefit Administration program audit protocol and data requests. Afterwards, Kellie Simons will take over and review the Part D Coverage, Determinations, Appeals, and Grievances program, audit protocol and data requests. Both of these protocols are included in OMB-approved CMS-10717 and will be used for MAT audits beginning in 2022. It's our hope this training provides further clarity on our audit protocols and assists stakeholders as they prepare their systems for audits next year.

As a reminder, the third and final session of this user group training series is scheduled for this Thursday, August 26th, from 2:00 p.m. to 4:00 p.m. Easter Time. There we will review the Part C and Part D Compliance

Program Effectiveness protocol and the Special Needs, Plans, Care, Coordination protocol.

Okay, so before we begin, we would like to take a quick polling question for those who were on the call last week. We would like to know who is listening. So please take a look at this screen and let us know where you're from.

[Pause for responses]

All right, looking good – it looks like the majority of people are on the line from an MA or PDP plan, as well as the pharmacy benefit manager. So it appears the majority of us, or at least the vast majority of us, are in the right place.

Next slide.

Let's begin with our review of the Part D Formulary and Benefits Administration Program Audit protocol. As I mentioned, this protocol is part of OMB-approved CMS-10717 and will be used to conduct Medicare Part C and Part D program audits beginning in 2022. The FA 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 FA 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 on our FA audit process and set expectations for when an audit occurs. Afterwards we will review the Program Audit Data Request, focusing on the technical specifications for many of the fields in the FA record layouts. We will not review every field in each of the record layouts. We aim to address all of the FA topics that

were submitted in advance of today's presentation, as well as topics we know have caused misunderstandings in the past.

If a field is not covered during today's presentation, stakeholders may submit questions to our policy mailbox at: Part_C_Part_D_Audit@CMS.hhs.gov. We will share this e-mail again at the end of our presentation, and we should have it up for you on the screen shortly.

Throughout today's training, I'll be using the term "sponsor" to refer to organizations that participate in the Part C and Part D programs. These are also sometimes referred to as "plans," "sponsoring organizations," "Medicare Advantage organizations," "prescription drug plans," or "Part D sponsors."

Next slide.

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 Part D formulary and benefit administration should be directed to the appropriate CMS policy mailbox.

Next slide.

The FA Program Audit protocol has two audit elements: formulary administration, which has five compliance standards, and transition, which has two compliance standards. The purpose of the Formulary Administration Review is to ensure compliance of Part D plan sponsors in providing appropriate access to enrollees' medications and their prescription drug benefits. The Transition Review ensures Part D plan sponsors are adhering to the transition policy requirements. CMS will perform its program audit activities in accordance with the FA Program Audit Data Request in applying the compliance standards outlined in the protocol and the Program Audit Process Overview document.

At a minimum, CMS will evaluate cases against the criteria listed within the protocol. CMS may review factors not specifically addressed if it is determined that there are other related FA requirements not being met.

Next slide.

Beginning in 2022, CMS is implementing universe integrity testing for all program areas. For FA, CMS will conduct integrity testing on Universe Tables 1 and 2, which are the Rejected Claims Formulary Administration and Rejected Claims Transition Record layouts only. CMS will select five cases from these tables to verify the accuracy of the data submitted. The integrity of the universe will be questioned if data points specific to the sample cases are incomplete, do not match, or cannot be verified by viewing the sponsor's systems and/or other supporting documentation.

Sponsoring organizations 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 use the last universe submitted.

If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsoring organization'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. This information can be found in the Annual Audit Process Overview document. Sample selections for integrity testing will be provided to the sponsor approximately one hour prior to the scheduled webinar.

Next slide.

Once integrity testing is complete, CMS will select 30 targeted rejected claims relating to formulary administration. CMS will ensure the sample set represents a mix of claims of both non-protected class drugs and claims for protected class drugs. Auditors will have discretion in sample selection as it relates to protected versus non-protected class drug samples. Sampling criteria could include, but is not limited to, the following:

Rejections for formulary drugs

Prior authorization rejections where the prior authorization edit is not approved

Step therapy rejections where the step therapy edit is not improved

Quantity limit rejections where the quantity limit edit is not approved or the quantity amount and/or dates supplied are not within allowed limits

Rejection messaging is inconsistent with the drug's formulary status and the approved benefits, this includes non-formulary drugs

Rejections associated with high-cost edits

Rejections for opioid-related safety edits

Rejections associated with date-supplied limitations not consistent with the plan benefits

Rejections for Part B versus Part D medications

Rejections for short-cycle sales

And finally, rejections for prescriber identification.

Again, samples will be sent to the sponsor approximately one hour prior to the start of the review.

Next slide.

For Compliance Standard 1.1, CMS will review the 30 targeted samples to ensure sponsors adhere to their CMS-approved formularies; that unapproved utilization management edits are not applied to restrict formulary and benefit access; and ensure appropriate effectuation of authorization records typically resulting from a coverage determination. Some of the samples selected for review will be used to assess Compliance Standards 1.2 through 1.5.

Next slide.

For example, for Compliance Standard 1.2, CMS will review some of the samples to ensure appropriate administration of prior authorization or step therapy for enrollees taking protective class medications for the first time or are currently taking the drug. For enrollees determined to be currently taking the drug, CMS will ensure these enrollees have access to a day's supply consistent with their benefits.

Next slide.

For Compliance Standard 1.3, auditors will use some of the samples to ensure appropriate administration of special requirements for long-term care dispensing, such as short-cycle fill requirements.

Next slide.

For Compliance Standard 1.4, some samples will be selected to ensure appropriate claim rejections based on prescriber identification information and...

Next slide, please.

Finally, for Compliance Standard 1.5, CMS will review some of the claims to ensure appropriate administration of requirements related to a plan sponsor's Part D Drug Management program. This will include ensuring appropriate administration of care coordination opioid safety edits, pharmacy and prescriber coverage limitations, and appropriate administration of seven-day supply limit for initial opioid sales for beneficiaries considered to be opioid-naïve.

We received a question about why the RCT record layout is included within the "Data Request" column for Compliance Standard 1.5. This is because CMS may identify formulary administration issues in the RCT universe, such as those relating to the start of the new benefit year that it found would be appropriately cited under the regs associated with this standard. Compliance Standard 1.5 is the last of the formulary administration audit elements.

Next slide.

Moving on to the Transition Audit elements, CMS will select 30 targeted samples from Table 2. Fifteen samples will be chosen for continuing enrollees and consistent rejected claims related to cross-year formulary changes between the audit year and the previous contract year; for example, formulary deletions. And 15 samples will be chosen for new enrollees and consistent rejected claims related to formulary administration drugs during transition; for example, prior-auth, step therapy, non-formulary drugs, and quantity limitations.

Next slide.

For Compliance Standard 2.1, CMS will review the 30 targeted samples selected above to determine if the rejection is appropriate and identify and review any protected class rejections to look for broader issues that may affect one or more classes. Specifically, CMS will review samples to ensure that new and continuing enrollees eligible for a transition fill are afforded the full transition benefits; enrollees with a November or December effective enrollment data are afforded a full continuing enrollee transition benefit, if applicable; enrollees in long-term care are afforded access to emergency supplies while an exception or prior authorization request is being processed; and drugs available in their smallest package size are appropriately processed during transition.

