PUBLIC SUBMISSION

As of: 8/11/16 12:11 PM
Received: June 30, 2016
Status: Draft
Tracking No. 1k0-8qhu-v6lj
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0002
MI

Submitter Information

Name: Anonymous Anonymous
Address:
MI, 48226

General Comment

General:
1. Sponsor disclosed/self-identified issues: We do not believe this process is fair. This process is reliant upon all audited plans demonstrating (equally) a good faith effort to be transparent with CMS by releasing self-disclosed and self-identified issues to CMS. This process has the potential to punish plans that are transparent and honest with CMS and reward those that are not. Coupled with CMS' policy that "Issues that are reported as uncorrected will automatically be cited as conditions in the CMS audit report. Issues reported as corrected after the date of the audit start notice will be treated as uncorrected issues", there is a disincentive for a plan to be transparent. For plans that take the good faith path by being transparent, their scores may be higher. For plans that may not act in good faith, their scores will be lower. The process punishes honest plans. There are no controls in place to verify whether all plans have provided all self-identified issues to CMS. The process relies too much on each plan's judgment and good faith, and this has the potential of having an inconsistent outcome across the industry.
CPE:
1. Tables 3 & 4: CMS only requires the plans to provide all audits and monitoring activities that occurred, rather than all audits and monitoring activities against a CMS-defined list (as was the case in 2014 and prior). This current method places importance on the outcome of the audits that the plans actually conducted, rather than the volume and scope. This process dis-incentivizes plans from going too many audits as this may compromise on their tracer outcome.

Example: During the audit period, Plan A only conducted audits in the areas of CDAG, ODAG,

FA and CPE. Because its scope is limited, Plan A was able to do these areas very well and passed tracer. During the same audit period, Plan B audited Enrollment, Provider Network, Sales & Marketing, Premium Billing and BAE in addition to CDAG, ODAG, FA and CPE.

If one of the issues selected for Plan B's tracer did not meet all tracer requirements, this will be a finding. Plan A, on the other hand, only audited 4 areas and can invest all its resources into doing those areas very well, but leaving other important audit areas untouched (such as Enrollment and Provider Network). The process punishes Plan B for doing too much and rewards Plan A for doing just enough to pass.

We believe a more equitable process is to assess all plans against a set of CMS-defined list of audits and monitoring.

Example: Plans should provide to CMS a list of audits and monitoring in the areas of:

CDAG
ODAG
FA
CPE
Enrollment
Provider Network
Sales & Marketing
Premium Billing
Call Center
Etc

Plans must therefore demonstrate adequate auditing and monitoring over these areas (above and beyond the tracer test). If Plan A only audited CDAG, ODAG, FA and CPE, yet did not audit all the other important areas, Plan A should not be rewarded for passing its tracers in these limited areas while Plan B is punished for trying to do too much and possible missing a tracer. In the end, Plan B's wide scope may be more effective in resolving more issues than Plan A's approach, yet the audit outcome may not reflect this.

PUBLIC SUBMISSION

As of: 8/11/16 12:15 PM
Received: July 11, 2016
Status: Draft
Tracking No. 1k0-8qpd-myhe
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0003
CA

Submitter Information

Name: Colleen Matoon
Address:
San Diego, CA, 92020
Email: colleen.matoon@medimpact.com
Organization: MedImpact

General Comment

1. We are seeking clarification related to dates and time periods for claims included in the FA audit universes. The fill date of a prescription is the date that the pharmacy filled the prescription and not necessarily the date the prescription was processed. For example, a claim may have a fill date of 1/29/16 (the date the pharmacy filled the prescription) and a process date of 2/7/16 (the date the claim was submitted and processed). There is conflicting language in the program audit protocols that make it difficult to determine if the universes should include claims filled within the audit period or claims processed within the audit period. The protocols include the following:
Sponsors will provide universes of all rejected claims and prescription drug event (PDE) data (paid claims) with dates of service that fall within the related review periods.
all rejected claims for all contracts and PBPs in your organization that were received during the review period
The first bullet describes pulling claims by fill date (date of service) while the second bullet implies pulling claims based on processed date (date received).

To further complicate this, the fields "Date of Service" and "Date of Rejection" are described in a fashion that would render them identical in all cases. "Date of Service" is defined as the date a fill for a rejected claim was attempted. If attempted means submitted by the pharmacy, the date of rejection will always be the same as the date of service. The industry standard for date of

service is not the date that the claim was attempted (submitted), but rather the date that the pharmacy filled the prescription (fill date).

Questions
a. Should claims be included in the universes based on the date they were filled (fill date) or the date they were received and processed?
b. Is "Date of Service" in the universe layout representative of the date a claim was filled (fill date) or the date a claim was processed?
c. If the answer to question two is fill date, what is meant by, "the date a fill for a rejected claim was attempted"? Does 'attempt' mean filled by a pharmacy?
d. If the answer to question two is the date the claim was processed, what is the purpose of including "Date of Rejection", as this would be the same date?

2. The field length for "Request Disposition" was changed to 20 characters from 16 characters in most of the layouts, but remains 16 characters in ERD, ECDER and DMRRD. Was this an oversight?

3. Patient Residence has been removed from the SRD universe for 2017. Was this intentional?

4. In the DMRCD and DMRRD layouts, there was a field name change from "Date reimbursement mailed" to "Date reimbursement provided", but in the DMRRE layout, it is still labeled "Date reimbursement mailed". Was this an oversight?

5. The field length for "How was the Grievance/ Complaint Received" changed from 40 characters to 6 characters in the SGD layout, but remains 40 characters in the EGD layout. Was this intentional?

6. The field size for Issue Description in the SGD and EGD layouts is inconsistent with the other universes (1500 vs 2000). Was this intentional?

7. Formulary UM Exception Type was added to the Exception Coverage Determination Universes but is not included in the Redetermination Universes. Was this intentional?

PUBLIC SUBMISSION

As of: 8/11/16 12:16 PM
Received: July 20, 2016
Status: Draft
Tracking No. 1k0-8qv2-l9xh
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0004
PA

Submitter Information

Name: Shawn Adams
Address:
Philadelphia, PA, 19107
Email: sadams@hpplans.com

General Comment

Agency collection number: CMS-10191
Document number: 2016-13917
Document citation: 81 FR 38187.

The 2017 CMS SNP MOC draft audit protocol includes the following question "Did the sponsor conduct the initial HRA either 90 days before or after the enrollment effective date?" I'm unable to locate anything indicating regulations have been revised to now reflect "90 days before or after the enrollment effective date".

Revisions to the Medicare Managed Care Manual - Quality Assurance chapter do not appear to have been made to indicate the HRA may occur 90 days before or after the effective date. The manual indicates "The organization must complete the HRAT for each beneficiary, for initial assessment, and must complete an HRAT annually thereafter. At minimum, the organization must conduct initial assessment within 90 days of enrollment and must conduct annual reassessment within one year of the initial assessment."

The CFR reflects the following:

422.112(b)(4)(i)
"The MA organization makes a "best-effort" attempt to conduct an initial assessment of each

enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment"

Per the 2016 Final Call Letter, "SNPs are required to perform a comprehensive initial HRA that includes assessment of each enrollee's physical, psychosocial, and functional needs within the first 90 days of enrollment and conduct reassessments annually thereafter".

Furthermore, in the 2016 Final Call Letter (page 90 of 190), CMS addressed concerns raised that related to the SNP Care Management measure. In that Call Letter, CMS indicated "During 2014 CMS issued a clarification to this measure to make it explicit that the initial Health Risk Assessment (HRA) must occur on or after the date of the member's initial enrollment in the plan. That is, the initial HRA must occur when members are already eligible to receive benefits. The reasoning behind this requirement is that in its absence, plans could base enrollment decisions on the results of the HRA. This is not the purpose of the HRA."

I haven't come across anything other than the protocol that indicates the HRA may be conducted 90 days before the enrollment effective date. If possible, please provide clarification as to whether or not regulations will be codified to include an HRA may be accepted 90 days before the enrollment effective date.

Compliance Update

TO:	WILLIAM N. PARHAM, III DIRECTOR, PAPERWORK REDUCTION STAFF, OFFICE OF STRATEGIC OPERATIONS AND REGULATORY AFFAIRS
FROM:	ABARCA HEALTH'S COMPLIANCE
RE:	COMMENTS TO THE MEDICARE PARTS C AND D PROGRAM AUDIT PROTOCOLS AND DATA REQUESTS
DATE:	July 22, 2016
DOCUMENT ID:	CMS-10191

On Monday, June 13, 2016, OMB posted the ***2017 draft Program Audit Protocols*** for public comment in the *Federal Register*, as part of the Paperwork Reduction Act approval process. The *Medicare Parts C and D Oversight and Enforcement Group* highly encourages the industry to closely review the draft protocols and provide any comments and feedback on the documents and the information provided in the burden estimate.

The comment period closes August 12, 2016. The Agency collection number is CMS-10191, the document number is 2016-13917 and document citation is 81 FR 38187. Comments can be submitted using the following link: https://www.regulations.gov/document?D=CMS-2016-0097-0001

Below please find **abarca health's** comments to the proposed regulation. We hope this document is helpful in providing further insight and ensuring you are aware of these regulatory changes which may impact your business.

Table of Contents

General Comments to Supporting Statement Part A

1. Use of Information Technology:

   CMS understand that sponsoring organizations are able to produce approximately 70% of requested information from their internal systems. Based on the new protocols and the additional data requirements of existing protocols, we believed that the 70% assessment is not consistent with the audit process.

   For example, the following tasks for the Compliance Program Effectiveness audit are not system generated:
   - Attachment I-A Medicare Advantage and Prescription Drug Compliance Program Effectiveness Self-Assessment Questionnaire (SA-Q) includes 78 questions.
   - Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Compliance Officer Questionnaire (CO-Q) includes 47 questions.
   - Attachment I-C Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Audit Organizational Structure and Governance PPT Template includes at least 13 slides.
   - Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Sponsor's Accountability for and Oversight of First –Tier, Downstream and Related Entities Questionnaire (FDR-Q) includes 32 questions.
   - Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q) includes 51 questions.
   - Tracer Summaries includes a sample of 6 cases from the CPE universes.

   We suggest that CMS reevaluate the information technology estimates to be more representative of the actual process and the volume of requested information.

2. Duplication of Efforts:

   CMS understand that "this information collection does not duplicate any other effort and the information cannot be obtained from any other source." However, there is overlapping between the Formulary and Benefit Administration protocol review of Transition Fill requirements and the Part D Transition Monitoring Program (TMPA).

   We suggest that CMS eliminate duplication of efforts. Due to the importance of compliance with transition fills requirements, we suggest that the TMPA as an ongoing process is a best alternative than the FA audit.

3. Burden Estimates (Hours &Wages):

   CMS estimate a total of eight (8) positions for the staff needed during the audit process. The burden estimates are based on the following staff composition: program director (1), compliance officer (1), management analyst (1), quality assurance specialist (1), computers & information systems manager (1), administrative assistants (2), and claim analyst (1).

We suggest that CMS reevaluate the burden estimates based on the complexities of the audit process and significance of the outcomes for Sponsors. For Sponsors, the audit involves more that collecting data and uploading cases. The Medicare Parts C and D Program Audit is a resource intensive process that requires the participation of delegated entities, health professionals, coordination of several teams, and most important is an ongoing process.

Based on our experience as a PBM, the additional specialized staff needed for the CDAG, FA and MTM audits is as follows: pharmacists (8), software engineers (2), business specialist (2), business intelligence analyst (2), clinical specialists (6), compliance auditors (2), compliance specialist (1), project manager (1), infrastructure and communication specialists (2), and customer service manager (1).

4. Audit Protocols Revisions:

   CMS should provide sponsors a mark-up version of the protocols as is done with the Prescription Drug Manuals chapters so that sponsor can more easily identify changes required. This would eliminate some of the burdens of complying with the new requirements every year.

   CMS should consider reviewing data layouts with less frequency. The operational burden to set up data queries and test that universes conform to the layouts is very high, especially if CMS modifies layouts every year.

5. Routine Audits:

   CMS increased the estimate of total burden hours from 121 to 341 to more accurately reflect the entirety of the audit process. However, we believe that the new estimate is understated. In light of the seriousness of enforcement actions for noncompliance, we suggest that CMS reevaluate the Calculation of Total Audit Hours & Approximate Cost, to be more thoughtful of the Sponsor experience and participation of delegated entities. At a minimum, we suggest multiplying the estimate burden of hours per the number of delegated entities for the Sponsor. For example, the CDAG, FA, CPE and MTM audits requires active participation from the PBM, for a total burden of 682 hours. Specifically, the new protocols requirements include a minimum of 27 data universes, attachments, impact analysis documentation, and extensive questionnaires.

   In addition, depending on the severity of the conditions and enforcement actions, we suggest that CMS increase the hours spent on validation and audit close out activities.

Audit Purpose and General Guidelines

1. Sponsor Disclosed and Self-Identified Issues:

   Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from the starting date of each universe period through the date of the audit start notice, which CMS may find in your data universes. Within 5 business days after receipt of the

engagement letter, sponsors must provide a description of each issue as well as the remediation status using the Pre-Audit Issue Summary template (Attachment VIII).

CMS to clarify whether self-identified issues include issues the Sponsor identifies during the audit universe gathering process and reported to CMS within 5 days of the audit start date.

Formulary and Benefit Administration (FA)

2. Responding to Universe Requests:

   CMS understands that 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 they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

   We request that CMS clarify the methodology for citing the IDS condition relative to the number of untested elements and the classification by categories of type cases.

3. Sample Selection for Audit Elements:

   The current protocol explains the targeted sample methodology and sample size. In addition, CMS specifies the applicable compliance standard or criteria for evaluation of cases.

   We request that CMS further clarify the methodology for sample selection as a useful tool for Sponsors internal auditing and monitoring process.

4. Applicable Compliance Standard:

   CMS may review factors not specifically addressed in the questions guidance if it is determined that there are other related FA requirements not being met.

   We request that CMS clarify what other factors may be reviewed. The information may be used to enhance Sponsors internal auditing and monitoring process.

5. Sample Case Results:

   CMS understands that cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

   We request that CMS clarify the scoring methodology and provide examples of scenarios with a single condition or multiple conditions of non-compliance.

6. Clarification of Record Layouts Fields:

   - NDC Field from Table 1 (RCFA), Table 2 (RCT-N) and Table 3 (RCT-P):
     - Description:
       - 11-Digit National Drug Code
       - When no NDC is available enter the applicable Uniform Product Code (UPC) or Health Related Item Code (HRI). Do not include any spaces, hyphens or other special characters.
     - We request that CMS clarify what is the correct value for claims submitted with invalid NDCs or invalid values.

Coverage Determinations, Appeals & Grievances (CDAG)

1. Responding to Universe Requests:

   CMS understand that 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 they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

   We request that CMS clarify the methodology for citing the IDS condition relative to the number of untested elements and the classification by categories of type cases.

2. Timeliness Tests:

   CMS will run tests on each universe to determine percentage of timely cases from a sponsor's approvals (favorable cases). For the notification timeliness tests, auditors will determine the percentage of timely cases from a full universe of approvals and denials. If more than one universe tests the same compliance standard, multiple timeliness tests results will be merged for one overall score.

   According to the CDAG protocol, these universes may be combined with at least one other universe to determine an overall compliance score. The merges include: SCD will be combined with SCDER for effectuation and notification, ECD will be combined with ECDER for effectuation and notification, DMRRD will be combined with SRD for notification, SIRE will be combined with EIRE, SCD, SCDER, DMRCD, ECD, ECDER, ERD, SRD, and DMRRD for an IRE auto-forward test; and DMRRE will be combined with SIAM for effectuation.

   We request that CMS further clarify the calculation of the overall compliance score and the effect of multiple timeliness test on the same universe.

3. Calculate Universe Timeliness:

   CMS has determined 3 timeliness thresholds that apply to every test in each universe. Sponsors that fall at or above the first threshold will generally not be cited a condition. Sponsors that fall within the second threshold will generally be cited for a corrective action required (CAR) for unmet timeliness requirements. Sponsors falling below the third threshold may be cited an immediate corrective action (ICAR) for unmet timeliness requirements.

   We request that CMS clarify the threshold calculation (methodology) and disclose the three (3) timeliness thresholds.

4. Sample Selection for Audit Elements:

   The current protocol explains the targeted sample methodology and sample size. In addition, CMS specifies the applicable compliance standard or criteria for evaluation of cases.

   We request that CMS further clarify the methodology for sample selection as a useful tool for Sponsors internal auditing and monitoring process.

5. Applicable Compliance Standard:

   CMS may review factors not specifically addressed in the questions guidance if it is determined that there are other related requirements not being met.

   We request that CMS clarify what other factors may be reviewed. The information may be used to enhance Sponsors internal auditing and monitoring process.

6. Sample Case Results:

   CMS understand that cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

   We request that CMS clarify the scoring methodology and provide examples of scenarios with a single condition or multiple conditions of non-compliance.

7. Clarification of Record Layouts Fields for Date/Time oral notification to enrollee and Date/Time written notification to enrollee:

   With respect to this requirement, CMS should clarify what it will be looking at for the following fields:
   - Table 1: Standard Coverage Determinations (SCD) Record Layout (V, W, X and Y)
   - Table 2: Standard Coverage Determination Exception Requests (SCDER) Record Layout (AA, AB, AC and AD)
   - Table 4: Expedited Coverage Determinations (ECD) Record Layout (X, Y, Z and AA)
   - Table 5: Expedited Coverage Determination Exception Requests (ECDER) Record Layout (AC, AD, AE and AF)

In general terms, the date/time of oral notification and date/time in which written notification was provided to enrollee, respectively. The line items are described as the date and time (or documented good faith attempt) provided to enrollee with respect to a coverage determination or exception request determination. Chapter 18 of the Prescription Drug Manual provides the requirements for a good faith attempt and sets forth that if the oral notification is not successful (once good faith attempt criteria is met) the written notification should be provided immediately. On the other hand, if an attempt is successful, Sponsors have three (3) calendar days to send the letter.

CMS has not clarified what immediately means. We suggest that CMS clarify this point and consider "immediately" to mean, for purposes of the mailing date, 24 hours from the date in which the first oral notification attempt was not successful, provided good faith attempt requirements have been met and documented per Chapter 18. We are suggesting this because Sponsors should be provided this window as an incentive to contact the beneficiary orally. Otherwise, Sponsors may not be incentivized to make attempts to contact beneficiaries (which can be a burdensome task) and instead, only send out letters to communicate determinations.

8. Clarification of Table 16 - Call Logs Part D (CLD) Review of Sample Case Documentation:

   In the Grievances and Misclassification of Requests audit element, CMS will review all sample cases file documentation to determine that grievances were appropriately classified and that the notification properly addressed the issue raised in the grievance.

   We request that CMS clarify if Sponsor and/or delegated entities are going to include calls received directly from the beneficiary/AOR, calls from providers or both.

   CMS will also review call logs to determine that incoming calls were appropriately classified as either coverage determinations or grievances, as appropriate. The sponsor will need access to the documents or audio files during the live webinar and may be requested to produce screenshots or transcripts.

   We request that CMS clarify if in the absence of the Call log audio files (recorded calls), alternative documentation or evidence may be provided to substantiate a call. What type of alternative documents may be accepted by CMS?

   Table 16 (CLD) includes all calls received by the organization (or another entity) that relate to the Medicare Part D line of business. Based on the definition, this universe may be very extensive and data collection of audio files for 100% of the calls will most likely involve operational changes.

   We request that CMS reconsider the impact of the audio files requirement and reevaluate the Calculation of Total Audit Hours & Approximate Costs estimates.

Medication Therapy Management (MTM)

1. Responding to Universe Requests:

   CMS understand that 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 they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

   We request that CMS clarify the methodology for citing the IDS condition relative to the number of untested elements and the classification by categories of type cases.

2. Sample Selection for Audit Elements:

   The current protocol explains the targeted sample methodology and sample size. In addition, CMS specifies the applicable compliance standard or criteria for evaluation of cases.

   We request that CMS further clarify the methodology for sample selection as a useful tool for Sponsors internal auditing and monitoring process.

3. Applicable Compliance Standard:

   CMS may review factors not specifically addressed in the questions guidance if it is determined that there are other related requirements not being met.

   We request that CMS clarify what other factors may be review. The information may be used to enhance Sponsors internal auditing and monitoring process.

4. Sample Case Results:

   CMS understand that cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

   We request that CMS clarify the scoring methodology and provide examples of scenarios with a single condition or multiple conditions of non-compliance.

Provider Network Accuracy (PNA)

Currently, CMS publishes six (6) of the protocols. However, the audit process and data request for the PNA Pilot is not available. On the Audit & Enforcement Conference & Webinar held on June 16, 2015, CMS provided a brief outline of the process and timeline.

We request that CMS provide plans with the Provider Network Accuracy protocol for planning and monitoring purposes prior to the beginning of the 2017 program audits.