For Compliance Standard 2.2, CMS will ensure enrollees and prescribers received appropriate, timely, and accurate notices. You will note the RCFA record layout is included within the "Data Request" column for Compliance Standards 2.1 and 2.2. This is because CMS may identify

transition issues in the RCFA record layouts; for example, issues relating to midyear enrollments that if found would be appropriately cited under the rights associated for the standard.

Next slide, please.

That was the end of our Program Audit protocol review. Next, we're moving to the Program Audit Data Request which, as you can see on the screen, begins following Transition Compliance Standard 2.2. So when we refer to the Program Audit Data Request, we are referring to the record layouts and the impact analyses within the FA protocol.

Next slide, please.

All sponsors must submit universe Tables 1 through 4, comprehensive of all contracts and plan benefit packages identified in the audit engagement letter. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts. Characters are required in all requested fields unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsors must provide accurate and timely universe submissions within 15 business days of the audit engagement letter dates. Submissions that do not strictly adhere to the record layout specifications will be rejected.

The scope of each FA universe is different from other program areas in that the universe period varies depending on the number of enrollees and the specific universe. The RCFA and RCT have the same record layouts and share the same instructions; however, each universe is populated differently depending on the size of the organization's enrollment.

For Table 1, the Rejected Claims Formulary Administration record layout, sponsors with less than 20,000 MAPD and PDP enrollees must submit all rejected claims with dates and service for the eight-week period preceding and including the date of the engagement letter. Sponsors with a MAPD and PDP enrollment between 20,000 and 500,000 enrollees must submit four weeks of data. Finally, sponsors with more than 500,000 enrollees must submit two weeks' worth of data.

For Table 2, the Rejected Claims Transition record layout, sponsors with MAPD and PDP enrollments of less than 100,000 enrollees must submit all rejected claims with dates of service for January and February of the audit year. Sponsors with enrollment equal to or over 100,000 enrollees must submit all rejected claims for January of the audit year. For each record layout, sponsors must include all rejected claims with dates of service that fall within the applicable review period, including enrollees enrolled in employer plans and MMPs. Sponsors must not filter data under any circumstance.

Finally, only fields that are submitted blank by the pharmacy may be blank in the universe submission to CMS.

Next slide, please.

For Table 3, Prescription Drug Event record layouts, sponsors must submit all final-action PDEs accepted by CMS with dates of service between September and December of the contract year immediately prior to the audit year for all enrollees in Table 2 and enrollees with effective enrollment dates in November and December of the contract year prior to the audit year. However, we note here that sponsors must be certain to include enrollees in employer group plans and MMPs in the PDE record layout.

Finally, for Table 4, the New Enrollee record layout, sponsors with MAPD and PDP enrollment of less than 100,000 must submit all enrollees with effective enrollment dates between November of the previous audit year through February 1st of the current audit year. Sponsors with 100,000 or more enrollees must submit all enrollees with effective enrollment dates of November 1st of the previous audit year through January 1st of the current audit year. For instance, in 2022 if a sponsor has 50,000 enrollees, they will submit a New Enrollee universe with all enrollees with an effective enrollment date between November 1, 2021, through February 1, 2022.

The New Enrollee record layout instructions require that plans only include eligible enrollees for which the sponsor does not utilize prior

claims history. In some cases, the sponsoring organization may have the full claims history for the enrollee from the most recent PBP; and thus, the sponsor may be able to determine new versus ongoing therapy. In this example, the enrollees should not be included in the New Enrollee universe since they are determined to be a continuing enrollee. Also, if a member is switching PBPs within a contract and prior claims history is used in adjudication for certain edits, such as results too soon, these members should be excluded from the New Enrollee universe.

Next slide, please.

Now we will go over just a few of the fields within some of the record layouts. First, we will discuss the Enrollment Effective Date and Disenrollment Effective Date fields. These fields are found in the RCFA, RCT, and New Enrollee record layout.

For the RCFA and RCT record layouts, populate the enrollment and disenrollment dates for the enrollee at the PBP level at the time of the claim. In the New Enrollee table only, a separate record should be entered each time an enrollee is enrolled and considered a new enrollee. For the Effective Disenrollment Date in the New Enrollee record layout, enter the effective date of disenrollment for the enrollee. Because all universes are populated at the PBP level, the enrollment dates in the Rejected Claims and New Enrollee universes may not be consistent.

For example, a member who enrolls in any given contract Plan Benefit Package 001 on November 1, 2020, and disenrolled on December 31, 2020, may have a subsequent active enrollment in the same contract Plan Benefit package 002 effective January 1, 2021. In the New Enrollee universe, the enrollee would be inactive as of December 31, 2020, in the original PBP 001; however, in the RCFA and RCT universes, the enrollment date would be January 1, 2021, with no disenrollment date.

Next slide.

CMS has aligned the FA NDC field description with the field description in the CDAG protocol. In this field, enter the 11-digit national drug code using the NDC 11 format. Remove special characters separating the

labeler, product, and trade packet size. This field may be populated with less than 11 characters or as a blank if the pharmacy or delegate submitted the claim in this manner. When a pharmacy submits a value greater than 11 characteristics, enter "Value exceeded" as prescribed in the description language in this field. For multi-ingredient compound claims, sponsors should populate this field with the NDC as would be submitted on a paid claims PDE or as blank if all ingredients within the compound claim are excluded.

Next slide, please.

The final two fields we'll review today are in the RCFA and RCT record layouts, and they are the Reject Reason Code and the Pharmacy Message fields. These two fields go hand in hand. Enter the reject reason code in the Reject Reason Code field followed by the associated pharmacy message for that reject reason code in the adjacent field. Sponsors should repeat this format for every reject reason code. For instance, if there were two reject reason codes, sponsors would enter the first reject reason code in column "R" with its associated pharmacy message in column "S". Sponsors would enter the second reject reason code in column "T" with the associated pharmacy message in column "U," so on and so forth.

Please note, in limited circumstances when the messaging cannot be separated for purposes of populating the universe, sponsors may choose to include all pharmacy messaging in the first pharmacy message field only. For subsequent reject codes, please enter "N/A" in the associated pharmacy message field.

Next slide, please.

The FA program area has two impact analyses: Table 1IA, Impact Analysis Summary Record Layout, and Table 2IA, Enrollee Impact Analysis Record Layout. These IAs are used for both FA and transitions. When required, sponsors should submit each IA in the same workbook as two different worksheets. Sponsors should leave fields blank if a response cannot be completed. For instance, in Table 1IA, its enrollee

outreach and remediation has not occurred. Sponsors may leave the field "Date Enrollee Outreach and Remediation Initiated" blank.

Next slide.

The scope of each impact analysis is different depending on which element the non-compliance was uncovered. For Formulary Administration, sponsors must include a list of all medications and/or enrollees impacted by the non-compliance from the date the IA is requested through the start of the universe period. For transition, sponsors must submit a list of all medications and/or enrollees impacted by the non-compliance from the date the IA is requested through January 1st of the current year. However, when transition is being tested for enrollees with late enrollment in the previous year, such as November or December, the impact analysis should go back to the date of the enrollee's new enrollee enrollment in the previous year.

Next slide.

For Table 1IA, sponsors must include all medications impacted by the issue. CMS may request impact to medications that may not be associated with a rejected claim in limited circumstances; for example, issues related to inappropriate effectuation of prior authorization records. In these situations, CMS will specify which medications should be reported in the impact analysis.

Last slide, please.

For Table 2IA, for each enrollee impacted by the issue of non-compliance, sponsors must include all rejected claims affected by the issue of non-compliance and inaccurate records that may not be associated with a rejected claim, such as authorization or enrollment records. For inaccurate record scenarios, sponsors should only complete the following fields: Enrollee ID, Contract ID, PBP, Enrollment Effective Date, and Drug Name and Strength if applicable.

Inaccurate records that are not associated with the rejected claim are included because they would still require remediation by the sponsor

once the error is identified during a program audit because the inaccurate records could result in a point-of-sale claim rejection. Therefore, CMS would still expect to see these records included in the impact analysis.

Finally, sponsors should include separate entries for an enrollee each time the enrollee experienced an inappropriate rejection at the point of sale as a result of the non-compliance.

This concludes our review of the FA Program Audit Protocol and Data Request. I will now turn it over to Kellie Simons to review CDAG.

Kellie, over to you.

Kellie Simons: Thanks, Matt.

I'll give it a second for the slides to load.

[Pause]

Okay, good afternoon and welcome to the second portion of today's final MAPD Program Audit Protocol Training session. This part of the training will focus on Part D Coverage Determinations, Appeals, and Grievances or CDAG.

As Matt mentioned, my name is Kellie Simons. I also work in the Division of Audit Operations within the Medicare Parts C and D Oversight and Enforcement Group of CMS. I'll be presenting the CDAG portion of today's training.

For those listening by phone and following with the slides, the final presentation for today can be accessed via the link in the "Presentation Update" e-mail that was sent this morning. There are 80 CDAG slides today; so as we move through, I'll be sure to announce the slide numbers.

Slide 2, please.

Today we'll be reviewing contents of the Final CDAG Program Audit Protocol and Data Requested approved by OMB. This document is available in the Resources pod of the Adobe Connect application.

CMS announced via an HPMS memo on May 26, 2021, that these protocols and supporting data collection instruments will be used for Medicare Parts C and D program audits starting in 2022.

The first part of today's session will focus on the CDAG Program Audit protocol, where we'll review the audit elements tested and methods of evaluation. The second portion of the training will focus on the CDAG Program Audit Data Requests and a review of the technical specifications for populating the CDAG record layouts.

Throughout today's presentation, 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."

Slide 3.

Next, we have a polling question. Please respond "Yes" or "No." Our question is: "I have experience participating in a CMS Program Audit."

[Pause for responses]

Okay, great, it looks like we have about three-quarters, 74%, who have experience and 26% or so that do not.

Let's turn to slide 4.

As a note, the data collection specifications and tools described in the Program Audit protocols, including the record layout table 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 Part D Coverage, Determinations, Appeals, and Grievances should be directed to the appropriate CMS policy e-mail box.

Slide 5.

We'll now focus on the protocol portion of the CDAG program audit protocol and data request documents. This part of the protocol begins on page 3 and is currently being displayed on the screen.

There are four audit elements tested in CDAG: timeliness, processing of coverage requests, classification of requests, and administration of Drug Management program. The administration of Drug Management program element was included in CMS-10717 to test new requirements. CMS will begin auditing a sponsor's adherence to the Comprehensive Addiction and Recovery Act by ensuring that Drug Management programs, or DMPs, establish for beneficiaries at risk for misuse or abuse of frequently-abused drugs meet the regulatory requirements.

The purpose of the review is to evaluate performance in these areas related to Part D Coverage, Determinations, Appeals, and Grievances. CMS performs its program audit activities in accordance with the CDAG program audit data requests and applying the compliance standards outlined in the protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed within the protocol. CMS may review factors not specifically addressed if it is determined that there are other related CDAG requirements not being met.

Slide 6.

For CDAG's university integrity testing, CMS will select ten cases from each universe, Tables 1 through 7, for a total of 70 cases. Prior to field work, CMS will schedule a webinar with the sponsor to verify accuracy of data within the universe submissions and to confirm effectuation of approved requests for each of the sampled cases. For universe Table 2, CDER, CMS will verify during the webinar that the sample cases are exception requests. The integrity of the universe will be questioned if data points specific to the sample cases are incomplete, do not match, or cannot be verified by viewing a sponsor's systems and/or other supporting documentation.

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 and/or integrity of the audit findings. For example, sponsors will not be allowed to resubmit universes after CMS has shared timeliness test results with the sponsor.

When multiple attempts are made, CMS will only use the last universe 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's unable to provide an accurate universe within the time frame specified during the audit, the sponsor will be cited an invalid data submission, or IDS, 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 documents located on the Program Audit website. The universe integrity samples selection will be provided to the sponsor approximately one hour prior to the scheduled webinar.

Slide 7.

Next, we'll be discussing the CDAG Timeliness Audit element. CMS conducts timeliness tests at the universe level for notification in accordance with the applicable regulations. CMS will measure timeliness against the following time frames:

For Standard coverage determinations...

72 hours

For Standard coverage determination coverage exception requests 72 hours after receipt of the supporting statement.

If a supporting statement was not received by the end of 14 calendar days from receipt of the request, notification no later than 72 hours from the end of the 14 calendar days of receipt of the request.

For Expedited coverage determinations...

24 hours

For Expedited determination exception requests:

24 hours after receipt of the supporting statement

If a supporting statement was not received by the end of 14 calendar days from receipt of the request, notification no later than 24 hours from the end of the 14 calendar days of receipt of the request

For Payment coverage determinations...

Notification within 14 calendar days, and

Payment made no later than 14 calendar days

Slide 8.

For redeterminations, CMS will measure timeliness against the following time frames:

Payment Coverage redeterminations...

Notification of the determination within 14 calendar days, and

Payment made no later than 30 calendar days

For Standard redeterminations...

Notification of the determination within 7 calendar days

For Expedited redeterminations...

Notification of a determination within 72 hours

Slide 9.

For decisions overturned by the IRE, ALJ, or MACs, the following regulatory time frames are used by CMS to measure timeliness:

For Pre-benefit Standard cases...

Authorize or provide the benefit under dispute no later than 72 hours after receipt of the notice reversing the determination

For Post-service Payment cases...

Authorize the payment no later than 72 hours, and

Make payment within 30 calendar days after receipt of the notice reversing the determination

For Pre-benefit Expedited cases...

Authorize or provide the benefit under dispute no later than 24 hours after receipt of the notice reversing the determination.

Slide 10.