PUBLIC SUBMISSION

As of: 8/11/16 12:18 PM
Received: July 22, 2016
Status: Draft
Tracking No. 1k0-8qwk-resn
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0005
PR

Submitter Information

Name: LRA abarca health, LLC.
Address:
San Juan, PR, 00918
Email: LRA@abarcahealth.com

General Comment

See attached file(s)

Attachments

2017 Draft Program Audit Protocols - Comments - abarca health

PUBLIC SUBMISSION

As of: 8/11/16 12:28 PM
Received: August 02, 2016
Status: Draft
Tracking No. 1k0-8r3v-6u3t
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0007
CA

Submitter Information

Name: L.A Care Health Plan Anonymous
Address:
Los Angeles, CA, 90017
Email: LACMedicareRegulatoryNotification@lacare.org

General Comment

Pharmacy Comments - 2017 Draft Program Audit Protocols

1) Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD)
Record Layout: Column ID=M
Question: When would a DMR request be considered as "dismissed"?

2) Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD)
Record Layout: Column ID=O
Question: Is a written notification necessary to be provided to the enrollee if the Request Disposition for DMR (column M) is dismissed, withdrawn or re-opened denied?

Formulary and Benefit Administration audit protocol:

1. Are MMP's exempt from the website audit (audit element III)?

Attachments

L.A. Care Health Plan Comments

Pharmacy Comments - 2017 Draft Program Audit Protocols

1) Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout: Column ID=M
Question: When would a DMR request be considered as "dismissed"?

2) Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout: Column ID=O
Question: Is a written notification necessary to be provided to the enrollee if the Request Disposition for DMR (column M) is dismissed, withdrawn or re-opened denied?

Formulary and Benefit Administration audit protocol:

1. Are MMP's exempt from the website audit (audit element III)?

EXPRESS SCRIPTS®

SUBMITTED ELECTRONICALLY

August 5, 2016

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Attention: Document Control Number 2016-13917 [2017 Draft Program Audit Protocols]

Dear Mr. Parham:

Express Scripts appreciates the opportunity to comment on the 2017 Draft Program Audit Protocols. Express Scripts (ESI) is a pharmacy benefit manager (PBM) that provides integrated PBM services including network-pharmacy claims processing, home delivery services, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management, and medical and drug-data analysis services for over 85 million Americans.

ESI currently supports many plan sponsors that directly contract with CMS via a prescription drug plan (PDP) or Medicare Advantage (MA-PD) benefit, and we also sponsor our own prescription drug plans (PDP). We take an active and consultative role with these plan sponsors to ensure their Medicare solutions are comprehensive, compliant with regulatory requirements, and aligned with their beneficiaries' needs. ESI strives to provide the best possible support to our plan sponsors and patients to ensure optimal performance. In that spirit, we respectfully submit the following comments for your review and consideration.

I. **CPE Audit Process and Data Request; Attachment I-E; SIU/FWA Prevention and Detection Questionnaire (FWA-Q)**: Question number 49 within the SIU/FWA Prevention and Detection Questionnaire asks sponsors if, when receiving notifications from CMS concerning FWA studies, they are ". . . incorporating the findings into . . . monitoring and auditing work plans?"

***Express Scripts' Comments**: We respectfully request CMS to provide examples of what types of communications it intends to capture under the term "FWA studies," as referenced in the above question so that plans can reply accurately.*

II. **CDAG Audit Process and Data Request: Audit Elements- Grievances and Misclassification of Requests**: The Call Log universe protocol indicates that CMS may request to review a sponsor's audio files of Call Log samples during an audit webinar.

***Express Scripts' Comments**: Although not explicitly stated, CMS generally provides plans with the audit timeframe, or "universe" of desired samples ahead of the audit webinar is scheduled, typically in the morning of the day before. We respectfully note that audio files are not always immediately available, and retrieval may take additional time beyond what CMS typically provides for sample review. We therefore request accordingly that CMS provide*

plans with reasonable flexibility for retrieving such files when finalizing the 2017 protocols. Moreover, Express Scripts also recommends CMS provide plans with the desired universe of audio samples at least 72 hours in advance of the Call Log webinar so as to allow sufficient time for retrieval of the required files and/or transcripts.

III. **CDAG Audit Process and Data Request: Appendix A - Table 14- Standard Grievances (SGD) and Appendix A – Table 15 – Expedited Grievance (EGD)**: The character limitation in the "Resolution Description" field of both the standard and expedited grievance record layout would be reduced from 3000 characters to 1500 characters.

Express Scripts' Comments: *We strongly urge CMS to reconsider the proposed reduction of the character limit for the Resolution Description fields and—at a minimum—maintain the current 3000 character limit. Reducing the character limit of these fields could force plan sponsors to exclude critical details about resolution actions that may otherwise trigger CMS to seek additional information through separate inquiries—an unnecessary administrative burden for **both** CMS and the plan sponsor. Express Scripts recommends instead that CMS increase the character limit to 5000 characters, as doing so would allow plan sponsors to provide a comprehensive description of the grievance resolution to CMS.*

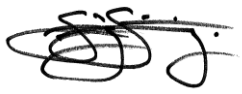
IV. **CDAG Audit Process and Data Request: Appendix A- Table 16- Call Logs**: The character limitation in the "Description of the outcome of the call" field in the Call Log record layout is 1000 characters.

Express Scripts' Comments: *For reasons similar to those described above regarding the Resolution Description field, we strongly urge CMS to expand the "Description of the outcome of the call" field from 1000 characters to at least 3000 characters. Per CMS' instruction that this field should indicate the full outcome and resolution of a call—including any subsequent action(s)—limiting the information to be captured in this field to 1000 characters would likely also lead to exclusion of important information from the form. It has been Express Scripts' experience that Medicare Part D member calls often cover multiple issues requiring customer service agents to pursue several actions when interacting with the member—often leading to lengthy descriptions of the call's outcome and cataloguing of subsequent actions. Again, we respectfully offer that expanding the proposed character limit in the field would prevent CMS **and** plan sponsors from having to engage in follow-ups that might otherwise be avoided if more space was provided from the outset.*

*****

We again thank CMS of this opportunity to comment on the 2017 Draft Program Audit Protocols, and remain eager to assist with the Centers' efforts to improve the administration and quality of the Medicare program. Please don't hesitate to contact me at sasantiviago@express-scripts.com or 202.383.7987 if we can be of any assistance.

Sincerely,



Sergio A. Santiviago
Director – Government Affairs
Express Scripts

PUBLIC SUBMISSION

As of: 8/11/16 12:34 PM
Received: August 05, 2016
Status: Draft
Tracking No. 1k0-8r5y-zm8i
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0008
DC

Submitter Information

Name: Sergio Santiviago
Address:
Washingtonq, DC, 20001
Email: sasantiviago@express-scripts.com
Organization: Express Scripts

General Comment

See attached file(s)

Attachments

ESI_Cmts_CMS Audit Protocol_17

2017 Draft Audit Protocol Comments for CMS
Comment/Response Form

Contact Person's Name: Dana Harrington **Email: dana.harrington@medica.com** **Phone: 952-992-3827**

Organization Name	Document Title	Page Number	Section Title	Section Number	Suggested Revision/Comment
Medica	Attachment I-B Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Compliance Officer Questionnaire (CO-Q)	4	Compliance Committee and Board of Directors Reporting	17, 20	Potential duplicate: Questions 17 and 20 ask the same question. Medica recommends removing one of the duplicate questions.
Medica	Parts C and D Compliance Program Effectiveness (CPE) Audit Process and Data Request	15-16	Table 1 FTEAM Record Layout	M, O	Potential duplicate: In the FTEAM layout the Description column for element M (Description of Deficiencies) and element O (Corrective Action Description) both ask for root cause. Medica suggests removing root cause from the Description column for element M and leave the root cause under element O. By doing so the FTEAM layout would be consistent with the IA and IM record layouts which both request root cause only under the Corrective Action Description element.
Medica	Part C Organization Determinations, Appeals, and Grievances (ODAG)	53	Call Logs Part C (CLC) Record Layout	14	In 2016, our average Medicare member call volume is 26K calls per month. A two-month file universe would contain in excess of 50K records. Given CMS will only select 10 calls for review, we would propose CMS take the universe size into consideration and consider selecting a shorter timeframe. For a plan our size (50k to 250k members), we would propose that the call log universe timeframe consist of two weeks to one month. Another option for CMS consideration is to limit the volume of records a health plan submits for the Call Log universe. A shorter universe timeframe will still contain thousands of records for CMS to choose calls from and it also allows the health plan greater ability to produce and quality check a universe containing thousands of records. We are currently unable to systematically produce all data elements in the proposed CMS Call Log format due to the following: • Medicare phone calls in our operating system are not separated by Part C and Part D. We are a cost plan with a Part D Rider. All of our members have Part C with us, and they may or may not have Part D. This means that thousands of our phone calls contain both Part C and Part D inquiries. It is common for a member to ask a question about a Part D drug and a Part C benefit in one phone call. As a result, we would be challenged to effectively choose one primary call type. • In our operating system, the “Description of the call” and the Outcome/Resolution” are free form comments and are contained in one data field that is not reportable. With a potential universe of over 50k records (2 months of calls), it is not feasible to manually look up the data and enter it in the universe in the timeframe we are given to produce such a universe. In order to comply with the proposed call log universe, it will require significant health plan time and expense to implement the necesary system enhancements. We propose that in 2017 CMS allow flexibility with the call log universe data elements and consider reducing the universe timeframe.

Organization Name	Document Title	Page Number	Section Title	Section Number	Suggested Revision/Comment
Medica	Part D Coverage Determinations, Appeals, and Grievances (CDAG)	60	Call Logs Part D Record Layout	16	In 2016, our average Medicare member call volume is 26K calls per month. A two-month file universe would contain in excess of 50K records. Given CMS will only select 10 calls for review, we would propose CMS take the universe size into consideration and consider selecting a shorter timeframe. For a plan our size (50k to 250k members), we would propose that the call log universe timeframe consist of two weeks to one month. Another option for CMS consideration is to limit the volume of records a health plan submits for the Call Log universe. A shorter universe timeframe will still contain thousands of records for CMS to choose calls from and it also allows the health plan greater ability to produce and quality check a universe containing thousands of records. We are currently unable to systematically produce all data elements in the proposed CMS Call Log format due to the following: • Medicare phone calls in our operating system are not separated by Part C and Part D. We are a cost plan with a Part D Rider. All of our members have Part C with us, and they may or may not have Part D. This means that thousands of our phone calls contain both Part C and Part D inquiries. It is common for a member to ask a question about a Part D drug and a Part C benefit in one phone call. As a result, we would be challenged to effectively choose one primary call type. • In our operating system, the "Description of the call" and the Outcome/Resolution" are free form comments and are contained in one data field that is not reportable. With a potential universe of over 50k records (2 months of calls), it is not feasible to manually look up the data and enter it in the universe in the timeframe we are given to produce such a universe. In order to comply with the proposed call log universe, it will require significant health plan time and expense to implement the necesary system enhancements. We propose that in 2017 CMS allow flexibility with the call log universe data elements and consider reducing the universe timeframe.

PUBLIC SUBMISSION

As of: 9/30/16 9:21 AM
Received: August 09, 2016
Status: Draft
Tracking No. 1k0-8r8h-hvoc
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0099
Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey (CMS-10623)

Comment On: CMS-2016-0099-0001
(CMS-10623) Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey

Document: CMS-2016-0099-DRAFT-0002
MN

Submitter Information

Name: Dana Harrington
Address:
Minnetonka, MN, 55305
Email: dana.harrington@medica.com
Organization: Medica

General Comment

See attached file(s)

Attachments

2017 Draft Audit Protocols Comments to CMS

PUBLIC SUBMISSION

As of: 8/11/16 12:37 PM
Received: August 09, 2016
Status: Draft
Tracking No. 1k0-8r8m-9f8f
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0009
CA

Submitter Information

Name: L.A. Care Health Plan Anonymous
Address:
1055 West 7th Street, CA, 90017
Email: LACMedicareRegulatoryNotification@lacare.org

General Comment

2017 Draft Audit Protocol Analysis
Key Changes and Clarification - Navitus Health Solutions

Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area
I. Changes Noted:
a. All universes now include reopened cases.
b. CMS may select an additional 5 cases to review dismissals, withdrawals and/or re-openings to assess whether the request was appropriately classified and processed.
Clarifying Questions:
Will CMS be providing a clear definition of reopenings? (i.e. should only reopenings with a revised decision be included in the universe?)
Will CMS be providing a clear definition of Dismissals?

II. Changes Noted:
a. Added a Call Log Universe
b. CMS will also select a targeted sample of 10 calls from the sponsors Part D call logs
Clarifying Questions:
Are all Medicare Part D provider calls (i.e. pharmacy calls) to be included in the Call Log Universe?
Please clarify character length of Column ID's A, B & C for the CLD universe. They are not

consistent with all other universes.

III. Changes Noted (Grievances and Misclassification of Requests):
a. CMS added requirements for the Sample Case Documentation for Call Logs
Clarifying Questions:
Are audio recordings required, or only if available?
Is a summary of the call (including all activity that occurred) sufficient for documentation of the call details, or are all notes required?

Part D Formulary and Benefit Administration (FA) Program Area
I. Changes Noted:
a. New Rejected Claims Transition - Previous Contract Year (RCT-P) universe
Clarifying Question:
Within the FA universes, the pharmacy message associated with the reject code is required. If our system cannot map the individual pharmacy messages to the individual reject code, is it acceptable to populate all messages in the "pharmacy message" field for all reject codes; OR is it acceptable to provide the NCPDP reject message associated with each reject code in the pharmacy message field?

Attachments

2017 Draft Audit Protocol Analysis -FINAL

2017 Draft Audit Protocol Analysis

Key Changes and Clarification – Navitus Health Solutions

Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area

I. Changes Noted:
   a. All universes now include reopened cases.
   b. CMS may select an additional 5 cases to review dismissals, withdrawals and/or re-openings to assess whether the request was appropriately classified and processed.

Clarifying Questions:

- Will CMS be providing a clear definition of reopenings? (i.e. should only reopenings with a revised decision be included in the universe?)
- Will CMS be providing a clear definition of Dismissals?

II. Changes Noted:
   a. Added a Call Log Universe
   b. CMS will also select a targeted sample of 10 calls from the sponsors Part D call logs

Clarifying Questions:

- Are all Medicare Part D provider calls (i.e. pharmacy calls) to be included in the Call Log Universe?
- Please clarify character length of Column ID's A, B & C for the CLD universe. They are not consistent with all other universes.

III. Changes Noted (Grievances and Misclassification of Requests):
   a. CMS added requirements for the Sample Case Documentation for Call Logs

Clarifying Questions:

- Are audio recordings required, or only if available?
- Is a summary of the call (including all activity that occurred) sufficient for documentation of the call details, or are all notes required?

Part D Formulary and Benefit Administration (FA) Program Area

I. Changes Noted:
   a. New Rejected Claims Transition – Previous Contract Year (RCT-P) universe

Clarifying Question:

- Within the FA universes, the pharmacy message associated with the reject code is required. If our system cannot map the individual pharmacy messages to the individual reject code, is it acceptable to populate all messages in the "pharmacy message" field for all reject codes; OR is it acceptable to provide the NCPDP reject message associated with each reject code in the pharmacy message field?

Comments: Draft CMS Program Audit Protocols			
Plan/Non-health Plan Entity:	Centene		
Contact Person Name:	Laura Kelley	**Dept:** Medicare Compliance	
Email:	lakelley@centene.com		
Section #	**Page #**	**Description of Issue or Comment**	**Suggested Revision or Comment**
General Comment - Impact Analysis	NA	CMS requires impact analyses to be developed and produced as issues are identified during the audit. These impact analyses often needs to be done by the same staff participating in the webinar audits. This results in staff needing to work nearly 20 hours a day to participate in the webinar audit and conduct the analysis late in the evening in order to meet CMS's deadline for submission.	We are requesting that CMS hold-off requesting the impact analysis until the week following the webinar audit to allow staff to continue to participate in the webinar audit.
General Comment - DRLs	NA	During the audit (both webinars and onsite) CMS requests additional information through the DRL process that must often be provided by the sponsor within 24 hours of the request. This documentation must be collected and quality reviewed by the same staff participating in the audit. This results in staff needing significant overtime in the evening and still be available early the following morning in order to meet CMS's deadline for submission. This documentation is often not critical and does not directly impact member's access to care.	We are requesting CMS increase the length of time for sponsors to produce the additional documentation to allow staff to continue to participate in the webinar audit.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 2: Employees and Compliance Team (ECT) Record Layout	18	Column G Direct Phone Number Description states, "Contact phone number for employee's office or desk. Submit in 10-digit hyphenated number format (e.g., 410-555-5555)."	Add an option for NA as some employees, especially those that work in the Member Call Center may not have direct telephone numbers.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	12	4th bullet under Include states, "Audit and monitoring activities that are performed on a scheduled basis (e.g., daily, monthly, quarterly, annually), should be included in the universe each time it was performed. If an activity is conducted daily, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all monitoring performed throughout the audit review period."	Add weekly as a frequency option to be consistent with the field description under column F and explain, if an activity is conducted weekly, whether it should be listed only once similar to daily or each time the activity was performed
508_Attachment_I_CPE_AuditProcess_DataRequest Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	14	Column I Activity Start Date Description states, "For an audit or monitoring activity conducted on a daily basis, only include the most recent start date."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description. Also, confirm how "the most recent start date" is defined. Is this the earliest start date within the review period or the start date closest to the last date of the review period.

Section #	Page #	Description of Issue or Comment	Suggested Revision or Comment
508_Attachment_I_CPE_AuditProcess_DataRequest Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	14	Column J Activity Completion Date Description states, "For an audit or monitoring activity conducted on a daily basis, only include the completion date for the previously indicated most recent start date."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description. Also, confirm how "the most recent start date" is defined. Is this the earliest start date within the review period or the start date closest to the last date of the review period.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	15	Column L Number of Deficiencies Description states, "For an audit or monitoring activity conducted on a daily basis, include the total number of deficiencies identified in all of the daily audit or monitoring activities during the audit review period."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	15	Column M Description of Deficiencies Description states, "For an audit or monitoring activity conducted on a daily basis, include all deficiencies identified in all audit or monitoring activities during the audit review period."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 3: Internal Auditing (IA) Record Layout	20	2nd bullet under Include states, "Audit activities that are performed on a scheduled basis (e.g., daily, monthly, quarterly, annually), should be included in the universe each time it was performed. If an audit activity is conducted daily, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all auditing performed throughout the audit review period."	Add weekly as a frequency option to be consistent with the field description under column D and explain, if an activity is conducted weekly, whether it should be listed only once similar to daily or each time the activity was performed
508_Attachment_I_CPE_AuditProcess_DataRequest Table 3: Internal Auditing (IA) Record Layout	21	Column G Audit Start Date Description states, "For an audit activity conducted on a daily basis, only include the most recent start date."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description. Also, confirm how "the most recent start date" is defined. Is this the earliest start date within the review period or the start date closest to the last date of the review period.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 3: Internal Auditing (IA) Record Layout	21	Column H Audit Completion Date Description states, "For an audit activity conducted on a daily basis, only include the completion date for the previously indicated most recent start date."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description. Also, confirm how "the most recent start date" is defined. Is this the earliest start date within the review period or the start date closest to the last date of the review period.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 3: Internal Auditing (IA) Record Layout	21	Column J Number of Deficiencies Description states, "For an audit activity conducted on a daily basis, include the total number of deficiencies identified in all of the daily audit activities during the audit review period."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 3: Internal Auditing (IA) Record Layout	22	Column K Description of Deficiencies Description states, "For an audit activity conducted on a daily basis, include all deficiencies identified in all audit activities during the audit review period."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description.

Section #	Page #	Description of Issue or Comment	Suggested Revision or Comment
508_Attachment_I_CPE_AuditProcess_DataRequest Table 4: Internal Monitoring (IM) Record Layouts	25	2nd bullet under Include states, "For monitoring activities that are performed on a scheduled basis (e.g., daily, monthly, quarterly, annually), it should be included in the universe each time it was performed. If a monitoring activity is conducted daily, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all monitoring performed throughout the year."	Add weekly as a frequency option to be consistent with the field description under column D and explain, if an activity is conducted weekly, whether it should be listed only once similar to daily or each time the activity was performed
508_Attachment_I_CPE_AuditProcess_DataRequest Table 4: Internal Monitoring (IM) Record Layouts	25	Column G Audit Start Date Description states, "For a monitoring activity conducted on a daily basis, only include the most recent start date."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description. Also, confirm how "the most recent start date" is defined. Is this the earliest start date within the review period or the start date closest to the last date of the review period.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 4: Internal Monitoring (IM) Record Layouts	25	Column H Audit Completion Date Description states, "For a monitoring activity conducted on a daily basis, only include the completion date for the previously indicated most recent start date."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description. Also, confirm how "the most recent start date" is defined. Is this the earliest start date within the review period or the start date closest to the last date of the review period.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 4: Internal Monitoring (IM) Record Layouts	25	Column J Number of Deficiencies Description states, "For a monitoring activity conducted on a daily basis, include the total number of deficiencies identified in all of the daily monitoring activities during the audit review period."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description.
508_Attachment_I_CPE_AuditProcess_DataRequest Table 4: Internal Monitoring (IM) Record Layouts	25	Column K Description of Deficiencies Description states, "For a monitoring activity conducted on a daily basis, include all deficiencies identified in all monitoring activities during the audit review period."	If the intent is to include activities that are conducted on a weekly basis only once, then add this to the description.
508_Attachment_V_SNP-MOC_Audit Process and Data Request I. Population to be Served – Enrollment Verification	8	Bullet 6 is repetitive of the information in bullet 4.	Recommend deleting the 6th bullet.

Section #	Page #	Description of Issue or Comment	Suggested Revision or Comment
508_Attachment_V_SNP-MOC_Audit Process and Data Request I. Population to be Served – Enrollment Verification	8	In some states, passive enrollment transactions and voluntary enrollment requests can only be initiated/accepted and processed by the State. Therefore, we would not be able to produce some of the specific documentation being requested. For example: **1.1. For All Beneficiaries:** • Receipt of the enrollment request (by whichever medium the enrollment is received, e.g., paper, telephonic, online); • Documentation showing sponsor's verification of SNP eligibility prior to submission of the enrollment to CMS; and • Documentation of the completed enrollment request. **1.4. For D-SNP beneficiaries:** • Documentation of both Medicare and Medicaid eligibility prior to enrollment. • Documentation of beneficiary attestation of eligibility for the election period submitted by the sponsor.	Unless it is CMS' intent for sponsors to exclude MMP members who were enrolled by the State enrollment broker from the SNPE universe, we recommend either adding a subsection titled "1.5 For MMP beneficiaries" to clarify what documentation these MMPs are expected to produce in the event an enrollment is received and processed by the state or the state's enrollment broker.
508_Attachment_V_SNP-MOC_Audit Process and Data Request I. Population to be Served – Enrollment Verification	8	For sample cases that are selected where "Seamless" is entered as the Enrollment Mechanism on the SNPE universe, sponsors may need to be permitted to provide alternate documentation for the following: **1.1. For All Beneficiaries:** • Documentation of receipt of the enrollment request (by whichever medium the enrollment is received, e.g., paper, telephonic, online). **1.4. For D-SNP beneficiaries:** • Documentation of beneficiary attestation of eligibility for the election period submitted by the sponsor.	**1.1. For All Beneficiaries:** Please clarify what kind of documentation sponsors should provide for the "receipt of the enrollment request." **1.4. For D-SNP beneficiaries:** Because seamless enrollment transactions must always use the initial coverage election period (ICEP), please clarify what kind of documentation sponsors should provide for the "beneficiary attestation of eligibility for the election period submitted by the sponsor."
508_Attachment_V_SNP-MOC_Audit Process and Data Request 2.4.1 Care Transitions: Did the sponsor plan & implement care transition protocols to maintain member's continuity of care as defined in the MOC?	11	Does this include ER visits only, Inpatient to home, inpatient to SNF or NF?	Please clarify which transition protocols CMS is requiring and define the level of care transition and expectation for documentation.

Section #	Page #	Description of Issue or Comment	Suggested Revision or Comment
508_Attachment_V_SNP-MOC_Audit Process and Data Request Table 1: Special Needs Plan Enrollees (SNPE)	17	With respect to providing paid and denied claim number and amounts for SNP MOC Table 1, pharmacy rejects and multiple attempts to adjudicate drives up these numbers. Does CMS really want these included? Including this information could result in the perception of more services/Rx received or requested than is accurate.	Suggest CMS provide further clarification.
508_Attachment_V_SNP-MOC_Audit Process and Data Request CMS-approved Health Risk Assessment Tool(s) (HRA) used by the SNP	6	CMS requests copies of the HRA tool. However, while the original HRA tool may have been CMS approved, CMS has indicated in the past that the HRA could be revised without resubmission to CMS.	Suggest CMS clarify how to respond to this request. Do we provide the originally approved HRA or the HRA in use?
Appendix A, Table 1: Special Needs Plan Enrollees (SNPE) Record Layout	15		We recommend adding a valid value of "MMP," as this will assist the Team Lead when selecting sample cases (unless the Contract ID will be used for this purpose). This edit supports the information already provided under the Sample Selection section on page 7: CMS will select a sample of 30 beneficiaries from the sponsor-submitted universe as follows: • % selected = % of D-SNP beneficiaries • % selected = % of I-SNP beneficiaries • % selected = % of C-SNP beneficiaries **• % selected = % of MMP beneficiaries**
Appendix A, Table 1: Special Needs Plan Enrollees (SNPE) Record Layout	16	In reference to Column H, for some states, passive enrollment transactions and voluntary enrollment requests can only be initiated/accepted and processed by the State or state enrollment broker. Therefore, we would not be able to produce some of the specific documentation being requested.	Please clarify if it is CMS' intent for sponsors to exclude MMP members who were enrolled by the state from the SNPE universe, or if CMS expects MMPs to work with the state to obtain the Enrollment Mechanism. Another option would be to allow MMPs to enter "N/A" in this field for these enrollments with the use of other enrollment source codes (e.g. an Enrollment Source Code of L (opt-in enrollments) or an Enrollment Source code of J (passive enrollments)).
Appendix A, Table 1: Special Needs Plan Enrollees (SNPE) Record Layout	16	Similar to above, In Column I, for some MMP states the sponsor will not be able to provide the actual Date of when the completed enrollment request was received by the state or state enrollment broker.	Please clarify if it is CMS' intent for sponsors to exclude these MMP members or include the date that we received the enrollment information from the state.

Section #	Page #	Description of Issue or Comment	Suggested Revision or Comment
Appendix A, Table 1: Special Needs Plan Enrollees (SNPE) Record Layout	16	In Column K, the information currently provided in the Field Name and Description is only applicable to SNPs. Note: This comment also applies to II. Care Coordination, 2.1.2. on page 10.	Recommend revising the Field Name and Description for Column K to also include the MMP guidelines for completing the HRA, but this may become lengthy and/or confusing considering states may have different guidelines. <u>CA MMPs: Revised State-Specific Reporting Requirements (03.25.2016)</u> For MMPs that have requested and obtained CMS approval to do so, Health Risk Assessments (HRAs) may be completed up to 20 days prior to the individual's coverage effective date for individuals who are passively enrolled. Early HRA outreach for opt-in members is permitted for all participating MMPs. <u>Duals Plan Letter 15-005</u> HRAs must be administered within 45 calendar days of enrollment for those identified as higher risk and 90 calendar days for those identified as lower risk.
Appendix A, Table 1: Special Needs Plan Enrollees (SNPE) Record Layout	17	In Columns S and T, it is unclear whether sponsors should include the number of capitated paid/denied claims.	Please clarify if sponsors should include the number of capitated paid/denied claims since capitated services are still services and could fulfill a care need identified in the HRA and/or the ICP.
Appendix A, Table 2: Plan Performance Monitoring and Evaluation (PPME) Record Layout	18	The instruction "Submit one universe for each Model of Care administered" is not the same process we were required to adhere to when Health Net was audited by CMS in 2015.	We believe it may have been an oversight for this instruction to remain unchanged in the 2017 protocols, as this same instruction was also present in the 2015/2016 protocols. Fatima Mohamed-Hancock advised us that "Columns should be added for contract numbers & PBP and the Sponsor should submit a single universe." We therefore had to combine our PPME universes into one with the "CMS Contract ID" becoming Column A and the "CMS Plan ID" field becoming Column B to help CMS distinguish which Contract/PBP the metrics applied to. If this is the same process that CMS will be following going forward, please update the PPME universe fields in the 2017 protocols accordingly to avoid sponsor confusion.
508_Attachment_III_CDAG_AuditProcess_Data _Request: Table 16: Call Logs Part D Record Layout & 508_Attachment_IV_ODAG_AuditProcess_Data Request: Table 14: Call Logs Part C (CLC) Record Layout	60	Should calls using alternate technologies (IVR) be included?	If the intent is to include all types of telephony, indicate as description to include land line, alternate, VoIP and other types of telephony technologies.
508_Attachment_IV_ODAG_AuditProcess_Data Request: Table 14: Call Logs Part C (CLC) Record Layout	53	Should calls using alternate technologies (IVR) be included?	If the intent is to include all types of telephony, indicate as description to include land line, alternate, VoIP and other types of telephony technologies.

Section #	Page #	Description of Issue or Comment	Suggested Revision or Comment
508_Attachment_IV_ODAG_AuditProcess_Data Request: Table 7: Requests for Payment Reconsiderations (PREC) Record Layout	38	Per the instructions, we are to "include all requests processed as payment reconsiderations from non-contracted providers" and Exclude all requests processed as direct member reimbursements." Based on these instructions, we identified a possible gap regarding member appeal requests of denied claims where the member made no payment. We are looking for CMS to clarify whether member submitted requests for appeal of denied payment requests that are not direct member requests for reimbursement (i.e. the member did not pay out of pocket for the claim) should be excluded from the PREC universe, record layout table 7?	We posed this question to CMS and received the following response: The types of cases you are describing should be populated in the DMR universe (Table 4). For auditing purposes, we are mostly concerned with who made the request rather than who ultimately wound up being reimbursed. Based on this, we believe the instructions for the DMR universe should clearly indicate that this includes member appeals of adverse contracted provider payment organization determinations.

PUBLIC SUBMISSION

As of: 8/11/16 2:36 PM
Received: August 10, 2016
Status: Draft
Tracking No. 1k0-8r9a-ukh0
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0014
CA

Submitter Information

Name: Jamee Sunga
Address:
Woodland Hills, CA, 91367
Email: jamee.e.sunga@healthnet.com
Organization: Centene Corporation

General Comment

Please see the attached file with our comments.

Thank you for this opportunity. We are available for discussion, if needed.

Attachments

Centene Comments - CMS_Draft 2017 Program Audit Protocols (v2)

Part C Organization Determinations, Appeals and Grievances (ODAG):

Request clarification for the ODAG protocol and record layouts.

Location	Current Language	Comments
Table 1: Standard Pre-service Organization Determinations (SOD) Record Layout Table 2: Expedited Pre-service Organization Determinations (EOD) Record Layout	Include all requests processed as standard pre-service organization determinations, including all supplemental services, such as dental and vision, and include all approvals and denials. Exclude payment requests, withdrawn requests , all requests processed as standard organization determinations concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, requests for extensions of previously approved services, duplicate claims and payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or separately payable items, denied claims for beneficiaries who are not enrolled on the date of service, and claims denied due to recoupment of payment	Should partial approvals be included in Table 1 and 2? How should they be classified- approval or denial? Clarify whether the exclusion applies to denied claims for bundled or separately payable items, or should it be for not separately payable items as stated in the 2015 and 2016 Audit Protocol. Same question for EOD, SREC, and EREC. Table 2, 2nd Bullet: Withdrawn requests: Does this mean that cancelled cases (pre and post determination) should be EXCLUDED from the Table 1 Universe? If EXCLUDED, should cancelled cases even after approval or denial notification has been given be EXCLUDED from the Table 1 Universe? Requests for extensions of previously approved services: Does this mean for home health or DME and other requests that extensions of each service should be EXCLUDED either approved or denied? If so, should each service code (i.e. RN, PT, ST, etc.) be only listed once on the universe as long as there are different request dates for each individual service? Table 2: It appears per the universe

		columns and description that all requests, including pended requests should be INCLUDED in the universe pull, is that correct?
Record Layout 1 (Column ID N) Subsequent Expedited Request	If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.	The instruction field needs clarification. Please clarify or provide a scenario where this would be applicable? Clarify the description. It looks like it's saying that Plans have to list the requestor for cases expedited after the org determination decision was rendered. Same question for several universes.
Record Layout 2 (Column ID O) Subsequent Expedited Request	If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.	The instruction field needs clarification. Is this applicable to Table 2 Expedited Request? How can a request be made to expedite after an organization determination?
Record layout 1 Columns K Record Layout 2 Column L	Provide a description of the service, medical supply or drug requested and why it was requested (if known). For denials, also provide an explanation of why the expedited pre-service request was denied.	If we are treating Pended cases as Denials, what is the appropriate denial reason? What should be the explanation for pended cases listed as denied? Column Q says any requests that are untimely and not yet resolved should be treated as denied. For pended cases do we say that the case is in a pended status because they really were not denied? Same question for several universes?
Record Layout 14 Call Logs	All calls received by your organization (or delegated entity) that relate to your Medicare Part C line of business.	Need clarification on what type calls need to be included. Does this include provider calls or just member calls

		related to MA Part C line of business?
Record Layout 11 & 12 Column I and J respectively Category of the grievance/complaints	Record Layout 11 (Column I) Category of the grievance/complaint. At a minimum categories must include each of the following: Enrollment/Disenrollment, Benefit Package, Access, Marketing, Customer Service, Organization Determination and Reconsideration Process, Quality of Care, Grievances Related to "CMS" Issues, and Other. Record Layout 12 (Column J) Category of the grievance/complaint. Indicate whether the expedited grievance was submitted by the enrollee because the plan declined to process a case on the expedited timeframe (ETD) or whether it was submitted due to the enrollee's dissatisfaction with the plan taking a processing timeframe extension (PTE).	For Record Layout 11 CMS provided specific category of grievance/complaint. Record Layout 12. The Field Name does not align with the description.
Standard Pre-service Organization Determinations (SOD) Record Layout Pg 18 Column F	The associated authorization number assigned by the sponsor for this request. If an authorization number is not available, please provide your internal tracking or case number. Answer NA if there is no authorization or other tracking number available	The question of whether duplicate authorization numbers appear on the universe, with the same diagnosis but the issue description is different. The response was The universe should include only one case for the scenario that you described. Where there is one pre-service request comprised of multiple services, one record, including the first authorization number in the sequence, should be submitted in the universe. Please clarify this in the description. Same question for several universes.

Standard Pre-service Organization Determinations (SOD) Record Layout Pg 19 Column R	Date of the sponsor decision. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Sponsors should answer NA for untimely cases that are still open.	Should NA also be used for pended cases? Same question for several universes.
Standard Pre-service Organization Determinations (SOD) Record Layout Pg 19 Column S	Yes (Y)/No (N) indicator of whether the request was denied for lack of medical necessity. Answer NA if the request was approved. Answer No if the request was denied because it was untimely.	Should NA be populated for pended cases?
Expedited Pre-service Organization Determinations (EOD) Pg 22 Column N	If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.	There is a Yes or No indicator of whether the request was made under a standard timeframe but was processed under the expedited timeframe. Clarify if this means plan decided that processing the case as a standard request could jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, and intentionally process the case as expedited. How can a request be made to expedite after an organization determination?

Expedited Pre-service Organization Determinations (EOD) Pg 23 Column T	Time of the sponsor decision (e.g., approved, denied). Submit in HH:MM:SS military time format (e.g., 23:59:59). Sponsors should answer NA for untimely cases that are still open.	Should NA be populated for pended cases?
Expedited Pre-service Organization Determinations (EOD) Pg 23 Column U	Yes (Y)/No (N) indicator of whether the request was denied for lack of medical necessity. Answer NA if the request was approved. Answer No if the request was denied because it was untimely.	Should NA be populated for pended cases?
Claims Pg 25 Bullet 3	Submit payment organization determinations (claims) based on the date the claim was paid or denied, or should have been paid or denied (the date the request was initiated may fall outside of the review period).	Protocol says submit payment organization determinations (claims) based on the date the claim was paid or denied, or should have been paid or denied. In the 2016 version it said submit claims based on the date the sponsor's decision was rendered, or should have been rendered. Could this presents an issue? Same question for PREC, p. 38.
EREC Pg 35 Column N	If an expedited timeframe was requested, indicate who requested the expedited reconsideration timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested. Answer BR if a contract provider submitted the expedited reconsideration request on behalf of an enrollee.	The second sentence should request that they answer CP (not BR) if a contract provider submitted the expedited reconsideration request on behalf of the enrollee.
IREEFF Pg 40 Bullet 3	Submit cases based on the date of receipt of the IRE overturn decision (the date the request was initiated may fall outside of the review period).	Cases should be submitted based on the date or receipt of the IRE overturn decision. The 2016 audit protocol cases were submitted based on the date the sponsor's date was

		rendered. Now mirrors Table 9. We don't believe this presents an issue but wanted to raise it to your attention.
IRE ClaimsEFF Pg 42 Column J	Yes (Y)/No (N) indicator of whether interest was paid on the claim or reimbursement request.	Field name expanded to say "Was interest paid on the claim or reimbursement request" (reimbursement request was added). Does this include DMR? The 2016 version said to answer NA for overturns of DMR requests. The 2017 protocol says Yes or No indicator of whether interest was paid on the claim or reimbursement request. Same question for ALJMACEFF.
Call Log Pg 53 Table 14		We would like confirmation that the call logs (table 14) are inclusive of all calls received and handled during the universe period. Please confirm the purpose of providing these calls logs; i.e. will they be picked as samples to see if the Plan handled appropriately as inquiry or we should have sent through as an appeal or grievance? In terms of excluding Part D calls from the Part C (ODAG) universe, we do have instances where the beneficiary calls about both Part C and Part D benefits in the same call. How should these be categorized for universe purposes?
Pull Universe Pg 5		The Pull Universes section no longer indicates how to determine which cases fall into the audit period. For example, in previous versions, various universes were specified to pull based on decision date, receipt date, date auto forwarded, or IRE receipt date. This detail would alleviate confusion and support a standard process across the

		plans.

Part D Coverage Determinations, Appeals and Grievances (CDAG)

Location	Current Language	Comments
Call Logs Table 16 Pg 60		We would like confirmation that the call logs (table 16) are inclusive of all calls received and handled during the universe period. Please confirm the purpose of providing these calls logs; i.e. will they be picked as samples to see if the Plan handled appropriately as inquiry or we should have sent through as an appeal or grievance? In terms of excluding Part C calls from the Part D (CDAG) universe, we do have instances where the beneficiary calls about both Part C and Part D benefits in the same call. How should these be categorized for universe purposes
Pull Universe Pg 5		The Pull Universe section no longer indicates how to determine which cases fall into the audit period. For example, in previous versions, various universes were specified to pull based on decision date, receipt date, date auto forwarded, or IRE receipt date. This detail would alleviate confusion and support a standard process across the plans.

PUBLIC SUBMISSION

As of: 8/11/16 2:39 PM
Received: August 11, 2016
Status: Draft
Tracking No. 1k0-8r9q-4b9n
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0015
PA

Submitter Information

Name: David Moore
Address:
Philadelphia, PA, 19103
Email: david.moore@ibx.com

General Comment

See attached file(s)

Attachments

2017 Draft Program Audit Protocols Comments

PUBLIC SUBMISSION

As of: 8/11/16 2:42 PM
Received: August 11, 2016
Status: Draft
Tracking No. 1k0-8r9t-vure
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0016
WA

Submitter Information

Name: Anonymous Anonymous
Address:
WA, 98101

General Comment

UNIVERSES: There is a field that asks for all these things to be answered in one cell: "Provide a description of the service, medical supply or drug requested and why it was requested (if known). For denials, also provide an explanation of why the request was denied."
This is very hard to do given the diverse information request requirements and the space restrictions in the cell. It is very difficult to respond to all three of those very different questions in one cell.
Can you break this cell apart and ask three separate questions in three separate cells please?
1. Provide a description of the service, medical supply or drug requested and
2. Why it was requested (if known).
3. For denials, also provide an explanation of why the request was denied.

FDR QUESTIONNAIRE: Please ensure you are not asking the questions twice - once on the self-assessment questionnaire and once on the FDR questionnaire. It is make work to have to complete information twice.

QUESTIONNAIRES: Please remove all the "personal" questions from the SIU and the FDR Questionnaire. Please request employee information when you are reviewing the Employee and Compliance Team Universe. By asking "personal" information on the SIU and FDR Questionnaires you are mixing apples and oranges in information collection. Please streamline your requests for these types of information in the Employee and Compliance Team request section.
Please only ask questions on the SIU and FDR Questionnaires as how the ORGANIZATION does the work, not the individual.
Please only ask for the same thing as you do at the end of the Self Assessment Questionnaire <<Title of Questionnaire>>Questionnaire Submitted By:
[Name]

[Title]
[Company]
[Address]
[Phone Number]
[Email Address]

UPMC HEALTH PLAN

U.S. Steel Tower
600 Grant Street
Pittsburgh PA 15219
412-454-7500
412-454-7520 (fax)
www.upmchealthplan.com

August 12, 2016

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Office of Strategic Operations and Regulatory Affairs,
Room C4-26-05, 7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted Electronically via www.regulations.gov

RE: Program Audit Protocols: CMS-10191, the document number is 2016-13917 and document citation is 81 FR 38187

The UPMC Insurance Services Division ("UPMC") is pleased to submit the following comments in response to the above-referenced Program Audit Protocols, as published in the Federal Register on June 13, 2016.

UPMC, through UPMC Health Plan and the integrated companies of the UPMC Insurance Services Division, is proud to offer a full range of commercial individual and group health insurance, Medicare Advantage, Medicare Special Needs, CHIP, Medical Assistance, behavioral health, employee assistance, and workers' compensation products. UPMC Health Plan serves a combined 154,000 members in its Medicare Advantage and Medicare Special Needs Plans, and our collective commercial and government program membership today exceeds 2.9 million.

We thank the Centers for Medicare & Medicaid Services (CMS or the "Agency") for affording Plans and other stakeholders the opportunity to provide input regarding the proposed Program Audit Protocols. UPMC supports the Agency's commitment to assure that Medicare Advantage plans continue to adhere to program standards and to provide high quality services to their beneficiaries. It is with this support in mind that we respectfully offer the following comments.