CMS will measure grievance notification timeliness against the following time frames:

For Standard...

30 calendar days after receipt of the grievance, or

44 calendar days if an extension was taken

For Expedited...

24 hours after receipt of the grievance

Slide 11.

The review for auto-forwarding to the IRE is conducted at the universe level. If notification was untimely and auto-forwarding to the IRE is required, CMS will determine if the sponsor auto-forwarded the case to the IRE. CMS will determine the total number of cases in Tables 1

through 4, the number of cases in Tables 1 through 4 that required auto-forwarding to the IRE, and the total number of cases in Tables 1 through 4 that were not auto-forwarded to the IRE as required.

Slide 12.

Now we'll turn to the second CDAG audit element, Processing of Coverage Requests.

For approvals, CMS will select ten cases from Tables 1 through 4. CMS will ensure the sample set represents various types of coverage determinations; for example, prior authorization, step therapy authorization, tiering exception, formulary exception including both non-formulary and formulary drugs with a UM requirement, and reimbursement requests. For each approval case, CMS will review case file documentation for proper notification of the approval decision. If the enrollee identified a representative, CMS will review the case file to determine if notification was sent to the enrollee's representative.

If a prescriber requested the coverage, CMS will review the case file to determine if notification of the decision was also sent to the prescriber. Approval sample selections will be provided to the sponsor approximately one hour prior to the scheduled webinar. For each sampled approved case, CMS will also review case file documentation for proper effectuation duration. This would be, for example, in accordance with the sponsor's CMS-approved formulary or for an approved exceptions request for the remainder of the plan year.

We received a question asking whether inappropriate consideration of clinical information would be out-of-scope for the ten approval cases. As stated in the protocol, CMS may review factors not specifically addressed if it's determined there are other related CDAG requirements not being met.

Next slide, slide 13.

For denials, CMS will select 30 cases from Tables 1 through 4. CMS will target cases that are protected class drug denials and ensure the sample

set represents various types of coverage determinations. For example, as mentioned for the approval selections, prior authorization, step therapy, tiering exception, formulary exceptions, and reimbursement requests.

For each denial case, CMS will review case file documentation for proper notification and appropriate consideration of clinical information. The notification will be reviewed by CMS in accordance with the applicable regulations. For example, for coverage determination denials, CMS will review the written notification to determine if it used approved notice language in a readable and understandable form; states the specific reasons for the denial; informs the enrollee of his or her right to a redetermination; and complies with any other notice requirement specified by CMS.

As an example, the current Notice of Denial of Medicare Part D Prescription Drug Coverage includes language to be inserted for prescription drugs that are or may be covered under Medicare Parts A or B. CMS will review denial notifications to ensure that Medicare Advantage plans that also provide Part D coverage, MAPD, include the following language in the denial notice: "This request was denied under your Medicare Part D benefits; however, coverage/payment for the requested drugs has been approved under Medicare Part A/B," and explained the conditions of the approval and are readable in an understandable format.

If the enrollee identified a representative, CMS will review the case file to determine if notification was sent to the enrollee's representative. If the prescriber requested the coverage, CMS will review the case file to determine if notification of the decision was also sent to the prescriber. Denial sample selections will also be provided to the sponsor approximately one hour prior to the scheduled webinar.

Slide 14.

CMS will also review each denial case sample for evidence that the sponsor's medical director or other appropriate health care professional with sufficient medical and other expertise reviewed the request for clinical accuracy.

If the sponsor denies a request for expedited determination, CMS will review that determination and for proper notification to the enrollee and prescribing physician or other prescriber that explains that:

The sponsor must process their request using the 72-hour time frame for standard determinations.

Informs the enroll of the right to file an expedited grievance if he or she disagrees with the decision by the sponsor not to expedite.

Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support.

And provide instructions about the sponsor's grievance process and its time frames.

Slide 15.

For the sampled redetermination cases, CMS will review case file documentation for proper evidence that the person or persons who were involved in making the coverage determination or at-risk determination under a drug management program did not conduct the redetermination.

If the denial of coverage was based on a lack of medical necessity, CMS will review to ensure that the redetermination was made by a physician with expertise in the field of medicine that was appropriate for the services at issue.

Next slide, slide 16.

The next CDAG element we'll be discussing is Classification of Requests. CMS will select up to ten dismissed cases from Tables 1 through 4 and review case file documentation to determine if the request was appropriately dismissed or whether it should have been treated as a coverage request or grievance. Dismissed sample selections will be provided to the sponsor approximately one hour prior to the scheduled webinar.

Slide 17.

CMS will also select 20 grievance sample cases from Table 6. CMS will sample both verbal and written grievances and target samples that appear to relate to quality of care, involve multiple issues, and do not appear in the coverage determination and redetermination universes and appear to be misclassified requests. CMS will review sample case file documentation in accordance with the applicable regulations to determine if proper notification was provided.

For example, if the grievance was submitted in writing, CMS will review to determine if it was responded to in writing. If the grievance was submitted orally, CMS will review to determine if it was responded to either orally or in writing. If the grievance was submitted orally and the enrollee requested a written response, CMS will review to determine if it was responded to in writing.

If the grievance relates to quality of care, regardless of how the grievance is filed CMS will review to determine if the grievance was responded to in writing. CMS will also ensure the response includes a description of the enrollee's right to file a written complaint with the QIO. If the sponsor extended the grievance deadline, CMS will review the case file for documentation stating how the delay is in the interest of the enrollee and for written notification to the enrollee of the reasons for the delay. If the enrollee identified a representative, CMS will review the case file to determine if notification was sent to the enrollee's representative.

Grievance sample selections will be provided to the sponsor approximately one hour prior to the scheduled webinar.

Slide 18.

The fourth CDAG audit element is Administration of Drug Management Program. For this element, CMS will select up to 15 Drug Management program administration cases from Table 7. For each case sample, CMS will review case file documentation for proper initial written notice to the enrollee for at-risk determinations. CMS will also review case file documentation to ensure the sponsor made reasonable efforts to provide

the enrollee's prescriber of frequently-abused drugs with a copy of the notice. If the enrollee identified a representative, CMS will review case file documentation to determine if notification was sent to the enrollee's representative. DMP sample selections will be provided to the sponsor approximately one hour prior to the scheduled webinar.

Slide 19.

For cases wherein the sponsor determined that the enrollee is an at-risk beneficiary, CMS will review case file documentation to determine whether the enrollee submitted preferences for prescribers or pharmacies and will review for proper written second notice to the enrollee. CMS will also review to ensure the sponsor made reasonable efforts to provide the enrollee's prescriber of frequently-abused drugs with a copy of the notice.

For cases wherein the sponsor determined the enrollee is not an at-risk beneficiary, CMS will review the case file documentation for proper alternated second written notice to the enrollee and will also review to ensure the sponsor made reasonable efforts to provide the enrollee's prescribers of frequently-abused drugs with a copy of the notice.

Slide 20.

There are three timeliness measures specific to DMP at-risk determinations:

Compliance Standard 1.6 – Timeliness is conducted at the universe level for at-risk determination, second notice, or alternate second notice.