Proposed Addition of CDAG and ODAG Call Logs Universes

We understand, share and support the Agency's commitment to assuring that beneficiary calls taken by member services personnel are appropriately classified, routed and addressed. With that said, we have significant concerns about the proposed approach to both CDAG and ODAG Call-Logs Universes. Specifically, as we understand the Proposal, sponsors would be required in CDAG and ODAG Universes to both describe

the "full description of the call" and the "outcome or resolution of the call." This approach would require a manual review by member-services personnel of the entirety of all call entry notes to first determine the "full description of the call" and then determine whether the "outcome or the resolution" of each call was achieved and documented by member-services personnel. In those instances in which, given the nature of the call, the outcome or resolution of the call was instead achieved and documented in another department (enrollment, premium billing, medical management, pharmacy, and/or complaints and grievances), the applicable processing department would additionally be called upon to manually review all entries from data-sources distinct from member-services call logs to populate the Universe.

We (and many other sponsors) simply cannot populate the Universes with this information without first manually reviewing all member service entries and as applicable, thereafter cross-referencing against information in myriad departments' systems. We receive over 30,000 calls per month and could not accomplish the necessary review in the time allotted to pull Universes. We respectfully ask that the Agency reconsider this proposal and instead work with sponsors to determine an alternate means by which this information can be collected.

Additional Clarification Needed

In addition to the concerns we noted above, we have questions as to the intent and/or meaning of some of the other proposed changes. We address these questions in turn below:

SNP-MOC

Section II. Care Coordination, 2.1.2 of the 2017 Draft SNP MOC Audit Protocols:

The protocol provides that sponsors can conduct the initial heath risk assessment (HRA) "within" 90 days of the effective date of enrollment. It has been our understanding that a Plan is prohibited from conducting an HRA before the effective date of a beneficiary's enrollment. Please clarify whether our understanding is correct and/or whether this protocol will allow for pre-enrollment completion of HRAs.

Audit Purpose and General Guidelines, 2. Review Period:

The Protocols provide that the review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017). Would this not increase the review period to almost a full 14 months (at least in some cases)?

CPE, Attachment 1-E, SIU/FWA Prevention and Detection Questionnaire

Question #25. What is the status of the fraud cases referred to either the NBI MEDIC or to law enforcement, but now have been returned back to the SIU?

The meaning of this requirement is unclear to us. If we send 10 cases to the MEDIC/law enforcement, will the Agency expect to see a breakdown of the status of each case? For example, would the Agency expect to see that 7 cases were closed, 1 case was documented

and 2 cases are still under review? Or would it instead expect to see a description of the Plan's process once it received a follow-up from the MEDIC/law enforcement?

Table 3: IA or Table 4: IM

As CMS has removed the "FWAM" table from the CPE audit, is the expectation that the FWA-related cases will be included in the appropriate Internal Monitoring or Internal Auditing table? Please advise.

Table 3: IA & Table 4: IM

In Column G (Audit/Monitoring Start Date) for a daily activity, CMS provides "For an audit/monitoring activity conducted on a daily basis, only include the most recent start date." If the plan started doing an audit/monitoring activity on 6/1/2015 and its audit period runs from 4/1/16 to 4/1/17, what date would CMS expect to see populated? Would it be 6/1/15 (the original start date of the monitoring activity) or 4/1/16 (the first day the activity occurred during the audit period)?

ODAG

Table 3, Claims, Column R (Date written notification provided to enrollee)

If the plan approves a claim for a D-SNP member and the member does not have any cost-sharing, how would CMS expect to see this field populated? As we understand CMS' EOB guidance, plans should not send EOBs in this situation. During our recent CMS audit, we were instructed to populate this field with NA-DUAL in these situations. Any available clarification would be greatly appreciated.

Table 13 Dismissals, Column H (Type of Request)

There is an option for a "non-contract provider claim." We respectfully ask that you provide us some additional information on this type of request. We assume that, were a Plan to receive such a claim from a non-contracted provider, it would approve/deny the claim rather than dismiss it. Please advise.

CDAG

CDAG Supplemental Questionnaire

Question #4 provides that if the response to #6 is "yes", etc. Shouldn't question #4 refer to whether the response to #3 is "yes", and not #6? Please advise.

All Tables

In a situation where a Plan has a case that was re-opened, what date would CMS expect to see in the "Date the request was received" column? Would it be the date the original request was received or the date the re-opening request was received? Please advise.

Table 16: Call Logs Part D

If the plan's PBM receives a call from a pharmacy regarding a Medicare Part D question, would CMS expect to see this call included in this universe?

CDAG & ODAG

CDAG, Table 16: Call Logs and ODAG, Table 14: Call Logs

If the plan's provider services department receives a call from a provider's office regarding a Medicare question, would CMS expect to see that call included in these universe? Please advise.

Thank you again for affording UPMC Health Plan and other stakeholders the opportunity to provide input on the Agency's proposed Program Audit Protocols. We look forward to continued collaboration on this and other issues in the future.

Sincerely,

Kathleen Withers
Medicare Compliance Officer
UPMC *for Life*

PUBLIC SUBMISSION

As of: 8/11/16 2:43 PM
Received: August 11, 2016
Status: Draft
Tracking No. 1k0-8r9u-badq
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0017
PA

Submitter Information

Name: Anonymous Anonymous
Address:
PA, 15219
Email: witherskm@upmc.edu

General Comment

See attached file(s)

Attachments

20160811CMS.10191 Documentv2016.13917 81 FR 38187134943

2017 Draft Audit Protocol Analysis

Key Changes and Clarification – Navitus Health Solutions

Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area

I. Changes Noted:
   a. All universes now include reopened cases.
   b. CMS may select an additional 5 cases to review dismissals, withdrawals and/or re-openings to assess whether the request was appropriately classified and processed.

Clarifying Questions:

- Will CMS be providing a clear definition of reopenings? (i.e. should only reopenings with a revised decision be included in the universe?)
- Will CMS be providing a clear definition of Dismissals?

II. Changes Noted:
   a. Added a Call Log Universe
   b. CMS will also select a targeted sample of 10 calls from the sponsors Part D call logs

Clarifying Questions:

- Are all Medicare Part D provider calls (i.e. pharmacy calls) to be included in the Call Log Universe?
- Please clarify character length of Column ID's A, B & C for the CLD universe. They are not consistent with all other universes.

III. Changes Noted (Grievances and Misclassification of Requests):
   a. CMS added requirements for the Sample Case Documentation for Call Logs

Clarifying Questions:

- Are audio recordings required, or only if available?
- Is a summary of the call (including all activity that occurred) sufficient for documentation of the call details, or are all notes required?

Part D Formulary and Benefit Administration (FA) Program Area

I. Changes Noted:
   a. New Rejected Claims Transition – Previous Contract Year (RCT-P) universe

Clarifying Question:

- Within the FA universes, the pharmacy message associated with the reject code is required. If our system cannot map the individual pharmacy messages to the individual reject code, is it acceptable to populate all messages in the "pharmacy message" field for all reject codes; OR is it acceptable to provide the NCPDP reject message associated with each reject code in the pharmacy message field?

PUBLIC SUBMISSION

As of: 9/1/16 1:54 PM
Received: August 11, 2016
Status: Draft
Tracking No. 1k0-8r9v-7y7d
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0018
VA

Submitter Information

Name: Anna Brooks
Address:
Clifton Forge, VA, 24422
Email: annabrooks@coeha.com

General Comment

Please see our list of questions regarding CDAG and Part D Formulary and Benefit Administration (FA) Program Area.

Thank you.

Attachments

2017 Draft Audit Protocol Analysis -FINAL

August 1, 2016

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

To Whom It May Concern:

As an organization that offers both a Fully Integrated Dual Eligible Special Needs Plan (H2225) and a Medicare-Medicaid Plan (H0137), Commonwealth Care Alliance (CCA) welcomes the opportunity to comment on the CMS audit protocols and strategy and we appreciate CMS' resolve to hear from plans regarding the burden of these audits.

Attached please find a list of itemized comments for the individual draft documents under review. CCA understands the importance of audits to measure plan performance. Thank you for providing the opportunity to comment.

Sincerely,
Gail Coleman
Compliance Officer
Commonwealth Care Alliance

30 Winter Street, Boston, MA 02108 Tel: (617) 426-0600 Fax: (617) 426-3097

Supporting Statement Part A

Section: Background
Subsection/field: Paragraph 2: "CMS will develop an annual audit strategy which describes how sponsors will be selected for audit and the areas that will be audited."
Page Number: 1
Comments: Commonwealth Care Alliance (CCA) encourages CMS to release general information from this strategy, such as selection methodology and the number or percentage of sponsors that will be selected annually. We would like CMS to consider releasing an annual schedule of audit notifications (e.g. the approximate planned dates on which audit notifications will be sent). While we understand CMS cannot release names of organizations being selected for audit ahead of time, it would be helpful for logistical and planning purposes to have a schedule of when audit notifications are expected to be released from CMS. Finally, when sponsors are being selected for program audits, it would be appreciated if consideration is given to the number and timing of audits, especially when a sponsor is subject to multiple audits (such as One Third Financial Audit and other CMS initiatives).

Section: Background
Subsection/field: Paragraph 2: "CMS has developed several audit protocols and these are posted to the CMS website each year for use by sponsors to prepare for their audit."
Page Number: 1
Comments: CCA thanks CMS for making protocols available; they have been invaluable tools for process improvement and audit readiness and we encourage CMS to continue releasing the protocols and other preparatory tools (for example, the ODAG and CDAG job aids) in coming years. We appreciate CMS' transparency and the educational opportunities available via channels such as HPMS memos, the annual Audit and Enforcement conference, and the audit email box.

Section: Background
Paragraph 2: "Special Needs Model of Care (SNPMOC) (only administered on organizations who operate SNPs)."
Page Number: 1
Comments: CMS has indicated that MMPs may be subject to Model of Care evaluation (e.g. elements of the SNP MOC protocol altered for MMP requirements). We encourage CMS to provide further clarification in this area. If some version of this protocol will be applied to MMPs, we would appreciate more detail on exactly what would be audited and how criteria would be applied to MMPs so that we can prepare for potential audit selection.

Section: Background

Subsection/field: Provider Network Accuracy (PNA)
Page Number: 1
Comments: The HPMS memo *CY 2016 Pilot Audit Protocol Release and Updates: Medication Therapy Management (MTM) and Provider Network Accuracy (PNA)* released 3/16/16 indicates that PNA assessment will not occur at part of the regular program audit. We encourage CMS to continue to release details about the PNA assessment process so that our organization can prepare for this in addition to program audit readiness.

Section: Background
Subsection/field: Finally, to assist in improving the audit process, CMS sends sponsors a link to a survey (Appendix D) at the end of each audit to complete in order to obtain the sponsors' feedback.
Page Number: 1
Comments: We have been unable to locate a copy of this survey in the protocol documentation that was released for comment. We encourage CMS to include this document in future releases so that sponsors can provide feedback on its content as they can with the rest of these protocol documents. If CMS does not already do so, we encourage them to include questions about hours worked, number of staff, and costs in this survey so that they can collect burden data from entities that have undergone audit. Finally, if survey responses can be shared without compromising sponsor confidentiality or otherwise releasing sensitive information, we encourage CMS to share audited sponsors' feedback publicly. Learning of other sponsors' experiences has been extremely valuable as our organization maintains audit readiness and we would appreciate any opportunity to hear more.

Section: Burden Estimates
Subsection/field: "Total Salary/hour: $639, $639 / 8 positions = $79.86. Taking the average of the above rates, we estimate an average hourly rate of $79.86"
Page Number: 5
Comments: CMS' method of estimating hourly rate is not accurate because it assumes that all positions are contributing time equally and in fact assumes that 1/3 of all time is contributed by administrative assistants. During an actual audit, higher level staff such as the Compliance Officer are contributing more time than administrative assistants and other lower level staff, meaning that costs would higher than the average of all salaries. Furthermore, CMS' list of eight positions involved is an underestimate. A program audit at CCA would involve senior leaders, the entire compliance department, numerous staff from operational areas, and extensive IT and administrative support, resulting in a minimum of thirty people involved. This number is based on how many staff have been necessary for our mock program audit and other continuous readiness activities and is consistent with industry practices and guidance.

Section: Burden Estimates
Subsection/field: Routine audits: "This is a total of approximately 341 hours for each sponsoring organization."
Page Number: 5
Comments: CMS' estimate of burden hour does not provide an accurate idea of time required because it does not take into account how many staff would be required for this project. For example, while eighty hours of real time might be spent with the auditors during administration, the amount of person-time is much higher because approximately thirty CCA staff members would be involved in operational webinars and the CPE site visit. The amount of time per step is also an underestimate. For example, while the operational webinars and compliance site visit may require only eighty hours of interaction with the auditor (eight hours each day for two weeks), we anticipate a substantial amount of extra time before and after the auditor sessions each day to prepare samples, conduct research, debrief, and follow up on auditor findings, meaning that each day will probably involve a minimum of ten to twelve hours of work, not eight. All told, CCA expects that it would take a minimum of 6,000 hours of person-time from thirty or more staff members for the complete process from notification to validation and close-out.

Section: Burden Summary
Subsection/field: "Total Cost of Collection Effort = $ 1,089,290" resulting in $27,232.25 per sponsor
Page Number: 13
Comments: This estimated cost is an underestimate because, as noted above, CMS does not take into account how many staff members are actually working on the audit. Multiplying hourly cost times the number of person hours, not actual time elapsed, gives a more accurate sense of the financial impact of this audit. Also, this cost estimate is based only on the number of hours the sponsor spends on the audit. It does not include the cost of hiring an independent validation auditor. Based on our previous experiences hiring outside auditors, CCA estimates that hiring an independent auditor for validation could exceed $100,000. Note that unlike internal staff costs, the independent auditor is not covered by regular salaries and so requires an additional outlay of cash.

Audit Process and Data Request- Audit Process Overview

Section: Audit Elements I-2
Subsection/field: “CMS will also conduct interviews while onsite to provide insight and

additional information on the sponsor's compliance program"
Page Number: 9
Comments: Recent communications from CMS (10/20/2015 HPMS memo and 6/16/16 Audit and Enforcement Conference) indicate that CMS will be restricting interviews to certain key staff. Adding a list of the specific roles/positions that CMS expects to interview to the protocol would be helpful for staff to understand their obligations during audit.

Audit Process and Data Request- Table 1 FTEAM

Section: Table 1: FTEAM
Subsection/field: Include list, bullet 2: "Audit and monitoring activities of first-tier entities that were conducted by the compliance department and operational areas to evaluate the compliance performance of first-tier entities."
Page Number: 12
Comments: Both the Compliance department and Operational department managing the first-tier entity relationship undertake auditing and monitoring activities. However, there is a distinction to consider. The Compliance department will receive regulatory compliance related monitoring reports from the Operational areas or from the first-tier directly. The Compliance department will also conduct regulatory compliance audits. Operational areas, in addition, monitor the first-tier as part of general oversight, for items such as work completion, financials, and operational efficiencies, as examples. These monitoring and oversight efforts are outside the scope of the Compliance department. We believe CMS's intent is to collect information on monitoring and auditing reports related to regulatory compliance, but would appreciate clarification in the direction to Table 1: FTEAM.

Audit Process and Data Request- Table 2 ECT

Section: Table 2: Employees and Compliance Team (ECT) Record Layout
Subsection/field: Column G: Direct Phone Number
Page Number: 19
Comments: It is CCA's understanding that CMS now conducts a small number of targeted employee interviews (such as with staff responsible for FDR oversight) but does not otherwise interview staff. We therefore inquire if it is still necessary for CMS to request phone numbers; if this information is not currently being used, removing it would streamline the protocol for greater efficiency. If phone numbers are still necessary, CCA requests that the existing requirement of direct dial phone numbers be revised to accommodate extensions off the main phone number. At CCA, not all employees have direct dials and the field size on the existing template is too small to include the main number plus employee extension.

Audit Process and Data Request- Table 4 IM

Section: Table 4: Internal Monitoring (IM) Record Layouts
Subsection/field: Bullet point 2: "For monitoring activities that are performed on a scheduled basis (e.g., daily, monthly, quarterly, annually), it should be included in the universe each time it was performed. If a monitoring activity is conducted daily, only include it once in the universe, but identify all deficiencies, corrective actions, etc. for all monitoring performed throughout the year."
Page Number: 25
Comments: CCA suggests that CMS allow sponsors to condense entries for weekly and monthly monitoring, as is already allowed for daily monitoring. Having to list each instance of such monitoring reports individually results in a large amount of repeat information throughout the universe and condensing this information would make the universe quicker and easier to work with for both the sponsor and CMS.

Self-Assessment Questionnaire

Section: Self-Assessment Questionnaire
Subsection/field: Overall questionnaire design
Page Number:
Comments: The self-assessment questionnaire only has "Yes" and "No" as answer choices and does not have "Not Applicable" as a choice. There are five questions that only have to be answered if a certain condition is met (example: question 9 "If employed by your parent or corporate affiliate, does your compliance officer have detailed involvement in and familiarity with your Medicare operational and compliance activities?"), but there is no clear way to indicate that the question does not apply because the condition is not met. A field for Not Applicable or directions on how a sponsor should answer when a question does not apply would be helpful.

Compliance Officer, FDR and FWA Questionnaires

Section: General comment on proposed new surveys (Compliance Officer, FWA and FDR)
Subsection/field:
Page Number:
Comments: CCA thanks CMS for these additional questionnaires that provide valuable insight into CMS' interests in the audit. They will allow sponsors to provide key information about their compliance programs and will prompt fruitful discussion between CMS and sponsors.

Organizational Structure and Governance PPT Template

Section: Entire presentation
Subsection/field:
Page Number:

Comments: The 2017 draft protocols contain four questionnaires in addition to the structure and governance presentation. Several of the questions in the presentation seem to duplicate information that would have already been provided in these questionnaires- for example, "How many first-tier entities are currently delegated to perform Medicare functions on your organization's behalf?" is asked in both the FDR questionnaire and the governance presentation. CCA encourages CMS to cross-reference all materials to remove duplicate information and increase efficiency.

PUBLIC SUBMISSION

As of: 8/11/16 12:22 PM
Received: August 01, 2016
Status: Draft
Tracking No. 1k0-8r38-svf9
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0006
MA

Submitter Information

Name: Kathryn Patterson
Address:
Boston, MA, 02108
Email: kpatterson@commonwealthcare.org

General Comment

Please see attached letter Federal Register CMS-10191 CCA Response.

Attachments

Federal Register CMS–10191 CCA Response

BCBSA July 2016 Comments_2017 Draft Medicare Advantage & Medicare Part D Audit Protocols and Data Request- Compliance Program Effectiveness (CPE), Coverage Determination Appeals & Grievances (CDAG), Organizational Determinations Appeals & Grievances (ODAG) and, Special Needs Plan Model of Care (SNP-MOC)

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Compliance Program Effectiveness (CPE) Comments				
Attachment I- Compliance Program Effectiveness (CPE) *Page 5*	CPE Audit Process- Universe Preparation & Submission	2. Pull Universes and Submit Documentation	The universes and documentation collected for this program area test the sponsor's performance in compliance program effectiveness. Sponsors will provide universes and supporting documentation that describe the framework and operation of its compliance program and universes to support the implementation of compliance activities conducted within the audit period.	We noted the removal of Fraud Waste & Abuse related activities from the universe. We request CMS clarify that a Fraud Waste and Abuse universe will not be requested during a 2017 program audit.
Attachment I- Compliance Program Effectiveness (CPE) *Page 5*	CPE Audit Process- Universe Preparation & Submission	2.2 Data Universes	Universes should be compiled using the appropriate record layouts as described in Appendix A. These record layouts include: First-Tier Entity Auditing and Monitoring (FTEAM) class drugs. Employee and Compliance Team (ECT) Internal Auditing (IA) Internal Monitoring (IM)	We noted the removal of Fraud Waste & Abuse related activities from the universe. We request CMS clarify that a Fraud Waste and Abuse universe will not be requested during a 2017 program audit.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			NOTE: For each respective universe, the sponsor should include all items that match the description for that universe for all contracts and PBPs in its organization as identified in the audit engagement letter. Please refer to Section 40 of the Medicare Parts C and D Compliance Program Guidelines for definitions, flowcharts and guidance on relationships between sponsor and first-tier entities. Please refer to Section 50.6 of the Medicare Parts C and D Compliance Program Guidelines for definitions and guidance for routine internal auditing and monitoring requirements and expectations.	
Attachment I-Compliance Program Effectiveness (CPE)	Column ID	M-Description of Deficiencies	Provide a description of all deficiencies, findings or issues identified during the audit or monitoring activity, including the root cause. If the audit or monitoring activity was identified in the	The new protocols require plans to include the root cause/root cause analysis in both "Description of Deficiencies" and "Corrective Action Description." The inclusion of "root

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Page 15			pre-audit issue summary submitted to CMS, provide the issue number in the description. For an audit or monitoring activity conducted on a daily basis, include all deficiencies identified in all audit or monitoring activities during the audit review period. Separate by a number as needed (e.g., 1. 2017/01/01 monitoring of sponsor's pharmacy network mail order identified incorrect dosage for 200 members, 2. 2017/01/02 monitoring of sponsor's pharmacy network mail order identified no issues). Answer TBD if deficiencies have yet to be identified for an ongoing activity.	cause" for each identified deficiency noted during routine monitoring of Medicare FDRs seems exhaustive for a universe pull and has the potential to be administratively burdensome to plans. We respectfully request CMS to not include the root cause analysis in the universe, but allow it to be an item for review and discussion during tracer samples. Alternatively, please revert to the approach taken in the 2016 protocol requiring the root cause only in the Corrective Action Description field. In addition, please continue to allow plans to provide a summary of the deficiencies identified instead of listing each out separately.
Attachment I-Compliance Program Effectiveness (CPE) *Page 16*	Column ID	N-Corrective Action Required	Yes (Y), No (N), or To Be Determined (TBD) indicator of whether corrective action was required for each deficiency/issue identified. Answer "Y" if every previously described deficiency identified during	We believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			the audit or monitoring activity required a corrective action. Answer "N" if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit or monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N). Answer TBD if corrective actions have yet to be determined for an ongoing activity.	one (1) response encompassing corrective actions required for all deficiencies.
Attachment I- Compliance Program Effectiveness (CPE) *Page 16*	Column ID	O- Corrective Action Description	Yes (Y), No (N), or To Be Determined (TBD) indicator of whether corrective action was required for each deficiency/issue identified. Answer "Y" if every previously described deficiency identified during the audit or monitoring activity	The inclusion of "root cause" for each identified deficiency seems exhaustive for a universe pull and has the potential to be administratively burdensome to plans. We respectfully request CMS not include the root cause analysis in the universe, but allow it to be an

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			required a corrective action. Answer "N" if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit or monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N). Answer TBD if corrective actions have yet to be determined for an ongoing activity. Provide a full description of the corrective action(s) implemented by the sponsor and FTE in response to the noncompliance or potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.	item for review and discussion during tracer samples. In addition, we believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide one (1) summary response encompassing corrective actions required for all deficiencies.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			For an audit or monitoring activity that identified multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01 pharmacy mail order monitoring activity, 2. member remediation was conducted for 50 members that never received their approved medication). Answer TBD if corrective measures have yet to be determined for an ongoing activity. Answer NA if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.	
Attachment I-Compliance Program Effectiveness (CPE)	Column ID	P-Activity Results Shared?	Describe how the results of the audit or monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior	We believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Page 17			management, and/or the FTE. For an audit or monitoring activity that identified multiple issues, separate how the results of each issue were communicated with internal and external stakeholders by a number as needed (e.g., 1. the compliance department sent the pharmacy services department a formal report of the billing errors and member impact identified during the pharmacy mail order monitoring and is responsible for the ongoing tracking and trending of the pharmacy's performance with the mail order benefit, 2. the members impacted by the pharmacy errors were communicated to the Medicare Pharmacy Officer and Pharmacy Services staff for immediate remediation). Answer TBD if results have yet to be determined and shared with others for an ongoing activity.	approach taken in the 2016 protocols, allowing plans to provide one (1) summary response encompassing how results were shared for all deficiencies.
Attachment I-	Table 3: Internal	K-Description of	Provide a full description of all	We believe the requirement to list

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Compliance Program Effectiveness (CPE) *Page 22*	Auditing (IA) Record Layout-Column ID	Deficiencies	deficiencies, findings or issues identified during the audit activity. If the audit was identified in the pre-audit issue summary submitted to CMS, please include the issue number. For an audit activity conducted on a daily basis, include all deficiencies identified in all audit activities during the audit review period. Separate by a number as needed (e.g., 1. 2017/01/01 audit of sponsor's pharmacy network mail order identified incorrect dosage for 200 members, 2. 2017/01/02 audit of sponsor's pharmacy network mail order identified no issues). Answer TBD if deficiencies have yet to be identified for an ongoing activity.	each deficiency separately has the potential to be administratively burdensome on plans. Please continue to allow plans to provide a summary of the deficiencies identified instead of listing each out separately. In addition, we noted CMS removed the "NA" option and request it be added back so it remains an option for closed audits when no issues were identified.
Attachment I-Compliance Program Effectiveness (CPE)	Table 3: Internal Auditing (IA) Record Layout-Column ID	L-Corrective Action Required	Yes (Y), No (N) or To Be Determined (TBD) indicator of whether corrective action is required for each deficiency/issue identified. Answer "Y" if every previously	We believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Page 22			described deficiency identified during the audit activity required a corrective action. Answer "N" if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N). Answer TBD if corrective actions have yet to be determined for an ongoing activity.	approach taken in the 2016 protocols, allowing plans to provide one (1) response encompassing corrective actions required for all deficiencies.
Attachment I-Compliance Program Effectiveness (CPE) *Page 23*	Table 3: Internal Auditing (IA) Record Layout-Column ID	M-Corrective Action Description	Provide a description of the corrective action(s) implemented by the sponsor in response to the noncompliance or potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective	The inclusion of "root cause" for each identified seems exhaustive for a universe pull and has the potential to be administratively burdensome to plans. We respectfully request CMS not include the root cause

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			action satisfactorily. For an audit activity that identifies multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01 pharmacy mail order audit activity, 2. member remediation was conducted for 50 members that never received their approved medication). Answer TBD if corrective measures have yet to be determined for an ongoing activity. Answer NA if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.	analysis in the universe, but allow it to be an item for review and discussion during tracer samples. In addition, we believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide one (1) summary response encompassing corrective actions required for all deficiencies.
Attachment I-Compliance Program Effectiveness (CPE)	Table 3: Internal Auditing (IA) Record Layout-Column ID	N-Audit Results Shared?	Describe how the results of the audit activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE.	We believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Page 24			For an audit activity that identified multiple issues, separate how the results of each issue were communicated with internal and external stakeholders by a number as needed (e.g., 1. the compliance department sent the pharmacy services department a formal report of the billing errors and member impact identified during the pharmacy mail order monitoring and is responsible for the ongoing tracking and trending of the pharmacy's performance with the mail order benefit, 2. the members impacted by the pharmacy errors were communicated to the Medicare Pharmacy Officer and Pharmacy Services staff for immediate remediation). Answer TBD if results have yet to be determined and shared with others for an ongoing activity.	recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide one (1) summary response encompassing how results were shared for all deficiencies.
Attachment I-	Table 4: Internal	K-Description of	Provide a full description of all	We believe the requirement o list

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Compliance Program Effectiveness (CPE) *Page 27*	Monitoring (IM) Record Layouts-Column ID	Deficiencies	deficiencies, findings or issues identified during the monitoring activity. If the monitoring activity is identified in the pre-audit issue summary submitted to CMS, please include the issue number. For a monitoring activity conducted on a daily basis, include all deficiencies identified in all monitoring activities during the audit review period. Separate by a number as needed (e.g., 1. 2017/01/01 monitoring of sponsor's pharmacy network mail order identified incorrect dosage for 200 members, 2. 2017/01/02 monitoring of sponsor's pharmacy network mail order identified no issues). Answer TBD if deficiencies have yet to be identified for an ongoing activity.	each deficiency separately has the potential to be administratively burdensome on plans. Please continue to allow plans to provide a summary of the deficiencies identified instead of listing each out separately. In addition, we noted CMS removed the "NA" option and request it be added back so it remains an option for closed audits when no issues were identified.
Attachment I-Compliance Program	Table 4: Internal Monitoring (IM) Record Layouts-	L-Corrective Action Required	Yes (Y), No (N) or To Be Determined (TBD) indicator of whether corrective action is required for each	We believe listing a response for each identified deficiency has the potential to be administratively

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Effectiveness (CPE) *Page 27*	Column ID		deficiency/issue identified. Answer TBD if corrective actions have yet to be determined for an ongoing activity. Answer "Y" if every previously described deficiency identified during the monitoring activity required a corrective action. Answer "N" if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N). Answer TBD if corrective actions have yet to be identified for an ongoing activity.	burdensome on plans. As such, we recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide one (1) response encompassing corrective actions required for all deficiencies.
Attachment I-Compliance Program	Table 4: Internal Monitoring (IM) Record Layouts-	M-Corrective Action Description	Provide a description of the corrective action(s) implemented by the sponsor in response to the noncompliance or	The inclusion of "root cause" for each identified seems exhaustive for a universe pull and has the potential

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Effectiveness (CPE) *Page 28*	Column ID		potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily. For a monitoring activity that identifies multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01, pharmacy mail order monitoring activity, 2. member remediation was conducted for 50 members that never received their approved medication). Answer TBD if corrective measures have yet to be determined for an ongoing activity. Answer NA if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.	to be administratively burdensome to plans. We respectfully request CMS not include the root cause analysis in the universe, but allow it to be an item for review and discussion during tracer samples. In addition, we believe listing a response for each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide one (1) summary response encompassing corrective actions required for all deficiencies.
Attachment I-	Table 4: Internal	N-Monitoring Results	Describe how the results of the	We believe listing a response for

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Compliance Program Effectiveness (CPE) *Page 29*	Monitoring (IM) Record Layouts-Column ID	Shared?	monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE. For a monitoring activity that identified multiple issues, separate how the results of each issue were communicated with internal and external stakeholders by a number as needed (e.g., 1. the compliance department sent the pharmacy services department a formal report of the billing errors and member impact identified during the pharmacy mail order monitoring and is responsible for the ongoing tracking and trending of the pharmacy's performance with the mail order benefit, 2. the members impacted by the pharmacy errors were communicated to the Medicare Pharmacy Officer and Pharmacy Services staff for immediate remediation).	each identified deficiency has the potential to be administratively burdensome on plans. As such, we recommend CMS revert to the approach taken in the 2016 protocols, allowing plans to provide one (1) summary response encompassing how results were shared for all deficiencies.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			Answer TBD if results have yet to be determined and shared with others for an ongoing activity.	
I-CPE	I-E SIU/FWA Prevention Detection Questionnaire.pdf		New questionnaire including 51 questions for the Medicare SIU Director	**Comment #1** When the 2017 audit protocols are compared to those of 2016, we note the Fraud Waste and Abuse Monitoring (FWAM) universe, while present in 2016, is not included in 2017. We request CMS confirm a FWAM universe will not be requested during the 2017 audit process. Additionally, we request CMS confirm a Fraud Waste and Abuse (FWA) tracer will not be a part of the 2017 audit process. If a FWA tracer becomes a part of the 2017 program audit review, please explain how the tracer will be selected given the FWAM universe is no longer part of the audit protocol. **Comment # 2**

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
				In question 25 of the SIU/FWA Prevention Detection Questionnaire, CMS is requesting information on the status of cases referred to the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) and law enforcement (LE). We request CMS clarify the time period under review for this question is 12 months as referenced in question # 23.
Coverage Determination Appeals & Grievances (CDAG) Comments				
Attachment III- Part D Coverage Determinations, Appeals and Grievances (CDAG)	Universe Preparation & Submission	2. Pull Universes	The universes collected for this program area test whether the sponsor has deficiencies related to timeliness, clinical decision making and appropriateness, and grievances and the misclassification of requests in the area of CDAG. Sponsors will provide universes of all of their expedited and standard coverage determinations	The calls received are voluminous, consist of calls received from members, providers, pharmacies, or prospective members and may be stored in multiple systems in different locations. As a result, gathering the data for this universe has the potential to be administratively burdensome for

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Page 5			(CDs) (e.g., prior authorization, step therapy authorization, etc.), all expedited and standard CD exception requests (prior authorization exception, non-formulary exception, tiering exception, etc.), all expedited and standard redeterminations (RDs), all direct member reimbursement requests (initial CDs, RDs, and overturns by review entities), all untimely CDs and RDs auto-forwarded to the Independent Review Entity (IRE), all expedited and standard IRE, Administrative Law Judge (ALJ), or Medicare Appeals Council (MAC) determinations that overturned the sponsor's decision, and all expedited and standard grievances (e.g., written correspondence, calls received by customer service representatives, etc.), as well as a call log of all calls received by the sponsor during the audit period relating to their Part D benefit. For each respective universe, the sponsor should include all cases that	plans. We respectfully request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the previous universe and sample reviews. If CMS includes the new universe in the 2017 protocols, please provide more direction regarding which calls should be included (i.e., pharmacy, provider, beneficiary, prospective members, etc.)

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			match the description for that universe for all contracts and Plan Benefit Packages (PBPs) in its organization as identified in the audit engagement letter (e.g., all standard tiering exception CDs for all contracts and PBPs in your organization). The universes should be 1) all inclusive, regardless of whether the request was determined to be favorable, partially favorable, unfavorable, auto-forwarded, dismissed, withdrawn or reopened and 2) submitted in the appropriate record layout as described in Appendix A. These record layouts include: • Table 1: Standard Coverage Determinations (SCD) • Table 2: Standard Coverage Determination Exception Requests (SCDER) • Table 3: Direct Member Reimbursement Request Coverage Determinations	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			(DMRCD) • Table 4: Expedited Coverage Determinations (ECD) • Table 5: Expedited Coverage Determination Exception Requests (ECDER) • Table 6: Standard Redeterminations (SRD) • Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) • Table 8: Expedited Redeterminations (ERD) • Table 9: Standard IRE Auto-forwarded Coverage Determinations and Redeterminations (SIRE) • Table 10: Expedited IRE Auto-forwarded Coverage Determinations and Redeterminations (EIRE) • Table 11: Standard IRE, ALJ, or MAC Determinations (SIAM) • Table 12: Direct Member Reimbursement Requests By	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			Other Review Entity (DMRRE) • Table 13: Expedited IRE, ALJ, or MAC Determinations (EIAM) • Table 14: Standard Grievances Part D (SGD) • Table 15: Expedited Grievances Part D (EGD) • Table 16: Call Logs Part D (CLD)	
Attachment III-Part D Coverage Determination, Appeals and Grievances (CDAG) Audit Process and Data Request Page 16	III. Grievances and Misclassification of Requests	1. Select Sample Cases	CMS will select a targeted sample of 10 total grievances: 7 from the standard grievances record layout and 3 from the expedited grievances record layout (Appendix A, Tables 14 and 15). The sample will consist of oral and written grievances. CMS will also select a targeted sample of 10 calls from the sponsor's Part D call logs (Table 16).	The calls received are voluminous, consist of calls received from members, providers, pharmacies, or prospective members and may be stored in multiple systems in different locations. As a result, gathering the data for this universe has the potential to be administratively burdensome for plans. We respectfully request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the previous universe and sample reviews. If the new universe is included in the 2017 protocols, we respectfully

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
				request CMS to provide more direction regarding which calls should be included (i.e., pharmacy, provider, beneficiary, prospective members, etc.)
Attachment III- Part D Coverage Determinations, Appeals and Grievances (CDAG) *Page 16*	III. Grievances and Misclassification of Requests	2. <u>Review Sample Case Documentation</u>	CMS will review all sample cases file documentation to determine that grievances were appropriately classified and that the notification properly addressed the issue raised in the grievance. CMS will also review call logs to determine that incoming calls were appropriately classified as either coverage determinations or grievances, as appropriate. The sponsor will need access to the following documents or audio files during the live webinar and may be requested to produce screenshots or transcripts of any of the following: 2.1 For Grievances: • Initial complaint:	The calls received are voluminous, consist of calls received from members, providers, pharmacies, or prospective members and may be stored in multiple systems in different locations. As a result, gathering the data for this universe has the potential to be administratively burdensome for plans. We respectfully request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the previous universe and sample reviews. If the new universe is included in the 2017 protocols, we respectfully

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			○ If complaint was received via fax/mail/email, copy of original complaint. ○ If request was received via phone, copy of CSR notes and/or documentation of call including the call details. • Copy of appointment of representative (AOR), or other conforming instrument, if patient's representative filed grievance or received notification. • Documentation explaining the grievance issue(s). ○ Copy of all notices, letters, call logs, or other documentation showing when the sponsor sent acknowledgement of grievance receipt to the beneficiary and/or	request CMS to provide more direction regarding which calls should be included (i.e., pharmacy, provider, beneficiary, prospective members, etc.)

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			requested additional information from the beneficiary and/or their representative date/time stamp of the request. If request was made via phone call, copy of call log detailing what was communicated to the enrollee. If the enrollee is complaining about a specific drug or about not having received a drug, provide any information relative to the drug in question and whether a coverage request was	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			initiated. ○ Copy of all supplemental information submitted by beneficiary and/or their representative. ▪ If information was received via fax/mail/email, copy of documentation provided. ▪ If information was received via phone, copy of CSR notes and/or documentation of call. • Documentation showing the steps the sponsor took to resolve the issue, including appropriate correspondence with other departments within the organization, referral to	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			sponsor's fraud, waste, and abuse department, outreach to network pharmacies, and description of the final resolution. • Documentation showing resolution notification to the beneficiary and/or their representative. o Copy of the written decision letter sent and documentation of date/time letter was mailed. ▪ If oral notification was given, copy of CSR notes and/or documentation of call. 2.2 For Call Logs: • Initial call record: o Date and time call received o Copy of Customer	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			Service Representative (CSR) notes and/or documentation of call details • Documentation explaining the call issue(s) o Call log audio files (recorded calls) • Documentation of how the call was processed, routed, or handled o If the call was classified as a grievance: ▪ Copy of grievance case file ▪ Copy of all notification sent to the beneficiary concerning the grievance • Documentation of resolution of issue	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			○ If the call was classified as a coverage determination or redetermination: ▪ Copy of coverage determination or redeterminatio n case file ▪ Dates and times request was initiated ○ Documentation of case file notes ○ Any notification sent to the beneficiary of the resolution ▪ If the call was classified as an inquiry ○ Any follow-up done, if applicable. ○ Call notes, dates and times of the call	
Attachment	Appendix	Appendix A—Coverage	• The universes for the Part D	In the 2017 protocols, CMS asked

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
III- Part D Coverage Determinations, Appeals and Grievances (CDAG) *Page 18*		Determinations, Appeals, and Grievances (CDAG) Record Layouts	Coverage Determination, Appeals and Grievances (CDAG) program area must be submitted in the Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file format with a header row (or Text (.txt) file format without a header row). Do not include the Column ID variable which is shown in the record layout as a reference for a field's column location in an Excel or Comma Separated Values file. Do not include additional information outside of what is dictated in the record layout. Submissions that do not strictly adhere to the record layout will be rejected. • Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field. Please ensure	plans to ensure "all cases in your universes are in one standardized time zone." We respectfully request CMS revert to the approach used in 2016 asking plans to ensure "all dates and times are entered based on the time zone where the request was received." Changing the times to a standardized time zone in the universes will require manual manipulation, which increases the opportunity for error, and will also cause the times in the universe to be different than the times noted in our systems.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			that all cases in your universes are in one standardized time zone. • If you don't have data for any of the fields identified below, please discuss that with your Auditor in Charge (AIC) prior to populating or submitting your universes. NOTE: There is a maximum of 4,000 characters per record row. Therefore, should additional characters be needed for a variable, enter this information on the next record at the appropriate start position.	
Attachment III- Part D Coverage Determinations, Appeals and Grievances (CDAG)		Table 16: Call Logs Part D Record Layout	• Include all calls received by your organization (or another entity) that relate to your Medicare Part D line of business. • Exclude any calls not relating to your Part D business (i.e., Medicare advantage, commercial).	The calls received are voluminous, consist of calls received from members, providers, pharmacies, or prospective members and may be stored in multiple systems in different locations. As a result, gathering the data for this universe has the potential to be

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Page 60			• Submit all calls based on the date the call was received by your organization, PBM or other entity.	administratively burdensome for plans. We respectfully request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the previous universe and sample reviews. If CMS includes the new universe in the 2017 protocols, please provide more direction regarding which calls should be included (i.e., pharmacy, provider, beneficiary, prospective members, etc.)
Organizational Determination Appeals & Grievances (ODAG) Comments				
Attachment IV- Part C Organizational Determinatio	Universe Preparation & Submission	2. <u>Pull Universes</u>:	The universes collected for this program area test whether the sponsor has deficiencies related to timeliness, clinical decision making and appropriateness, dismissals and grievances and the misclassification of	<u>Table 14: Call Logs Part C (CLC)Record Layout</u> The calls received are voluminous, consist of calls received from members, providers, pharmacies, or

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
ns, Appeals and Grievances (ODAG) – Audit Process and Data Request *Page 5*			requests in the area of ODAG. Instructions for what should be included in each universe are listed above the tables listed in Appendix A. For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and Plan Benefit Packages (PBPs) in its organization as identified in the audit engagement letter (e.g., all standard ODs for all contracts and PBPs in your organization). The universes should be 1) all inclusive, regardless of whether the request was determined to be favorable, partially favorable, unfavorable, auto-forwarded or dismissed and 2) submitted in the appropriate record layout as described in Appendix A. Please note that for audit purposes, partially favorable decisions are treated as denials. These record layouts include: • Table 1: Standard Pre-Service Organization Determinations (SOD) • Table 2: Expedited Pre-Service Organization Determinations	prospective members and may be stored in multiple systems in different locations. As a result, gathering the data for this universe has the potential to be administratively burdensome for plans. We respectfully request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the previous universe and sample reviews. If CMS includes the new universe in the 2017 protocols, please provide more direction regarding which calls should be included (i.e., pharmacy, provider, beneficiary, prospective members, etc.)