Compliance Standard 1.11 – Timeliness conducted at the universe level or on standard at-risk determination decisions overturned by the IRE, ALJ, or MAC.

Compliance Standard 1.14 – Timeliness conducted at the universe level on expedited at-risk determination decisions that were overturned by the IRE, ALJ, or MACs.

Timeliness is also conducted on at-risk redeterminations.

Slide 21.

The measure related to classification of requests and dismissed cases will include a review of case file documentation to determine if the request was appropriately dismissed. This will be measured by CMS in accordance with the applicable regulations. For example, for coverage determination requests, CMS would look to the regulation 42 CFR, § 423.568(i), and § 423.568(j), to determine if the request was appropriately dismissed and will also review the content of the dismissal notice per the regulatory requirements.

Slide 22.

For the Administration of Drug Management program audit element, CMS will be reviewing case file documentation for proper initial written notice to the enrollee, proper second written notice to the enrollee, and proper alternate second written notice to the enrollee as applicable. CMS will review these notices in accordance with the applicable regulations, 42 CFR, § 423.153(f).

Slide 23.

The second half of today's CDAG session will focus on the CDAG Program Audit Data Request. This part of the protocol is currently shown on the screen and starts on page 15.

Sponsors must submit each universe comprehensive of all contracts and plan benefit packages identified in the audit engagement letter. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts. Characters are required in all field unless otherwise specified, and data must be limited to the requests specified in each record layout.

An example of when a blank entry is acceptable for CDAG is the NDC field. Sponsors may populate the NDC field as blank if a blank field is submitted by the pharmacy or delegate. 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.

If the sponsor does not have any cases responsive to a particular universe request, the sponsor must upload an Excel spreadsheet to the Health Plan Management System, HPMS, (audio break) during the requested audit period.

Slide 24.

The CDAG Scope of Universe Request for all tables is determined by the sponsor's PDP and MAPD enrollment:

For enrollment of less than 50,000, the sponsor will submit the 12-week period preceding and including the date of the audit engagement letter.

For 50,000 but less than 250,000 enrollees, the sponsor will submit the eight-week period preceding and including the date of the audit engagement letter.

For more than 250,000 but less than 500,000 enrollees, the sponsor will submit the four-week period preceding and including the audit engagement letter date.

For enrollment of more than 500,000, the sponsor will submit the two-week period preceding and including the date of the engagement letter.

CMS reserves the right to expand the review period to ensure sufficient universe size.

Slide 25.

We have another polling question here: "How many CDAG record layouts does the final 2022 protocol include? Our options are 5, 6, or 7.

[Pause for responses]

Okay, it looks like we have about 90% who said "7," and that is the correct answer.

Slide 26.

As we just found out, CDAG includes seven universe requests. They are:

Universe Table 1: Standard and Expedited Coverage Determination

Universe Table 2: Standard and Expedited Coverage Determination Exception Requests

Universe Table 3: Payment Coverage Determinations and Redeterminations

Universe Table 4: Standard and Expedited Redeterminations

Universe Table 5: Part D Effectuations of Overturned Decisions by the IRE, ALJ, or MAC

Universe Table 6: Part D Standard and Expedited Grievances

Universe Table 7: Comprehensive Addiction and Recovery Act At-Risk Determinations

Slide 27.

Instructions are included for each record layout to indicate how requests for multiple drugs made at the same time should be populated. There are also instructions to enter all fields for a single request in the same time zone. For example, if the sponsor has systems in Eastern Standard Time and Central Standard Time, all data in a single line item must be in the same time zone.

Universe inclusion is based on the date the determination was made by the sponsor. The column ID used to determine inclusion within the universe request period is noted within the record layout instructions. I'll review these briefly for each CDAG table:

For Tables 1 through 4, the date of the sponsor's determination must fall within the universe request period.

For Table 5, the date of the sponsor's receipt of the overturned decision, Column ID "J," must fall within the universe request period.

For Table 6, the date of the sponsor's notification, Column ID "P" or "R" must fall within the universe request period.

For Table 7, the date of the sponsor's determination, Column ID "I" must fall within the universe request period.

Part B requests must be included based on the way in which the request was processed. For example, if a sponsor processed the request as a coverage determination first and issued a Part D Denial Notice, then the case would be included in the CDAG CD universe. If a grievance concerning a Part B drug is processed under Part D, it would be included in the Grievance D universe. Similarly, for decisions overturned by the IRE, ALJ, or MACs, if the overturned decision was a Part D determination, it would be included in the EFSD universe.

The record layout instruction specified this by stating, for example, for Table 1 to include all coverage determinations the sponsor approved, denied, reopened approved, reopened denied, auto-forwarded to the IRE, or dismissed for Part D coverage during (audio break).

Moderator: It looks like Kellie is having a little trouble with her audio, but she's calling right back in. Right now, we are on slide 27; and we're just going to give Kellie just one moment to call back in.

Sorry, everyone. Kellie is having some audio trouble. So we're just going to give her another second. She's reconnecting her audio line.

Kellie Simons: Sorry, everyone, Kellie is back. I hope you can hear me okay. I lost connection. I'm sorry about that.

Moderator: There you are, Kellie, thank you. We're on slide 27.

Kellie Simons: Okay, perfect, let me backtrack just a tad in case got cut off.

So we've received questions if it's okay for sponsors to populate fields in the universe that are not required; for example, entering a time for a

standard request with the regulatory notification requirement in days. Sponsors have the option to enter a time in a field even if the time is not required per the field description. CMS has added this language into the CDAG protocol in the Universe Submission section:

We've received questions about this in context of the time of determination and time effectuated in system fields as well. If, for example, the field description states to enter "None" for dismissed cases for the Time of Determination field, sponsors may enter either a time if available or "None." Similarly, if the field description states to enter "None" for dismissed and standard cases, sponsors may enter a time for dismissed or standard cases if available; or they may enter, "None."

Slide 28.

Next, we'll discuss a couple of CDAG record layout exclusions. Sponsors must exclude from their CDAG universe submissions requests where a decision has not been issued while the sponsor awaits the appropriate representative documentation. Requests that have been dismissed for no AOR or equivalent written notice would be included in the applicable CDAG universe submissions, as indicated in the record layout instructions. Sponsors are not required to include requests that are pending a decision within any of their universe submissions.

Sponsors must also exclude requests from members whose coverage is not yet effective as of the date of the engagement letter.

Slide 29.

Next, we'll be reviewing technical specifications for CDAG field descriptions that apply to more than one CDAG record layout. Where noted within the field description, sponsors may enter "None" for dismissed requests. In earlier iterations, CMS offered the use of N/A, N/F, N/E, and None as field description options within multiple CDAG record layouts. However, we have listened to feedback and now permit sponsors to just enter "None."

CMS included a "Who Made the Request" field in Tables 1 through 4 and 6 and also updated the field description to allow for the ER option to apply to purported representatives as well.

We received a question regarding the "Who Made the Request" field for Table 3 asking what to enter if the prescriber made the request. Sponsors are to follow the field description and enter "P" for prescribing physician or other prescriber if they made the request.