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			(EOD) • Table 3: Requests for Part C Payment Organization Determinations (Claims) • Table 4: Direct Member Reimbursement (DMR) Requests • Table 5: Standard Pre-Service Reconsiderations (SREC) • Table 6: Expedited Pre-Service Reconsiderations (EREC) • Table 7: Requests for Payment Reconsiderations (PREC) • Table 8: Pre-Service IRE Cases Requiring Effectuation (IREEFF) • •Table 9: IRE Payment Cases Requiring Effectuation (IREClaimsEFF) • Table 10: All ALJ and MAC Cases Requiring Effectuation (ALJMACEFF) • Table 11: Part C Oral and Written Standard Grievances (GRV_S) • Table 12: Part C Oral and Written Expedited Grievances (GRV_E) • Table 13: Dismissals (DIS) • Table 14: Call Logs Part C (CLC)	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Attachment IV- Part C Organizational Determinations, Appeals and Grievances (ODAG) – Audit Process and Data Request Page 15	IV. Dismissals	1. <u>Select Sample Cases</u>	CMS will select a targeted sample of 15 dismissals as follows • 5 pre-service dismissals; • 5 payment dismissals; and • 5 grievances.	For timeliness tests, the table on pages 6-7 of the 2017 protocols indicates Dismissals will be tested using the compliance standards for "SOD, EOD, SREC, EREC and PREC timeframes." However on page 16 CMS indicates five (5) "payment dismissals" samples will be selected for review but there is no timeliness test noted for payment dismissal on page 6. We request CMS confirm that the payment dismissals will be payment reconsideration dismissals.
Attachment IV- Part C Organizational Determinations, Appeals and	Table 1: Standard Pre-service Organization Determinations (SOD) Record Layout Column ID	N-Subsequent expedited request	If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or	In the 2016 audit protocols, element M (Request for expedited timeframe) asked who requested an expedited review for each line in the Standard Pre-service Organization Determinations (SOD) universe. The universe is for all requests processed

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Grievances (ODAG) – Audit Process and Data Request *Page 18*			sponsor (S). Answer NA if no expedited timeframe was requested.	as standard organization determinations, so element M helps identify de-expedited organization determinations. This was changed in the 2016 protocols in column N (Subsequent expedited request) and it appears CMS is only asking who requested an expedited review *after* the plan made an organization determination decision. There is no guidance indicating how the field should be populated if the case was originally received as an expedited request and later de-expedited and processed under the standard timeframe. We request CMS provide additional clarification about what is needed for column N in the 2017 protocols.
Attachment IV- Part C Organizational Determinations, Appeals and		Table 14: Call Logs Part C (CLC) Record Layout	• Include all calls received by your organization (or delegated entity) that relate to your Medicare • Part C line of business. • Exclude any calls not relating to your Part C business (e.g., Medicare Part D, commercial)	The calls received are voluminous, consist of calls received from members, providers, pharmacies, or prospective members and may be stored in multiple systems in different locations. As a result, gathering the data for this universe

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Grievances (ODAG) – Audit Process and Data Request *Page 53*			• Submit calls by the date the call was received by either your organization or another entity.	has the potential to be administratively burdensome for plans. We respectfully request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the previous universe and sample reviews. If CMS includes the new universe in the 2017 protocols, please provide more direction regarding which calls should be included (i.e., pharmacy, provider, beneficiary, prospective members, etc.)
Special Needs Plan Model of Care (SNP-MOC) Comments				
Attachment V- SNP-MOC Audit Process and Data Request *Page 3*	Audit Purpose and General Guidelines	1. Purpose	To evaluate sponsor implementation and performance in the three areas outlined below related to Special Needs Plan (SNP) model of care (MOC). The Centers for Medicare & Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted). The three audit areas are: •Population to be Served – Enrollment Verification	We recommend CMS clarify what is meant by "care coordination" and describe the specific activities which are included.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			•Care Coordination •Plan Performance Monitoring	
Attachment V- SNP-MOC Audit Process and Data Request *Page 3*	Audit Purpose and General Guidelines	2. <u>Review Period</u>	The review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017) CMS reserves the right to expand the universe request as needed. Sponsors that have operated for more than one year, but have a new/updated MOC that has been implemented for less than a year, will be assessed using the previous MOC.	**<u>Comment #1</u>** We request CMS confirm the dates cited in the example "…(for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017)" as the review period for Special Needs Plans (SNPs) that have been operational for at least a year is correct. **<u>Comment # 2</u>** We request CMS confirm the audit review period will be limited to the (13) thirteen-month period preceding the date of the audit engagement letter or if the samples will include the complete history of the member.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Attachment V- SNP-MOC Audit Process and Data Request *Page 5*	Universe Preparation & Submission	2. Pull Universes and Submit Background Information	The universes collected for this program area tests the sponsor's performance in processing enrollments, care transitions, and plan performance monitoring and evaluation of the MOC. The sponsor will provide a universe consisting of all SNP beneficiaries who have been continuously enrolled for a period of at least 13 months as of the engagement letter date. The sponsor will also submit quality measurement and performance improvement metrics utilized by your organization to monitor and evaluate the effectiveness of the MOC. All applicable fields of the plan performance monitoring and evaluation record layout should be completed; a separate record layout should be submitted for each unique MOC. The universes should be compiled using the appropriate SNP-MOC record layout as described in Appendix A. These record layouts	We request CMS clarify if 13 months "continuous enrollment" means the member was with the same plan or 13 months of continuous enrollment even though the member changed plans.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			include: • Special Needs Plan Enrollees (PE) Record Layout (Table 1) • Plan Performance Monitoring and Evaluation (PPME) Record Layout (Table 2) NOTE: For SNPE, the sponsor should include all cases that match the description for that universe for all applicable SNP contracts and PBPs in its organization as identified in the audit engagement letter (i.e., for all beneficiaries enrolled in your organization' SNPs during the review period). The sponsor will provide the following background information documentation that is applicable to the audit timeframe: • Copies of all approved Models of Care (MOC) and any (red-lined) updates to the original submissions • Copies of the CMS-approved Health Risk Assessment Tool(s) (HRA) used by the SNP • Copies of any pre-enrollment eligibility verification tools for C-SNPs & I-SNPs	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			• Copies of policies and procedures related to enrollment and eligibility verification • Copies of policies and procedures for administration of the Health Risk Assessment Tool, the development of the Individual Care Plan, the composition and functions of the Interdisciplinary Care Team, and the coordination of members' transitioning across care settings • Copies of policies and procedures on the monitoring and evaluation of the MOC • Copies of performance monitoring/evaluation report(s) submitted to MOC/quality oversight staff and/or Board • Listing of FDRs that assist with the MOC and their functions/deliverables This documentation will have the same submission deadline as the universe. The auditors will conduct a desk review of these materials prior to the audit start date to gain an understanding of the criteria and protocols the organization's SNPs implement. The background	

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			information to be submitted may have been implemented outside of the audit period, but must be in effect during the audit period. There will be no pass or fail determinations made based on the review of these documents prior to the audit.	
Attachment V- SNP-MOC Audit Process and Data Request *Page 7*	Sample Selection	1. <u>Select Sample Cases</u>	CMS will select a sample of 30 beneficiaries from the sponsor-submitted universe as follows: •% selected = % of D-SNP beneficiaries •% selected = % of I-SNP beneficiaries •% selected = % of C-SNP beneficiaries •% selected = % of MMP beneficiaries CMS will sample proportionally with a minimum of 5 for each existing SNP type to obtain a total sample size of 30. The same sample will be evaluated for the first two elements of the audit (referenced in the purpose section). The sample	We request CMS clarify if Attachment V protocol is applicable to MMPs or not.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			selection will be provided to the sponsor by the close of business on the Thursday before the Monday of the audit week.	
Attachment V- SNP-MOC Audit Process and Data Request *Page 9*	Audit Elements- I. Population to be Served – Enrollment Verification	3. <u>Sample Case Results</u>	CMS will test each of the 30 cases. If there is lack of evidence that the sponsor is implementing its MOC and if CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. NOTE: Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.	We request CMS clarify whether there is a threshold being applied to cases when determining conditions which require CARs and ICARs. In the past, when samples were reviewed and some were found to have "failed" a specific compliance standard, CMS would determine a threshold (the specific number of cases required to "fail" before a condition would be cited). If the number of "failed" cases were below the threshold, no condition was cited. Can CMS clarify for 2017, if one case does not meet one compliance standard, will that case be considered a "fail" even if all other compliance standards are met? Will CMS issue a condition requiring a CAR or ICAR if only one case "fails"? Does the one-to-one or

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
				one-to-many scenario change the way each case is scored or is it still scored as "pass" or "fail" per case and condition regardless of scope of finding? How is a CAR or ICAR identified based on cited conditions?
Attachment V- SNP-MOC Audit Process and Data Request *Page 12*	Audit Elements- II. Population to be Served – Enrollment Verification	3. <u>Sample Case Results</u>	CMS will test each of the 30 cases. If there is lack of evidence that the sponsor is implementing its MOC and if CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. NOTE: Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.	We request CMS clarify whether there is a threshold being applied to cases when determining conditions which require CARs and ICARs. In the past, when samples were reviewed and some were found to have "failed" a specific compliance standard, CMS would determine a threshold (the specific number of cases required to "fail" before a condition would be cited). If the number of "failed" cases were below the threshold, no condition was cited. Can CMS clarify for 2017, if one case does not meet one compliance standard, will that case

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
				be considered a "fail" even if all other compliance standards are met? Will CMS issue a condition requiring a CAR or ICAR if only one case "fails"? Does the one-to-one or one-to-many scenario change the way each case is scored or is it still scored as "pass" or "fail" per case and condition regardless of scope of finding? How is a CAR or ICAR identified based on cited conditions?
Attachment V- SNP-MOC Audit Process and Data Request *Page 16*	Table 1: Special Needs Plan Enrollees (SNPE) Record Layout - Column ID	H-Enrollment Mechanism	Enrollment mechanism for the beneficiary. Enter one of the following descriptions: Paper, Electronic, Telephonic or Seamless. Only enter "Seamless" if the beneficiary was already enrolled in other health plans offered by Sponsor, such as commercial or Medicaid plans, and was seamlessly enrolled into the Medicare plan.	In some cases beneficiaries have to be moved from one plan to another and passively enrolled because of mandates from CMS to plans to remove one or more eligibility diagnosis from a plan which disqualify beneficiaries from their existing plan. Based on a review of the available response options proposed to describe the enrollment mechanism in Table 1, column H, it

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
				appears as though the passive enrollment option is not being considered. We request CMS add passive enrollment as an option in Table 1, column H. As an alternative, include passive enrollment to the explanation for seamless enrollment and allow plans to choose that option when beneficiaries are moved from one plan to another and passively enrolled as a result of mandates from CMS to remove an eligibility diagnosis which renders a beneficiary ineligible for his/her current plan.
Attachment V- SNP-MOC Audit Process and Data Request *Page 16*	Column ID	K-Was an initial HRA completed 90 days before or after the enrollment effective date?	Beneficiaries should receive a Health Risk Assessment (HRA) within 90 days (before or after) their effective date of enrollment. (Yes/No) Enter Yes if the beneficiary received an initial HRA within 90 days before or after his/her effective date of enrollment. Enter No if the beneficiary did not	We request CMS clarify that the completion of an initial Health Risk Assessment (HRA) is not needed for long- term members continuously enrolled in a plan prior to January 2010.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
			receive an initial HRA within 90 days before or after his/her effective date of enrollment.	
Attachment V- SNP-MOC Audit Process and Data Request *Page 16*	Table 1: Special Needs Plan Enrollees (SNPE) Record Layout - Column ID	L-Date initial HRA was completed?	Date of the beneficiary's first HRA after enrolling. Submit in CCYY/MM/DD format (e.g., 20130101). Enter N/A if no HRA was completed	We request that CMS confirm that the format specification should reflect CCYY/MM/DD and the example reflect 2013/01/01.
Attachment V- SNP-MOC Audit Process and Data Request *Page 17*	Table 1: Special Needs Plan Enrollees (SNPE) Record Layout - Column ID	N-Date of completion for HRA conducted during current audit period	Submit in CCYY/MM/DD format (e.g., 2013/01/01). If HRA was not conducted during the current audit period, please enter the date of the most recently conducted HRA.	We request CMS follow the same logic as that used for column O and consider including an "N/A" option for when the previous Health Risk Assessment (HRA) was not conducted especially given the completion of this field is mandatory and leaving this field blank can render the universe inaccurate.
Attachment V- SNP MOC-ICP_ICT Impact		Column # 1	Date Identified (MM/DD/YY) (Completed by Team Lead)	We request CMS provide more instruction and guidance on the use of the SNP-MOC-ICP-ICT Impact spreadsheet.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
				We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-ICP_ICT Impact		Column # 2	Brief Description Of Issue (Completed by Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-ICP_ICT Impact		Column # 3	Condition Language (Completed by Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-ICP_ICT Impact		Column # 4	Related to Pre-Audit Issue Summary? (Y/N) (Completed by Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-		Column # 5	Pre-Audit Issue Summary Number (Completed by Team Lead)(If	We request CMS confirm that "Team Lead" and "CMS Team Lead"

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
ICP_ICT Impact			Applicable)	are one and the same.
Attachment V- SNP MOC-Impact		Column # 1	Date Identified (MM/DD/YY) (Completed By The Team Lead)	We request CMS provide more instruction and guidance on use of the SNP-MOC Impact spreadsheet. We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Impact		Column # 2	Completed By The CMS Team Lead) Brief Description Of Issue (Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Impact		Column # 3	Condition Language (Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment		Column # 4	Related to Pre-Audit Issue Summary?	We request CMS confirm that

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
V- SNP MOC-Impact			(Y/N)(Completed By The CMS Team Lead)	"Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Impact		Column # 5	Pre-Audit Issue Summary Number (If Applicable)(Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Training Impact		Column # 1	Date Identified (MM/DD/YY) (Completed By The CMS Team Lead)	We request CMS provide more instruction and guidance on use of the SNP-MOC Training Impact spreadsheet. We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Impact		Column # 2	Brief Description Of Issue (Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.

Att #/Descript.	Element #/Name	Sub-Category/Task	Description	Comments
Attachment V- SNP MOC-Impact		Column # 3	Condition Language (Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Impact		Column # 4	Related to Pre-Audit Issue Summary? (Y/N)(Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.
Attachment V- SNP MOC-Impact		Column # 5	Pre-Audit Issue Summary Number (If Applicable)(Completed By The CMS Team Lead)	We request CMS confirm that "Team Lead" and "CMS Team Lead" are one and the same.

PUBLIC SUBMISSION

As of: 8/11/16 2:27 PM
Received: August 10, 2016
Status: Draft
Tracking No. 1k0-8r94-35xk
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0011
DC

Submitter Information

Name: Jane Galvin
Address:
Washington, DC, 20005
Email: Jane.Galvin@bcbsa.com
Organization: BCBSA

General Comment

Attached are comments from the BlueCross BlueShield Association on CMS-10191, the Audit Protocols for Medicare Part C and D

Attachments

BCBSA comments on the draft audit protocols, attachment 1 aug 10, 2016

One CVS Drive
Woonsocket, RI 02895

Submitted via electronic submission:
https://www.regulations.gov/

August 10, 2016

Centers for Medicare & Medicaid Services

Department of Health and Human Services

P.O. Box 8016
Baltimore, MD 21244-8016

Re: 2017 Draft Program Audit Protocols (CMS-10191)

Dear CMS:

In response to the Centers for Medicare & Medicaid Services (CMS) request for comments, we welcome the opportunity to share our thoughts on the 2017 Draft Program Audit Protocols. We also commend CMS for its commitment to having provided the industry with these protocols so early this year.

We offer the attached comments in the spirit of working collaboratively with CMS to ensure beneficiary access to care and regulatory compliance.

If you have any questions, please feel free to contact me at (480) 315-8445 or Mark.Biancucci@CVSHealth.com

Thank you for your time and consideration.

Sincerely,

Mark Biancucci
CVS Health, Director Government Services Regulatory Affairs, Medicare Part D

Comments for Draft 2017 CMS Audit Protocols

Organization Name: CVS Health
Organization Contact Name: Mark Biancucci
Email Address: Mark.Biancucci@CVSHealth.com
Telephone Number: (480) 314-8445

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Draft 2017 CMS Audit Protocols: All Program Area	4	Audit Purpose and General Guidelines 4. Sponsor Disclosed and Self-Identified Issues	Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from the starting date of each universe period through the date of the audit start notice, which CMS may find in your data universes.	Since enrollment size drives the audit timeframes (i.e., months back from the engagement letter), the universe start dates will vary in the different program areas. Given this, we would like to know how CMS wants plans to determine what timeframe to use for sponsor disclosed and self-identified issues.
Draft 2017 CMS Audit Protocols: All Program Areas	Various	Appendices	Universes with common fields (i.e., Beneficiary First Name, Beneficiary Last Name, Patient Residence, Request Disposition)	We notice that some fields common to universes within and across the program areas have varying field lengths. To ensure data consistency and integrity, we recommend that CMS standardize field lengths for fields common to universes within and across the program audit protocols.
Draft 2017 CMS Audit Protocols: Part D Formulary and Benefit Administration (FA) Program Area	12, 14, 16, 19	Appendix A: Part D Formulary and Benefit Administration Record Layouts Tables 1-3, 5	Field Name: Effective Disenrollment Date	We note this is a new field and would welcome CMS providing some context for its inclusion on these universes. Also, the potential exists that beneficiaries may have multiple disenrollment dates. We would like CMS to clarify which disenrollment date to use and at what level (i.e., contract, carrier, plan).

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Draft 2017 CMS Audit Protocols: Part D Formulary and Benefit Administration (FA) Program Area	13, 14, 16, 18	Appendix A: Part D Formulary and Benefit Administration Record Layouts Tables 1-4	Field Name: Claim Quantity Description: Number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]).	As this is a new component to the description, we would like CMS to confirm that it expects plans to enter fractional values in this field when appropriate.
Draft 2017 CMS Audit Protocols: Part D Formulary and Benefit Administration (FA) Program Area	13, 14, 16, 18	Appendix A: Part D Formulary and Benefit Administration Record Layouts Tables 1-4	Field Name: Claim Days' Supply	We note the use of the possessive character on this field name. As a field in a header row, this character will require considerable resources to modify universe queries, record layouts, and quality monitoring processes. We respectfully request that this character be removed from this field name.
Draft 2017 CMS Audit Protocols: Part D Formulary and Benefit Administration (FA) Program Area	13, 14, 16	Appendix A: Part D Formulary and Benefit Administration Record Layouts Tables 1-3	Field Name: Patient Residence Description: Patient residence code for the beneficiary as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.	We noticed the removal of valid NCPDP values for this field. We would like CMS to confirm that it still expects plans to use NCPDP values in this field and that if there are no data for this field, CMS expects an entry of "UNK" and not "00".
Draft 2017 CMS Audit Protocols: Part D Formulary and Benefit Administration (FA) Program Area	13, 14, 16	Appendix A: Part D Formulary and Benefit Administration Record Layouts Tables 1-3	Field Name: Pharmacy Service Type Description: Pharmacy service type as submitted by the pharmacy. Answer "UNK" if this field is left blank by the pharmacy.	We noticed the removal of valid NCPDP values for this field. We would like CMS to confirm that it still expects plans to use valid NCPDP values in this field. Also, if a pharmacy passes an unknown value, such as 00, how would CMS like that coded?
Draft 2017 CMS Audit Protocols: Part D Formulary and Benefit Administration (FA) Program Area		Appendix A: Part D Formulary and Benefit Administration Record Layouts Tables 1-3	Field Name: CMS Part D Defined Qualified Facility	We noticed the removal of this field. We would like CMS to confirm that this field is to be removed from these universes.

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	11	Audit Elements I. Timeliness - Coverage Determinations, Appeals and Grievances (TCDAG) 3. Apply Compliance Standard: 3.2 Calculate Universe Timeliness	CMS or its contractor, when applicable, will then calculate the applicable timeliness tests as identified in the record layout chart above. Some universes will have two timeliness tests performed	For CDA expedited universes (ECD, ECDER, ERD), we understand CMS does a two-part timeliness test for standard requests upgraded to expedited: Part 1: Ensure request is processed within 24 hours of the upgrade **Part 2: Ensure case is processed within the original 72 hours**. For upgraded requests, we understand that CMS expects the fields "Date the request was received" and "Time the request was received" to be populated with the date/time of the **original standard** request. We would ask CMS to confirm if our understanding is correct. If our understanding is correct, then CMS may want to consider adding clarifying language in the descriptions for these fields.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	11	Audit Elements I. Timeliness - Coverage Determinations, Appeals and Grievances (TCDAG) 3. Apply Compliance Standard: 3.2 Calculate Universe Timeliness	CMS has determined 3 timeliness thresholds that apply to every test in each universe. Sponsors that fall at or above the first threshold will generally not be cited a condition. Sponsors that fall within the second threshold will generally be cited for a corrective action required (CAR) for unmet timeliness requirements. Sponsors falling below the third threshold may be cited an immediate corrective action (ICAR) for unmet timeliness requirements.	We would like to know if CMS has considered sharing these thresholds with plans.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations,	19, 22, 28, 32	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG)	Field Name: Patient Residence Description:	We noticed the removal of valid NCPDP values for this field. We would like CMS to confirm that it still expects plans to use

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Appeals, and Grievances (CDAG) Program Area		Record Layouts Tables 1, 2, 4, 5	Patient residence code for the beneficiary as submitted on the coverage determination or as submitted by the pharmacy on the rejected claim that led to the coverage determination. Answer “UNK” if the patient residence is unknown. .	NCPDP values in this field and that if there are no data for this field, CMS expects an entry of “UNK” and not “00”.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	29, 33	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Tables 4, 5	Field Name: Was request initially made under the standard timeframe but processed by the plan under the expedited timeframe? Description: Yes (Y)/No (N) indicator of whether the initial request made under the standard timeframe was processed under the expedited timeframe based on updated request to expedite from enrollee, their authorized representative, or their prescriber, or based on medical exigency as determined by the sponsor. Answer NA if the initial request was made under the expedited timeframe.	We would ask that CMS clarify what is meant by “medical exigency” and what criteria should be used to determine this.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	46, 48	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Tables 9, 10	Field Name: Time the request was received Description: Provide the time of day the request was received from the enrollee, their authorized representative, or their prescriber. Time is in HH:MM:SS military time format (e.g., 23:59:59). Enter NA if the request was a reimbursement or a redetermination.	We noted that the descriptions for this field do not match as Table 10 (EIRE universe) does not contain the underlined statement. We would ask CMS to clarify if this field in Table 10 does not require such a designation.

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	19, 24, 30, 34, 37	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Tables 1, 2, 4, 5, 6	Field Name: Was the request denied for lack of medical necessity? Description: Yes (Y)/No (N) indicator of whether request denied for lack of medical necessity. Answer NA if the request was not denied (i.e., approved, auto-forwarded, dismissed, withdrawn). .	We would ask CMS to clarify if "NA" should also include re-openings.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	37	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Table 6	Field Name: If denied for lack of medical necessity, was the review completed by a physician ? Description: Yes (Y)/No (N) indicator of review by physician if case was denied for lack of medical necessity. Answer NA if the request was not denied for lack of medical necessity or not denied (e.g., approved).	We noted the field name and description do not match what we believe to be the same field and description in Tables 1, 2, 4, and 5 (field name: If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional?; description: Yes (Y)/No (N) indicator of review by physician or other appropriate health care professional if case was denied for lack of medical necessity. Answer NA if the request was not denied for lack of medical necessity or the request was not denied (i.e., approved, auto-forwarded, dismissed, withdrawn)) We would ask CMS to please clarify this.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	37	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Table 6	Field Name: Date effectuated in the plan's system Description: Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g., 2017/01/01). Answer NA if request was	We noted the description for this field does not match the description found in Tables 1, 2, 4, and 5 (field name: If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional?; description: Date effectuated in the plan's system. Submit in CCYY/MM/DD format (e.g.,

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
			not approved (e.g., denied, auto-forwarded).	2017/01/01). Answer NA for requests that were not approved (e.g. denials/auto-forwards). We would ask CMS to please clarify this.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	36, 42	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Tables 6, 8	Field Name: Patient Residence	We noted the removal of this field from these universes (SRD, ERD). We would ask CMS to confirm if this is correct.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	36	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Table 6	Field Name: Time of plan decision	We noted the removal of this field from this universe (SRD) yet its presence on the ERD universe (Table 8). We would ask CMS to confirm if this is correct.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	27, 40	Appendix A - Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts Tables 3, 7	Field Name: Date reimbursement provided Description: Date check or reimbursement provided to the enrollee (i.e., mailed to the enrollee). Submit in CCYY/MM/DD format (e.g., 2017/01/01). Answer NA if the request was not approved, or if check was not provided.	We would ask CMS to clarify what would constitute a reimbursement beyond a check. Also, we would ask CMS to clarify if "NA" would still apply for IRE auto-forwards.
Draft 2017 CMS Audit Protocols: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area	16	III. Grievances and Misclassification of Requests 3. Select Sample Cases:	CMS will select a targeted sample of 10 total grievances: 7 from the standard grievances record layout and 3 from the expedited grievances record layout (Appendix A, Tables 14 and 15)	We would ask CMS to clarify its sampling approach in the event a plan does not have any expedited grievances.
Draft 2017 CMS Audit Protocols:	17	III. Grievances and Misclassification of	3.1 Was the case or call correctly classified, and if not, was it quickly	We noted new protocols reflecting CMS intent to review call logs. Call Centers

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area		Requests 3. Apply Compliance Standard:	transferred to the appropriate process?	typically handle beneficiary calls and reflect an operational area separate from CDA and Grievances. We would ask CMS to consider expanding the CDAG program area to include Call Center Operations and attribute any issues or best practices identified during program audits to that area rather than to Grievances.
Draft 2017 CMS Audit Protocols: Part D Medication Therapy Management (MTM) Program Area PILOT	13, 17	Appendix A - Medication Therapy Management (MTM) Record Layouts Tables 1, 2	Field Name: Was the beneficiary residing in a long term care facility?	For Prescription Drug Plans (PDP) in particular, we have found this field challenging to populate using claim-level data. We would welcome CMS input on how it has seen the industry populate this field.
Draft 2017 CMS Audit Protocols: Part D Medication Therapy Management (MTM) Program Area PILOT		Appendix A - Medication Therapy Management (MTM) Record Layouts Tables 1, 2	Field Name: CMS Part D Defined Qualified Facility	We noticed the removal of this field. We would like CMS to confirm that this field is to be removed from these universes.
Draft 2017 CMS Audit Protocols: Part C and D Compliance Program Effectiveness (CPE) Program Area		Entire document		We welcome how CMS has re-organized and clarified the protocols for this program area. In particular, we note how CMS has re-organized the audit elements into core prevention, detection, and correction controls and activities that better reflect and support a more holistic view of the 7 elements. Given the extensiveness of these protocol changes, we would like to know if CMS intends to update Chapter 9 of the Prescription Drug Benefit Manual and Chapter 11 of Medicare Managed Care Manual.

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
Draft 2017 CMS Audit Protocols: Part C and D Compliance Program Effectiveness (CPE) Program Area	7	Tracer Evaluation 2. Tracer Summary and Documentation Reviews: 2.1 Tracer Summary	For each selected case, sponsors should prepare a written document that provides the specific facts, rationales, and decisions and describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor in chronological order.	We noted the removal of the Tracer PowerPoint template. We would like to know if CMS intends to provide a template that plans should use for the newly requested tracer narrative(s).
Draft 2017 CMS Audit Protocols: Part C and D Compliance Program Effectiveness (CPE) Program Area	8	Tracer Evaluation 3. Submit Tracer Documentation to CMS	Sponsors should be prepared to provide only the supporting documentation that is specific for each tracer either by uploading to the Health Plan Management System (HPMS) or onsite.	We would like to know if CMS would also accept submission of this documentation via Secure File Transfer Protocol (SFTP)
Draft 2017 CMS Audit Protocols: Part C and D Compliance Program Effectiveness (CPE) Program Area		Appendix	Table 5: Fraud Waste and Abuse Monitoring (FWAM)	We noted the removal of this universe from the protocols. We would ask CMS to confirm if this is correct.
Draft 2017 CMS Audit Protocols: Part D Organization Determinations, Appeals, and Grievances (ODAG) Program Area	6	Universe Preparation & Submission 4. Timeliness Tests	CMS will run the tests indicated below on each universe except for Table 14: Call Logs Part C. For the effectuation tests, auditors will determine percentage of timely cases from a sponsor's approvals (favorable cases). For the notification timeliness tests, auditors will determine the percentage of timely cases from a full universe of approvals and denials.	We would like to know if CMS intends to align its timeliness testing with the CDAG program audit protocols. Specifically, for ODAG, will CMS also use the following standard: If more than one universe tests the same compliance standard, multiple timeliness tests results will be merged for one overall score.
Draft 2017 CMS Audit Protocols: Part D Organization Determinations, Appeals, and Grievances (ODAG) Program Area	18, 21, 31, 34	Appendix Tables 1, 2, 5, 6	Field Name: Who made the request? Description: Indicate whether the pre-service request was made by a contract	We would like CMS to clarify the "Note" section of this description. Specifically, does the provider also have to be the provider performing the service?

Document Title	Page Numbers	Section Title	Specific Text from Document that is being commented upon	Comment to CMS
			provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR). Note, the term "provider" encompasses physicians and facilities.	
Draft 2017 CMS Audit Protocols: Part D Organization Determinations, Appeals, and Grievances (ODAG) Program Area	51	Appendix Tables 13	Field Name: Person who made the request? Description: Indicate whether the request was made by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR).	We noted the field name and description on this table does not match the field name and description found in Tables 1, 2, 5, and 6 (field name: Who made the request?; description: Indicate whether the pre-service request was made by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR). Note, the term "provider" encompasses physicians and facilities

PUBLIC SUBMISSION

As of: 8/11/16 12:42 PM
Received: August 10, 2016
Status: Draft
Tracking No. 1k0-8r94-t04y
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0010
AZ

Submitter Information

Name: Kathleen Abbott
Address:
Scottsdale, AZ, 85260
Email: Kathleen.Abbott@CVSHealth.com

General Comment

Good Day!

In response to the Centers for Medicare & Medicaid Services (CMS) request for comments (CMS-10191), please find attached a cover letter and comments from CVS Health.

Thank you!

Attachments

CMS-10191_CVS Health_2017 Audit Protocols Comments Letter 08-10-16

CMS-10191_CVS Health Comments for Draft 2017 CMS Audit Protocols - Final for CMS

2017 Audit Protocols - Feedback & Questions as submitted by BCBSA as attachment II

Contact: Jane Galvin, BCBSA, Jane.Galvin@bcbsa.com

Program Area	Table Name	Table #	Column #	Column Description	Feedback/Question
ODAG	Standard Pre-Service Organization Determinations (SOD) Record Layout	1	N/A	N/A	If a standard pre-service organization determination requests more than one service include all of the request's line items in a single row and enter the multiple line items as a single organization determination request. How is this different then what is done today based on the current Protocol?
ODAG	Part C Oral & Written Standard Grievances (GRV_S)	11	I	Category of the grievance/complaint	Column I has a maximum length of 50 characters. One of the valid responses, 'Organization Determination and Reconsideration Process' is 54 characters in length.
ODAG	Call Logs Part C (CLC)	14	N/A	N/A	This guidance states to include all calls. If several calls are made to resolve the grievance, are all of the calls required to be listed on this table? For example, if we have to make an outbound call to the provider as part of the grievance resolution process, should that call be included on the table? The guidance states that CMS will also select a targeted sample of 10 calls from the sponsor's Part C Call Logs. Are we expected to provide the recording of the call? If we are expected to provide recordings of all calls on the table, should we exclude any calls for which we do not have an audio recording?
ODAG	Call Logs Part C (CLC)	14	N/A	N/A	Please clarify if when the call starts in Customer Service and then gets transferred to the clinical department for authorization, whether those cases should be included in Table 14 or Tables 1 and 2? Should table 14 only include call logs from Customer Service that are not organization determinations?
CDAG	Call Logs Part D	16	N/A	N/A	This guidance states to include all calls. If several calls are made to resolve the grievance, are all of the calls required to be listed on this table? For example, if we have to make an outbound call to the provider as part of the grievance resolution process, should that call be included on the table? The guidance states that CMS will also select a targeted sample of 10 calls from the sponsor's Part C Call Logs. Are we expected to provide the recording of the call? If we are expected to provide recordings of all calls on the table, should we exclude any calls for which we do not have an audio recording?

Part D MTM	CY 2016 Medication Therapy Management Program (MTM-2016)	2	A-AN	Various	The audit year over year variations (e.g., expansion (Column ID: A – AN) and contraction (Column ID: A – T)) in the criteria for a calendar year (CY) universe file layout is programmatically challenging. We recommend whether the layout of Column ID: A – AN or Column ID: A – T is used, that it remain as consistent as possible year over year.
Part D MTM	CY 2016 Medication Therapy Management Program (MTM-2016)	2	N/A	N/A	Recommend that a CY universe layout remain as consistent as possible, regardless of the year the audit is performed in. Changes should be limited to only those necessitated as a result of year over year difference in Technical Specifications. For example the CY2015 Universe used in audit year 2016 should be consistent (static) in audit year 2017.
Part D MTM	CY 2016 Medication Therapy Management Program (MTM-2016)	2	N/A	N/A	Some of the audit universe elements are not currently required in annual CMS MTMP reporting and Technical Specification documentation and are therefore not currently captured in MTM software programs, additional design and programming would be necessary to meet the requirements. Examples include TMR Intervention Description(s).
Part D MTM	CY 2016 Medication Therapy Management Program (MTM-2016)	2	Various	Various	CMS has introduced year over year inconsistencies by alternating CY requirements using “first” or “last” date associated with certain report elements resulting in substantial report programming. Examples include: 1) CY2015 last CY2015 contract ID that offered an MTM program and CY2016 the first contract ID that offered an MTM program; 2) CY2015 Last effective date of auto-enrollment and CY2016 First effective date of auto-enrollment; and 3) …beneficiary opted-out of the last auto-enrollment in a CY2015 MTM program and…first auto-enrollment in a CY2016 MTM program.
Part D MTM	CY 2015 Medication Therapy Management Program (MTM-2015)	2	G	N/A	Column ID “G” in CY2015 criteria appears to have been omitted.
Part D MTM	CY 2016 Medication Therapy Management Program (MTM-2016)	2	AA	Date 1st CMR Delivery Method	Column ID “AA” in CY2016 criteria cites CY2015, we believe this is an error and should cite CY2016
Part D MTM	CY 2016 Medication Therapy Management Program (MTM-2016)	2	N/A	TMR Intervention Description(s)	CY2016 universe Column ID: AJ follow up intervention criteria lists the reporting options as “Accepted” or “Denied” recommendations. Although many prescribers formally respond with an acceptance or a denial, not all prescribers respond. MMS recommends the addition of “unknown” (Adherence/Unknown) as a reportable option for instances when a prescriber does not respond.
CPE SIU FWA Prevention Detection Questionnaire	N/A	N/A	N/A	N/A	Q8. About what percentage of the workload is spent on Medicare? Investigations typically include all lines of business. How does CMS recommend we capture the percentage of workload spent on Medicare? Also, what does workload include?

CPE SIU FWA Prevention Detection Questionnaire	N/A	N/A	N/A	N/A	Q10, 11, 12, 13 and 14 ask about hotlines for noncompliance and/or FWA issues. When a plan maintains separate hotlines for noncompliance and FWA and the answers may be different, will CMS consider separating the questions?
CPE SIU FWA Prevention Detection Questionnaire	N/A	N/A	N/A	N/A	Q19. Have you found it challenging to complete investigations due to resource or time constraints? What is CMS' expectation when the answer is Yes? Plans feel as though they must answer No to avoid unduly scrutiny.

PUBLIC SUBMISSION

As of: 8/11/16 2:30 PM
Received: August 10, 2016
Status: Draft
Tracking No. 1k0-8r95-21jf
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0012
DC

Submitter Information

Name: Jane Galvin
Address:
Washington, DC, 20005
Email: Jane.Galvin@bcbsa.com
Organization: BCBSA

General Comment

Attached are additional comments from the Blue Cross Blue Shield Association on the Medicare Part C and D Audit protocols

Attachments

2017 Audit Protocols BCBSA attachment 2

PUBLIC SUBMISSION

As of: 8/11/16 2:34 PM
Received: August 10, 2016
Status: Draft
Tracking No. 1k0-8r97-y9pg
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0013
OR

Submitter Information

Name: Anonymous Anonymous
Address:
OR, 97123

General Comment

Agency collection number: CMS-10191
Document number: 2016-13917
Document citation: 1 FR 38187

CDAG Part D Coverage Determination and Redetermination Auto-Forwarding to IRE
While all sponsors strive to be timely in regards to CDAG determinations, some determinations inevitably are found after 24 hours of the expiration of the coverage determination timeframe. Current guidance instructs plans to forward to the IRE in all scenarios. This however, can delay care for medically appropriate treatments. We have had cases that can be approved based on documentation provided, but instead are required to forward to the IRE. For example, a recent case took the IRE 93 days to make a determination in which the beneficiary met our CMS approved criteria. Meanwhile, the beneficiary was without medically appropriate treatment for 3 months. This seems to punish the member, and can put their health at risk, instead of the sponsor when forwarding cases that may be approved.

ODAG Record Layout 4 Direct Member Reimbursement and Record Layout 7 Requests for Payment Reconsiderations (PREC)
On both the Direct Member Reimbursement and Payment Reconsiderations (PREC) record layouts there is a column that states "Was interest paid on the reimbursement request". The time-frame to process these requests is 60 days. Per 42 CFR 422.520(a) a MA organization must pay interest on clean claims that are not paid within 30 days. The type of claims that require interest payments and the timeframe for processing these claims are not consistent with what is to be reported in these record layouts.

2017 Medicare Parts C and D Program Audit Protocols and Data Requests
To assist organizations with identifying the latest changes to the Final 2017 Audit Protocols, can the updates be identified on the document? Such as red-lining the changes, as we have seen with other forms of updated guidance from CMS.

CDAG and ODAG Timeliness Tests

For timeliness test that are conducted by a count of days it would be extremely helpful if CMS could specify when the clocks starts on the Audit protocol documents. The chapter guidance referenced on these tables has been interpreted by our organization to state that the day the request was received is considered Day 1. If this is not actually the case and the timeliness test during a Program audit would be calculated differently, such as counting day 1 as 24 hours after the request was received, this should be stated in the column "Compliance standard to apply". Transparency on how CMS administers the timeliness tests as stated on Page 6 of the ODAG Audit Process and Data Request and on Page 7 of the CDAG Audit Process and Data Request would allow MA organizations the ability to report and monitor the timeliness associated with these requests in same manner as CMS.

Call Logs Part C and D

Feedback on this exclusion that is stated on both the Part C and Call Log record layouts: "Exclude any calls not relating to your Part C business (e.g., Medicare Part D, commercial)" OR "Exclude any calls not relating to your Part D business (e.g., Medicare Part C, commercial)"

A customer service representatives can intake a call that relates to both Part C and Part D. The single call is documented once. Can CMS re-evaluate this exclusion as it would be extremely difficult to only pull the portion of the call that pertains to the appropriate record layout? Perhaps stating that if a call contains both Part C and D information it can be recorded on both record layouts.

PUBLIC SUBMISSION

As of: 9/1/16 2:09 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rac-au59
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0020
PA

Submitter Information

Name: Cathie Fartely
Address:
Harrisburg, PA, 17177
Email: cathie.fartely@capbluecross.com

General Comment

1. ODAG Table 14 and CDAG Table 16 - The instructions state to include all calls received by your organization that relate to your Medicare Part C/Part D line of business.
a. Are plans only to report calls from members or are plans to report calls from both members and providers?
2. The field lengths vary from ODAG Table 14 and CDAG Table 16. The identical fields that differ are:
a. A, Beneficiary First Name, field lengths 50 (ODAG) & 30 (CDAG).
b. B, Beneficiary Last Name, field lengths 50 (ODAG) & 30 (CDAG).
c. I & J, Description of the Call, field length 750 (ODAG) & 2000 (CDAG).
d. J & K, Resolution Description/Description of the Outcome of the Call, field length 3000 (ODAG) & 1000 (CDAG).
3. Table 5 & 7 CDAG, Request Disposition, Columns V & O.
a. The field length is 16, not 20 as all other CDAG tables show.
b. The field length of 16 does not accommodate the new values.
4. CDAG Tables 14 (Standard Grievances (SGD)) & 15 (Expedited Grievances, Part D (EGD)), How was the Grievance Received?
a. The field length value is 7 for Table 14, and 40 for Table 15.
5. CDAG Table 15 (Expedited Grievances, Part D [EGD]), Column J, Category of the grievance/complaint.
a. This table is for expedited grievances and according to Chapter 18, the only time a Part D grievance is expedited is when the plan "refuses to expedite a coverage determination or a redetermination" and the member has not already received/purchased the drug in question. Based on Chapter 18 guidance, the remaining categories listed would not appear as applicable to an expedited grievance. Please clarify.
6. ODAG tables 5 & 6, Column 'N'.
a. Please clarify when plans would be required to use the value CP? The description indicates to use BR if a contract provider submitted an expedited reconsideration as the enrollee's representative. A contracted

provider can always appeal on a beneficiary's behalf, but it is always considered a beneficiary appeal.
7. ODAG table 7 :
a. Please clarify what is being requested on this table. It's titled "Requests for Payment Reconsideration" and states to include all requests processed as payment reconsiderations from non-contract providers. However, it states to submit payment reconsiderations based on the date the reconsideration was paid or denied. Is CMS requesting the decision date of the reconsideration? Or the payment date of an approved reconsideration? Either or?
b. It also states that if a claim has more than one line, include all of the claim's line items in a single row and enter the multiple line items as a single claim. This table is for reconsiderations, not claims, correct?
c. This entire table and associated instructions are confusing in that at times the descriptions appear to relate to a claim and not a reconsideration.
8. ODAG Table 9:
a. Column J, in prior years, there was an NA value available and it's not there for 2017, however, the field length is still 2. Is NA permissible?
9. ODAG Tables 1, 2, 5, & 6.
a. The exclusion bullet states, in part, to exclude duplicate claims, payment adjustments to claims, claims that are denied for invalid billing codes, billing errors, denied claims for bundled or separately payable items, denied claims for beneficiaries who are not enrolled on the date of service, and claims denied due to recoupment of payment. Should this information be on Table 3 instead? It doesn't seem to make sense on Tables 1, 2, 5, & 6.
10. We would also ask that CMS consider stabilizing established tables and fields going forward, providing consistency for plan reporting.

Thank you.

Humana Inc.
500 W. Main St.
Louisville, KY 40202-2946
www.humana.com

Humana

August 12, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Attention: CMS–10191, Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

RE: Humana Comments on Medicare Parts C and D Program Audit Protocols and Data Requests

To whom it may concern:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the Medicare Parts C and D Program Audit Protocols and Data Requests. The request was published in the June 13, 2016, issue of the *Federal Register*.