Slide 30.

The Authorization or Claim Number field is the sponsor's associated authorization or claim number for the request. If a sponsor is unable to look up a case file in its system based on an authorization number, this field can be populated with the internal tracking or case number.

Slide 31.

CMS has aligned the CDAG NDC field description with the field description in the FA protocol. As previously mentioned, the NDC fields may be populated as blank when a blank field is submitted by a pharmacy or delegate.

We received a question asking if there was no NDC provided with the Request for Reimbursement whether the field should be left blank rather than populating with "N/A." There is no N/A option for this field description; so in this case, the NDC field may be left blank.

CMS, as Matt mentioned in the FA presentation, also aligned the CDAG NDC field description with FA to address multi-ingredient compound claims. For multi-ingredient compound claims, the field is to be populated with the "NDC," as would be submitted on a paid claim PDE.

To accommodate at-risk determinations, in Tables 4 and 5 CMS allows the NDC fields to be populated as submitted if the NDC is not applicable; for example, for at-risk redeterminations.

Slide 32.

The AOR/Equivalent Notice Receipt Date/Time field descriptions have been updated for simplicity and consistency purposes. We eliminated the "N/A" option. Sponsors may enter "None" for these fields when no AOR or equivalent written notice was received, when an AOR or equivalent written notice was not required, and for dismissed requests when applicable. These fields are to be populated per the record layout field descriptions with the date or time the AOR form or equivalent written notice was received by the sponsor, regardless of whether the representative documentation was received prior to the date of the request or grievance.

These field descriptions were also updated to account for instances where a case was dismissed for reasons other than a lack of AOR form or equivalent written notice. For standard cases with timeliness requirement in days, CMS will accept the time populated for the AOR/Equivalent Notice Receipt Time field since CMS has not utilized the time field for these calculations.

Slide 33.

For the Time the Request was Upgraded to Expedited field, sponsors may enter "None" under the following circumstances: if the initial request was made under the expedited time frames, if the sponsor chose not to expedite the request, or if the request was received and processed under the standard time frame.

Slide 34.

If the sponsor is not able to successfully provide verbal notice, the Date Oral Notification Provided to Enrollee and Time Oral Notification to Enrollee fields would be populated with "None."

Slide 35.

For program audit purposes, CMS assesses notification timeliness according to the regulations located in 42 CFR, part 423, subpart "m." For the Date Written Notification Provided to Enrollee field, CMS would accept the notification date based on Section 10.5.3 of the Parts C and D

Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance so long as permitted by the guidance. Later in this presentation, we'll refer to this guidance as the "Combined Manual."

For dismissed cases, the Date Written Notification Provided to Enrollee field would be populated with the date the written notification of dismissal was provided to the enrollee. Sponsors may enter "None" if no written notification was provided.

Slide 36.

For the UM Exception Type field, sponsors may enter "None" if the request was not a formulary UM exception or safety edit exception. Examples of this would include a tiering exception, non-formulary exception, and hospice exception. Sponsors would enter "PA" if the case was a request to accept Prior Authorization Utilization Management criteria. For a request with multiple exception types, populate this field based on the approval or denial reasons.

Slide 37.

For the formulary UM Type field, sponsors may enter "None" if the enrollee did not satisfy or was not attempting to satisfy prior authorization and/or step therapy criteria. If the enrollee was attempting to satisfy formulary UM criteria, enter "PA" for prior authorization; "ST" for step therapy; or "SE" for safety edits. If multiple formulary UM criteria apply, sponsors would enter the criteria applicable based on the approval or denial reasons.

In general, sponsors are to include safety edit requests within Table 2 CDER. However, for Table 1 CD, sponsors may enter "FE" for the formulary UM Type field for cases where the safety edit is for an enrollee opioid naïve but wants to show evidence that he or she meets the criteria as not opioid naïve.

We have been asked if the permissible entries for this field description are associated with specific request determinations or dispositions. The formulary UM type field is not dependent on the request determination

type, and sponsors must adhere to the field description and enter data for this field as specified.

Slide 38.

Partially favorable decisions are populated as "Denied Request Determinations" in CDAG universes. For these types of cases, sponsors would include data regarding the approval and effectuation of the favorable portion of a decision; for example, for the following fields: expiration date of the approval, date effectuated in the system, and time effectuated in the system.

Slide 39.

If no authorization is required, sponsors would enter "None" for the Date and Time Effectuated in the System fields.

Slide 40.

If a request was not forwarded to the IRE, sponsors would enter "None" for the Date and Time Forwarded to the IRE fields.

Slide 41.

For the Request Determination field, any request denied in whole or in part would be populated as denied. This means, as previously mentioned, that partially approved cases would be populated as denied.

We were asked whether it's appropriate to dismiss requests for drugs on the formulary with no restrictions. This is a policy question related to request classification and should be addressed to the appropriate CMS Policy mailbox. For program audit purposes, if the request was processed as a dismissal, it would be included in the applicable universes that way.

Slide 42.

The date of the sponsor's determination must fall within the universe request period. For untimely coverage determinations or redeterminations that are auto-forwarded to the IRE, this would be a request determination

of IRE auto-forward. The sponsor may enter the date and time it closed the case file if untimely and begin preparing the case file for the IRE or when the file was sent to the IRE in the Date of Determination and Time of Determination fields.

Slide 43.

Next, we'll focus on a couple of points specific to the Table 1 CD record layout.

For requests for a single drug involving multiple UM criteria – for example, step therapy and prior authorization – these would be entered as a single line item in the universe. If the sponsor sends separate distinct letters addressing each of the UM criteria individually, they would be populated as separate line items in the universe.

Slide 44.

For Table 2 CDER, if a request for multiple drugs is made at the same time, each drug would be entered in a separate row within the universe. Requests for a single drug involving multiple UM criteria and exception types – for example, tiering exceptions, prior authorization exceptions, quantity limit exceptions, or step therapy exceptions -- must be entered as a single line item in universe Table 2 only. If the sponsor sends separate distinct letters addressing each of the UM criteria and exception types individually, they would be populated as separate line items in the universe.

A couple of additional points for Table 2 – if a request has multiple exception types and includes a tiering exception, the case would be reported as a tiering exception for program audit purposes within the universe. Also, sponsors are to include safety edit requests within the CDER universe.

Slide 45.

All payment coverage determinations and payment redetermination requests are to be reported in Universe Table 3 only. If, for example, a

payment covers determination date falls with the audit review period but the payment redetermination does not, only the original payment coverage determination would be included in the Payment D universe.

If a request for multiple drugs is made at the same time, sponsors must enter each drug in a separate row. Requests for a single drug must be entered as a single line item.

We received a question about how to populate the NDC Date of Determination and Date Effectuated in the System fields for Table 3 if some of the dates of service for the same drug are approved and some are denied. In this case, sponsors would enter the NDC as submitted. The date of determination in this example would be the date of the denied determination, and the date effectuated in the system would be the date the approved decision was effectuated in the system. "None" would be entered if the payment request was not approved.

If the payment request also requires a review because it had a utilization management edit or was a non-formulary drug, the clinical review aspect of the case is not to be reported within any other CDAG tables. It would be reported in Table 3 only. This is regardless of whether the case was processed as separate requests or treated holistically. This is to ensure that requests are not counted as duplicates while CMS assesses timeliness at the universe level.

We were asked whether certain fields in Table 3 that are clinical in nature could be populated with "N/A" for reimbursement requests -- such as exception type, UM exception type, date prescriber supporting statement received, and expiration date of the approval. As mentioned, if the payment request also requires a review because it had a utilization management edit or was a non-formulary drug, the clinical review aspect of the case is to be reported in the Table 3 universe only; and the information for these fields mentioned must be populated according to the field descriptions.

Slide 46.

Next, we'll be focusing on some fields found in Table 3.

For the Date Prescriber Supporting Statement Received field, populate the field based on the type of request. For Payment Coverage Determinations, sponsors would enter the date the prescriber's supporting statement was received for the payment coverage determination. For Payment Redeterminations, the sponsor would enter the date the prescriber's supporting statement was received for the payment redetermination.

Slide 47.

We also received a question regarding the difference between the Date Effectuated in the System and Date Reimbursement Provided fields in Table 3. For the Date Effectuated in the System field, sponsors are to enter the date the approved payment decision was effectuated in the system.

Slide 48.

For the Date Reimbursement Provided field, sponsors are to enter the date the check or reimbursement was provided to the enrollee. Sponsors would enter "NRD" if this request was approved but no reimbursement was due to the enrollee. "P" would be entered in the universe if the payment had not yet been issued at the time of universe submission. For example, "NP" would be used for a case where the request was approved and reimbursement was due to the enrollee, but the reimbursement had not yet been issued to the enrollee at the time of the universe submission to CMS.

Slide 49.

For CDAG Table 4: RD, cases with multiple restrictions that came in as a single redetermination request would be listed as a single line item in the submitted universe. However, if the sponsor sends separate distinct letters addressing each of the restrictions individually, they would be populated as separate line items in the universe.

If an at-risk redetermination with multiple restrictions came in as separate redetermination requests, these would be listed as separate line items in the submitted universe.

Slide 50.

Also for Table 4, requests with a single drug involving multiple UM criteria and exception types must be entered as a single line item. As mentioned previously, if the sponsors send separate distinct letters addressing each of the restrictions individually, they would be populated as separate line items in the universe.

If a request has multiple exception types and includes a tiering exception, enter the case in the universe as a tiering exception. At-risk determination appeals are to be included in Table 4. The date of the sponsor's redetermination/determination, Column ID X, determinations inclusion in the universe. Beginning in audit year 2022, CMS will test sponsors' compliance with auto-forwarding of upheld appeals of at-risk determinations to the IRE no later than 24 hours following the expiration of the adjudication time frame applicable to the plan level appeal.

Despite these regulations becoming effective in 2021, CMS delayed implementation of this requirement in the program audit process until the time period in which all sponsors are required to have a DMT.

Slide 51.

Next, we'll be reviewing some fields in Table 4.

For the Is This a Protected Class Drug, sponsors may enter "None" if this field does not apply for an at-risk determination. The same applies for the Drug Name, Strength, and Dosage field.

Slide 52.

For the Is This an Appeal of an At-Risk Determination field, sponsors are to enter whether their request was an appeal of an at-risk determination; for example, a request for a change in a pharmacy and/or prescriber limitation or a request for a change in an enrollee's at-risk determination

status. So long as permitted by the Combined Manual, sponsors may enter the date and time the sponsor received information establishing good cause for the Date and Time the Request was Received field where the request for an appeal was received after the 60-day time frame.

Slide 53.

For Exception Type field in Table 4, sponsors may enter "None" for at-risk redeterminations.

Slide 54.

The Was the Coverage Determination Request Denied for Lack of Medical Necessity field is populated based on the initial coverage determination denial for lack of medical necessity. For redetermination, this field will be populated with a response as to whether the coverage determination request was denied for lack of medical necessity.

Slide 55.

A couple of points regarding the expiration date of the Approval field in Table 4 – if it is an exception request, sponsors would enter the expiration date of the exception approval. If it is not an exception request or if the exception request was not approved, sponsors would enter "None". Sponsors may enter "None" for at-risk redetermination; for example, a pharmacy lock-in that resulted in the removal of a restriction authorization currently in place, a termination of the pharmacy lock-in.

Slide 56.

For the Was the Coverage Determination Request Denied for Lack of Medical Necessity field, sponsors would enter "None" for auto-forwarded cases.

Slide 57.

For standard redeterminations, sponsors may populate the Date Oral Notification Provided to Enrollee field with "None". Sponsors may choose to provide a date in the universe for the field if they'd like. In this case,

CMS would look to the applicable regulation to determine if oral notification applies to the timeliness calculation. If it is not applicable, the date in the universe would not be used for timeliness calculation purposes unless supported by guidance.

Slide 58.

For the Table 4 AOR/Equivalent Notice Receipt Time field, sponsors may enter "None" for standard cases or may populate this field for standard cases if desired.

Slide 59.

If a case was auto-forwarded to the IRE and the sponsor did not send written notification of a decision to the enrollee, the Date and Time Written Notification Provided to Enrollee field would be populated as "None".

Slide 60.

Turning now to Universe Table 5, this table includes all coverage determinations, redeterminations, or at-risk determinations fully or partially overturned by the IRE, ALJ, or MACs requiring effectuation as pre-benefit, post-service, or an at-risk determination. The decision must be received from the IRE, ALJ, or MACs during the universe request period. Withdrawn cases which do not require effectuation are to be excluded. This universe could include untimely coverage determinations that were forwarded to the IRE by the sponsor or pharmacy benefit manager.

For Table 5, sponsors are to exclude any cases that were reopened by the sponsor or its first-tier, downstream, or related entities.

Slide 61.

Next, we'll be discussing some fields found in Table 5.

For the Type of Request Reversed by Review Entity field, the priority of the case – standard or expedited – is determined by how the case was

received from the review entity per § 423.636(b) and § 423.638(b). If an overturn involves both reimbursement and coverage for the same drug going forward, sponsors would report the appeal as a "Standard Request for Benefits" in this field.

Slide 62.

For the Date/Time the Overturn Decision was Effectuated in the System field, sponsors may enter "None" if the overturn decision was effectuated or if no effectuation was required.

We received a question regarding the question between the Date the Overturn Decision Was Effectuated in the System and Date Reimbursement Provided fields in Table 5. For the Date the Overturn Decision Was Effectuated in the System field, sponsors are to enter the date the benefit was provided, payment was authorized, or the change to the at-risk determination was implemented. For the Date Reimbursement Provided field, sponsors are to enter the date the check or reimbursement was provided to the enrollee.

Slide 63.

For the Date Reimbursement Provided field, sponsors may enter "None" for pre-service requests.

Slide 64.

If the Drug Name, Strength, and Dosage Form is not applicable for Table 5, sponsors may enter "None" for this field.

Slide 65.

Similarly, for the Is This a Protected Class Drug field, sponsors may enter "None" if it is not applicable; for example, an at-risk appeal where no specific drug is under appeal.

Slide 66.

Now we're turning to Universe Table 6, Part D Grievances. For Universe Table 6, the request is included if either the Date oral notification provided to enrollee or the Date written notification provided to the enrollee falls within the universe request period. Grievances with multiple issues must be entered as a single line item in the universe unless the sponsor is treating the issues individually and issues separate notifications. In this case, the request would be entered as multiple line items in the universe. Withdrawn and dismissed grievances are excluded from the grievance universe.

Slide 67.

For maximum flexibility, sponsors may enter the category of the grievance as assigned by the sponsor based on their internal labeling system for the Category of the Issue field. If there are multiple categories for the grievance, the sponsor may enter all of the categories assigned based on the sponsor's internal labeling system. Although the protocol indicates submissions that do not strictly adhere to the record layout specifications will be rejected, CMS can allow greater than 50 characters in this field if needed.

Slide 68.

For the Grievance Description field, we were asked if the number of characters may exceed the 1,800-character limit. Similarly, although the protocol indicates submissions that do not strictly adhere to the specifications will be rejected, CMS can allow greater than 1,800 characters in this field if needed.

Slide 69.

For standard cases or if no oral notification was provided to the enrollee, sponsors may enter "None" for the Time Oral Notification Provided to Enrollee field.

Slide 70.

This is our final polling question for today's CDAG session. Our question is: "CDAG Table 7 includes all enrollees reviewed under a Drug Management Program (DMP)." Yes or No?

[Pause for responses]

At first it looked like we had more "No's," and now it looks like 89% say, "Yes," Table 7 does include all enrollees revised under a DMP. We're going to hold on the answer because it's going to be addressed in the next couple of slides.

Slide 71.

CDAG Table 7 is the Comprehensive Addiction and Recovery Act at-risk determination record layout. Section 2004 of the SUPPORT Act requires that all Part D sponsors have established DMPs no later than January 1, 2022. CMS finalized the proposal to make DMPs mandatory at 42 CFR, § 423.153(f). For program audits, CMS will begin review of this requirement effective January 1, 2022.

Universe Table 7 includes all at-risk and not-at-risk determinations that were made by the sponsor pursuant to § 423.153(f) within the universe request period. Each at-risk determination must be listed as its own line item in the submitted universe.

So back to our polling question, Table 7 does not include all enrollees reviewed under a DMP. Sponsors should consider information, such as whether the beneficiary went through case management, whether the beneficiary is exempt, and whether the sponsors made a decision of at-risk or not-at-risk pursuant to § 423.153(f) in order to determine whether the case would be included in Universe Table 7.

Sponsors may use OMS response forms and caseloads to identify beneficiaries for inclusion in Table 7. However, for CMS Program Audit, Table 7 includes all at-risk and not-at-risk determinations made by the sponsors pursuant to § 423.153(f).

Slide 72.

Next, we'll discuss a couple of scenarios and when to include or exclude a case from Table 7. If an enrollee goes through case management, is not exempt, and decision of at-risk or not-at-risk is rendered pursuant to § 423.153(f), the case would be included. If an enrollee is still going through case management and a decision of at-risk or not-at-risk has not yet been rendered by the sponsor, the case would be excluded. If the sponsor determines that a potentially at-risk beneficiary is exempt through the case management process and did not make an at-risk determination pursuant to § 423.153(f) during the universe request period implementing a coverage limitation, then the case would be excluded.

Universe Table 7 should not be limited to only those beneficiary records associated with the MARx TC 90 POS Drug Edit records because it's probability that an at-risk determination could be made and an entry could not have been made in MARx.

If an enrollee appeals after 60 days from receiving a second notice and the sponsor attempts to resolve the issue via case management, this second review by case management conducted after issuance of the second notice is excluded from the Table 7 universe.

We received a question asking for the definition of an at-risk determination. This would be an example of the DMP policy question that should be sent to the appropriate CMS Policy mailbox.

Slide 73.

Next, we'll be discussing some fields found in Table 7.

For the Request Determination field, if a not-at-risk determination was made and there is no type of at-risk limitation being imposed upon the beneficiary, the reason the coverage limitation was unnecessary does not need to be entered in the universe.

Slide 74.

For the Drug Name, Strength, and Dosage Form field in Table 7, enter the drug name, strength, and dosage form applicable to the specific

limitation the sponsor intends to place on the beneficiary's access to coverage for frequently-abused drugs under the programs.

Enter "Multiple" if the intended limitation applies to more than one drug; for example, a beneficiary level edit blocking all opioid access.

Enter "None" if the intended limitation is not related to a specific drug; for example, a pharmacy or prescriber lock-in.

Slide 75.

For the Confirmation of Agreement to Place Limitation Upon Enrollee field, enter "YPH" if there's a pharmacy advance agreement.

Enter "YPR" if the provider confirmed the limitation.

If both the pharmacy and provider confirmed, enter "YBO" for yes from both.

Slide 76.

The types of at-risk limitations that may be imposed upon an enrollee include Point of Sale Edit, Pharmacy Lock-In and Provider Lock-In. These are the limitations on access to coverage for frequently-abused drugs described in § 423.153(f)(3). Populate the Type of At-risk Limitation field with this information. If there are multiple limitations, enter all that apply.

Slide 77.

For the Date the Initial Written Notification of Potential At-Risk Status was Provided to Enrollee and Date Second Written Notification of At-Risk Determination Provided to Enrollee fields, for Program Audit purposes CMS would accept the notification date based on Section 10.5.3 of the Combined Manual so long as permitted by the guidance.

Policy questions pertaining to the Combined Manual should be directed to the appropriate CMS Policy mailbox.

Slide 78.

The Date the At-Risk Determination Was Made field is to be populated with the date the at-risk determination was made; for example, the date the limitation was entered by the sponsor or the date the clinical determination was made to restrict or not to restrict the member. This is not the date the sponsor sent the initial or subsequent notices to the beneficiary. There are separate fields in Table 7 for these dates.

This field determines the inclusion within Universe Table 7, the Date of the Sponsor's Determination.

Slide 79.

Next, we'll discuss CDAG Impact Analysis Submissions. When non-compliance with contract requirements is identified on audit, sponsors must submit each requested impact analysis, comprehensive of all contract and plan benefit packages identified in the audit engagement letter using one of the CDAG universe layouts as specified by CMS. This information collected as a result of identifying deficiencies will mirror the existing CDAG universe record layouts.

Slide 80.

This concludes our Part D Coverage, Determinations, Appeals, and Grievances section of the Final MAPD Program Audit Protocol training. We aimed to address all of the CDAG topics that were submitted in advance of today's presentation.

If you have any additional program audit process related questions following today's presentation, please send to the e-mail box listed on the slide here. As noted previously, policy questions should be directed to the appropriate CMS Policy mailbox.

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

Moderator: Thank you, Kellie.

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, goodbye.