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 3.18 million members and Medicare Prescription Drug Plans (PDPs) with approximately 4.68 million members, we are distinguished by our near 30-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. As evidence of the quality of care our members receive, Humana received a 4.5-star rating on CMS's 5-Star Rating System for six MA contracts offered in Delaware, Florida, Illinois, Louisiana, Michigan, Montana, Tennessee, Virginia and Wisconsin, an increase from five such contracts last year. Humana has 18 MA contracts rated four Stars or above and over 2.5 million members in four Stars or above rated contracts to be offered in 2016.

As always, we value this opportunity to provide comments and are pleased to answer any questions you may have with respect to the comments below.

Sincerely,

Heidi S. Margulis
Senior Vice President, Corporate Affairs
hmargulis@humana.com

Technical Comments on CMS–10191 Medicare Parts C and D Program Audit Protocols and Data Requests

Formulary and Benefit Administration Program Area Audit Process and Data Request
Attachment II, Formulary and Benefit Administration (FA) Program Area Audit Process and Data Request Tables 1-4 have Claim Quantity with the Field Length set at 10 characters.

> Comment: Humana recommends that the Claim Quantity Field Length be increased from 10 to 11 characters to match the D.0 (NCPDP) standard and avoid truncation.

Appendix A—Coverage Determinations, Appeals, and Grievances (CDAG)
CMS notes that there is a maximum of 4,000 characters per record row. CMS instructs that should additional characters be needed for a variable, the information should be entered on the next record at the appropriate start position.

> Comment: It does not appear that any of the tables have a combined total of field lengths that exceed 4,000 characters. Humana requests an example of this scenario, and how a continuation of characters should be represented in universe data.

CDAG Maximum Description field length Tables 14-16
The maximum description field length was reduced in each of these tables, in some cases to as few as 1,500 characters.

> Comment: Humana recommends maintaining the field length to previous protocol character amounts.

Organization Determinations, Appeals and Grievances (ODAG) Appendix A—Organization Determinations and Appeals and Grievances (ODAG) Record Layout
CMS notes that there is a maximum of 4,000 characters per record row.

> Comment: Humana requests an example of this scenario, and how a continuation of characters should be represented in universe data.

Attachment IV, Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request Table 1
Standard Pre-Service Organization Determination (SOD) Column N - Subsequent expedited request: If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.

> Comment: Column N refers to "subsequent expedited requests." Humana believes that subsequent expedited request cases would appear in Column O on Table 2: Expedited Pre-Service Organization Determinations (EOD) since they are truly expedited requests. In addition, Table 1: SOD states that "all requests processed as expedited organization determinations are excluded." We recommend removing "subsequent expedited requests" from Table 1: SOD.

Attachment IV, Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request Table 2

Expedited Pre-service Organization Determinations (EOD) Column G - Who made the request?: Indicate whether the pre-service request was made by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR). Note, the term "provider" encompasses physicians and facilities. Column I - Date the request was received: Provide the date the request was received by your organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Column O - Subsequent expedited request: If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.

> Comment: In Table 2 EOD, when an authorization request is originally received as a standard request and then later a second request upgrades the case to expedited please clarify: (1) Should Column I reflect the date of the first request or the expedited request; (2) Should who made the request under Column G reflect the person who made the first request; and (3) Should Column O reflect who made the later expedited request? If the receipt date under Column I is clarified as the original standard request, should we capture the date we received the request to upgrade the review to an expedited status?
>
> Also for Table 2: EOD, if you have a request that was initially received as an expedited request, please confirm that this is another instance for which you would populate Column O as "NA" in addition to no expedited timeframe being requested. We believe that you should answer "NA" if no expedited timeframe was requested or if the request was initially received as an expedited request.

Attachment IV, Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request Table 3

Requests for Payment Organization Determinations (Claims): 1) Include all requests processed as both contract and non-contract provider denied claims and only non-contract provider paid claims; and 2) Exclude all requests processed as direct member reimbursements, duplicate claims and payment adjustments to claims, reopenings, claims denied for invalid billing codes, denied claims for beneficiaries who are not enrolled on the date of service and claims denied due to recoupment of payment. Column H - Is this a clean claim?; Yes/No indicator flag to indicate whether the claim is clean (Y) or unclean (N). Answer NA for untimely requests that are still open. Column K - Issue description and type of service: Provide a description of the service, medical supply or drug requested and why it was requested (if known). For denials, also provide an explanation of why the pre-service reconsideration request was denied. Column K - Issue description and type of service: Provide a description of the service, medical supply or drug requested and why it was requested (if known). For denials, also provide an explanation of why the direct member reimbursement request was denied.

> Comment: Humana recommends excluding Part B drug claims from Table 3. We also recommend that if a claim is an open untimely request, but the claim has been identified as either clean or unclean, you may indicate Y or N. For Column K recommend that populating the first denial code and rationale associated with a claim denial in the "Issue description and type of service" data field as the "explanation of why the claim was denied" is appropriate for payment requests included in ODAG Tables 3 and 4.

Attachment IV, Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request Table 4

Direct Member Reimbursement (DMR) Requests exclude all requests processed as contract and non-contract provider claims.

> Comment: Humana recommends excluding Part B drug claims from Table 4.

Attachment IV, Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request Table 11

Part C Oral & Written Standard Grievances (GRV_S) Column J - Issue Description: Field Length 300 and Table 12: Part C Oral & Written Expedited Grievances (GRV_E) Column K - Issue Description: Field Length 300.

> Comment: This is the same restriction in the 2015/2016 protocol. We believe the 300 character length description may be a typo. Humana recommends modifying the Issue Description field length to 3,000 characters, to match the allowable field length for Resolution Descriptions.

Attachment IV, Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request Table 14

Call Logs Part C (CLC): 1) include all calls received by your organization (or delegated entity) that relate to your Medicare Part C line of business; 2) exclude any calls not relating to your Part C business (e.g., Medicare Part D, commercial); and 3) submit calls by the date the call was received by either your organization or another entity. Column I - Description of the Call: Field Length 750.

> Comment: It appears that only inbound calls received by Customer Service Representatives (CSRs) within the member call centers are included within this table. Please confirm that this table would not include calls received by a clinical team regarding care management or transferred organization determination requests. The maximum issue description field length is limited to 750 characters and may not allow sufficient space for a proper description. Humana recommends that the field length be 3,000 characters to match the Resolution Description field.

Special Needs Plans - Model of Care (SNP-MOC) Audit Purpose and General Guidelines

Review Period: The review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017). CMS reserves the right to expand the universe request as needed. Sponsors that have operated for more than one year, but have a new/updated MOC that has been implemented for less than a year, will be assessed using the previous MOC.

> Comment: Humana believes there is an error in the year for the engagement letter date. Please confirm that the engagement letter date for the example is intended to be January 25, 2017, instead of January 25, 2016.

Attachment V, Special Needs Plan Model of Care (SNP-MOC) Program Area Audit Process and Data Request

Sample Selection 1. Select Sample Cases: CMS will select a sample of 30 beneficiaries from the sponsor-submitted universe as follows: % selected = % of D-SNP beneficiaries, % selected = % of I-SNP beneficiaries, % selected = % of C-SNP beneficiaries, and % selected = % of MMP beneficiaries Table 1:

Special Needs Plan Enrollees (SNPE) Column G - Plan Type: Type of SNP. Valid values are: D-SNP (for dual-eligible beneficiaries), C-SNP (for beneficiaries in a chronic needs plan), and I-SNP (for beneficiaries in an institutional care setting).

> Comment: The sample selection now includes MMP, yet Column G under Table 1: SNPE does not include MMP as a choice under Plan Type.

Attachment, VI Medication Therapy Management (MTM) Program Area Audit Process and Data Request

Table 1. CY 2015 Medication Therapy Management Program (MTM-2015) Record Layout

> Comment: Columns A through F are located on page 11 and then page 12 begins with Column H. It appears that Column G was inadvertently omitted.

PUBLIC SUBMISSION

As of: 9/1/16 2:06 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rac-gdku
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0019
DC

Submitter Information

Name: Mark Newsom
Address:
Washington, DC, 20004
Email: mnewsom@humana.com

General Comment

See attached file(s)

Attachments

Humana audit protocol comments 8-12-16

PUBLIC SUBMISSION

As of: 9/1/16 2:11 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rad-x74p
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0021
NJ

Submitter Information

Name: Mario Vargas
Address:
Newark, NJ, 07105
Email: mario_vargas@horizonblue.com

General Comment

Agency Collection Number: CMS-10191
Document Number: 2016-13917
Document Citation: 81 FR 38187

1. Professional Claims - ODAG Protocols

Based on the Type of Service description requirement when a multi-line claim contains more than one type of service a single claim displays more than once in the claim universe.

Question: When a multi-line claim with more than one type of service causes a claim to display more than once should we include every line in that claim or should a hierarchy requirement be established for every possible type of service combination so that only 1 claim appears?

2. Special Needs Plan Model of Care Program Area Audit Process and Data Request (Preview Period - Page 3)

There appears to be an error in year for the review period example that was provided: "The review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017) CMS reserves the right to expand the universe request as needed."

3. Part C and D Compliance Program Effectiveness Program Area Audit Process and Data Request

(Tracer Evaluation - Page 7)

Please add language specifying when the samples for the CPE tracers will be provided to plans and when plans must submit completed tracers back to CMS.

4. Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request (Table 16: Call Logs Part D Record Layout - Page 60)
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request (Table 14: Call Logs Part C Record Layout - Page 53)

Questions: Should this universe contain calls from enrolled members only? Are calls from providers included? If so, this would be a problem because many providers call about multiple members at one time.

UCare's Comments on the Medicare Parts C and D Program Audit Protocols and Data Requests (CMS-10191)

General Comments about Review Periods:

- It would be helpful if all the Audit Process documents used consistent wording when describing the Review Period (where possible). For example, the Review Period for ODAG adds clarifying language that the day the audit engagement letter is received is included in the universe. The SNP MOC language does not use that language and instead illustrates that with an example (even though other language in the SNP MOC Review period says the universe is "the (13) thirteen month period *preceding* the date of the audit engagement letter.")
- If the review period should start on the first of a month, please state that clearly.
- Examples in the Review Period sections are helpful (please add more).

2017 Attachment IV ODAG Audit Process and Data Request:

- The document instructs "Please use a comma (,) to separate multiple values within one field if there is more than one piece of information for a specific field." Should we add spaces between the comma and the next value?
- Concerns about the new Call Log requirements.
    - This would require significant programming changes to pull this information into a universe.
    - Providers often call in about multiple members at the same time and they are not necessarily on Medicare. Not sure how this would be handled as we could not release a call for listening that had commercial member information in the call. It may be that we would have to completely change the call process for Customer Service and not allow providers to ask about more than Medicare members during a call, which would require the office to hang up and call in again.
- Concern about the requirement to use consistent time zones: Our FDR is located in a different time zone. This proposed requirement could entail converting all the times in their universe, which increases potential room for error with this process and is more burdensome.

2017 Attachment V SNP MOC Audit Process and Data Request:

- Review Period – is the new example correct? Wouldn't the review period be Dec. 1, 2014 – Jan. 25, 2016?
- We have members who have been continuously enrolled in our SNP for many, many years. Is the intent to include all of these members in the universe? If not, please clarify the instructions.
- SNPE, Column N, Date of completion for HRA conducted during current audit period – how should we complete this field if the client has never had an HRA?
- PPME, Column L, Goal Met/Not Met – These instructions do not account for a metric where the lower the threshold the better. (For example, a goal of maintaining a hospital readmission rate of 14% or less would be met if the readmission rate was less than 14%.)
- SNPE, Column H – Could you add an "other" option to help account for unique situations (for example CMS had us passively enroll certain beneficiaries when Part D was implemented)?

2017 Attachment I CPE Audit Process and Data Request:

- CPE-ECT, Column G, Direct Phone Number: what should we enter if we do not have a phone number? This could be an issue for a Board Member or temp employee.

UCare's Comments on the Medicare Parts C and D Program Audit Protocols and Data Requests (CMS-10191)

- CPE-ECT, Column H, Date of Hire: The Board of Directors are not employees and thus do not have a date of hire. Please clarify what to enter in this situation.
- CPE-ECT, Column I, Type of Employee: What should we enter for Board of Directors?
- CPE-ECT, Column L, Compliance Committee Member: Would this include both a Board of Directors Compliance Committee and an internal compliance committee?
- CPE-ECT: It can be difficult to identify employees who have job duties related to Part C and Part D.
- CPE-ECT, Column K, Compliance Department Job Description: This is confusing. The description asks for the job duties of an employee who works for the Compliance Department, but then says to answer NA if the employee does not work for or support the Compliance Department.

PUBLIC SUBMISSION

As of: 9/1/16 2:13 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rae-dwnv
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0022
MN

Submitter Information

Name: Tracy Hoisington
Address:
Minneapolis, MN, 55413
Email: thoisington@ucare.org
Organization: UCare

General Comment

See attached file(s)

Attachments

Comments 2017 Audit Protocols

Program Audit Area	Document Title	Description	Purpose	File Name	Comments for Submission to CMS
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Under section 3.2.8 of the CDAG Protocols**, one of the proposed audit protocols indicates that Health Plans would become responsible for a beneficiary receiving a therapeutic alternative or other formulary medication. Can you please expand on this? Under what circumstances would it be appropriate for the Health Plan to work with providers regarding their prescribing a formulary alternative versus utilizing the appeal rights of the member? Is there a recommended practice from CMS regarding outreach to providers regarding the requirement that they prescribe on formulary medications?
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Section I. Timeliness, 3.2** - What are the three thresholds for timeliness of cases in the various universes as noted in Section I. Timeliness, 3.2?
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Table 16 - Part D Call Logs:** Are the calls to be included in this universe from the member or member's authorized representative only, i.e., excluding provider calls and any calls by other parties?
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Table 16 - Part D Call Logs:** Are the calls to be included in this universe only customer service calls or include oral CD requests, oral grievance requests, etc.?
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Table 16 - Part D Call Logs:** We would like CMS to consider the volume of Part D call log universe. The volume could be very large based on plan sponsor size. We would recommend a shorten time frame i.e. two weeks.
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Multiple CDAG tables** include a field labeled "Date oral notification provided to enrollee". The instruction for that field now allows plans to provide a good faith effort attempt. Should plans list the first or the last good faith attempt?
CDAG	Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	CDAG audit process and data request	To evaluate Coverage Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_III_CDAG_Audit Process_Data_Request.pdf	**Multiple CDAG tables** include a field labeled "Issue Description" and the instructions for this field indicate that we must populate a reason for the denial, when applicable. What level of detail is required for this field?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 3, #4. Sponsor Disclosed and Self-Identified Issues**, statement - "Please do not include all issues identified by your organization, just those that are relevant to the areas being audited." Does this mean CMS only wants the CDAG, ODAG, SNPMOC, FA issues included on the Pre-Audit Issue Summary template? For example, if a disenrollment issue had been identified during the review period which is not one of the aforementioned areas of focus, should it be left off the template listing? Or if an FDR is audited for compliance program requirements, would that be on the listing?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 4, #4. Sponsor Disclosed and Self-Identified Issues**, statement – "Issues that are reported as uncorrected will automatically be cited as conditions in the CMS audit report." This approach penalizes sponsors who perform a high degree of self-identification of non-compliance and then require correction as part of an effective compliance program?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 5, #2.1, bullet 8** - what is the CMS definition of "Compliance Performance Mechanisms"?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 5, #2.2 Data Universes** - the FWAM universe was removed. Is it incorporated into any of the other universes or just reviewed through other data disclosures?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 12, FTEAM universe**, advises to include "FTEs that are truly delegated a function." Does CMS have a definition of "delegate" or "delegated" that their audit teams will apply across the board? Need to include the question contract date that we discussed this morning.
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 12, FTEAM universe**, advises that Downstream and FTEs that were not audited/monitored during the review period are to be excluded. Related entities that were not audited/monitored during the review period should also be excluded and listed here, correct? (They are currently not listed in the exclusion section as such.)
CPE	Attachment I-D Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) Sponsor's Accountability	Compliance Program Effectiveness (CPE) Sponsor's Accountability for and Oversight of First –Tier,	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_D_CPE_FDR Oversight_Questionnaire.pdf	**Pg 3, Question #4** – This question asks about a "Vendor Oversight Program" but no other type of FTEs so are "vendors" the only FTEs of interest here?
CPE	Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q)	Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q)	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_E_CPE_SIU_FWA Prevention_Detection_Questionnaire.pdf	**Pg 4, Questions #14 & #15 –** The numbering is off on what is being referred to in these questions. For example, Q14 advises if hotline is handled by SIU to answer Qs 13a-d but there are no 13a-d Qs – think it should state 14 a-d instead. (Same situation with Q15.)
CPE	Attachment I-E Medicare Advantage and Prescription Drug Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q)	Compliance Program Effectiveness (CPE) SIU/FWA Prevention and Detection Questionnaire (FWA-Q)	Evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_E_CPE_SIU_FWA Prevention_Detection_Questionnaire.pdf	**Question #49 & #50** – What is the definition of "FWA studies"?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Starting on Pg 12, FTEAM universe**, the fields of this universe (and others) have become more extensive for data needs and have ongoing definition changes. Field changes are problematic as they are costly and use extensive resources in order to produce the universe for CMS. Consistency is needed to ensure more automated accurate and complete universes for CMS.
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 20, IA Universe,** the Audit Frequency field has been changed to 10 characters in length and no longer include the type "incident/event-based". What Audit Frequency should be utilized for "incident/event-based"?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 21, IA Universe**, the "Number of Deficiencies" field no longer provides the instructions to populate with N/A if no deficiencies were identified or discovered. How should the field eb populated if there are no deficiencies identified.
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 21, IA Universe,** the "Description of Deficiencies" field; the instructions for what to populate when no deficiencies were discovered have not been included. Please confirm that that NA should be populated. In addition, instructions have changed for activities in progress. What should be populated for activities that are in process?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 25, IM Universe,** the "Monitoring Frequency" field has been changed to 10 characters in length and no longer includes the type "incident/event-based". However, within the top section where it states "Include: all monitoring activities (routine, scheduled and incident/event-based reviews as part of normal operations)" it includes incident/event-based"? What Monitoring Frequency should be utilized for "incident/event-based"?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 26, IM Universe,** the "Number of Deficiencies" field does not provide the instructions on how to populate if no deficiencies were identified or discovered. How should the field eb populated if there are no deficiences identified?
CPE	Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request	Compliance Program Effectiveness audit process and data request	To evaluate Compliance Program Effectiveness for MA and Part D Sponsors	508_Attachment_I_CPE_AuditProcess_DataRequest.pdf	**Pg 27, IM universe,** for the "Description of Deficiencies" field; the instructions for what to populate when no deficiencies were discovered have not been included. Please confirm that that NA should be populated. In addition, instructions have changed for activities in progress. What should be populated for activities that are in process?
FA	Part D Formulary and Benefit Administration (FA) Program Area Audit Process and Data Request	Formulary audit process and data request	To evaluate Formulary Administration Benefit Administration for MA and Part D Sponsors	508_Attachment_II_FA_AuditProcess_DataRequest.pdf	With the new focus on the November and December enrolled members and the prior year rejections- would like additional guidance using sample cases and expected outcomes to clearly express CMS' interpretation when a member should get another transition fill in the new year. Example Drug a is F with QL in 2015 and NF in 2016. If the member got a full TF fill in 2015 as a new member with enrollment date 11/1 or 12/1/2015 should they get another TF fill in 2016 since the TF reason would change. Or is the fact that they got one TF fill for the drug as a new member, and never took action to request a QL or formulary exception - be enough to deny in the new year since not ongoing therapy (most plans for non PCD drugs define ongoing as non TF fill in history &since only fill is a TF fill in history not ongoing) and thus not qualified for more. Request that CMS clearly provide examples of the expectations for transition of coverage.
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 14 - Part C Call Logs:** Are the calls to be included in this universe from the member or member's authorized representative only, i.e., excluding provider calls and any calls by other parties?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 14 - Part C Call Logs:** Are the calls to be included in this universe only customer service calls or include oral OD requests, oral grievance requests, etc.?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 1 and 2 - ODAG SOD and EOD**: contain fields labeled "Subsequent expedited request". Plans are to a value signifying the individual/entity that initiated the request for an expedited review(this sentence does not make sense). The draft 2017 protocols allow a new value for this field - "S" for sponsor. Should plans populate that field with an S only in cases where the plan decides on its own accord to expedite the case based on our assessment of the member's condition?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Multiple ODAG universes (e.g., SOD, EOD)** continue to include a Diagnosis field. The instructions for these fields now indicate that plans should populate the ICD-10 code related to the request and the NDC for drugs. In addition, are plans required to list the NDC when the request involves a drug, or do we just list the ICD-10 code? If we must list the NDC, in cases where the drug does not have a NDC, should we populate the diagnosis or "N/A"?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Multiple ODAG universes (e.g., SOD, EOD)** continue to include a field labeled "Was the request denied for lack of medical necessity?" The instructions indicate we must answer Y or N to indicate whether the claim was denied for medical necessity, NA if the request was approved, and "No" if the request was denied if it was untimely. In cases where the plan denies for untimeliness, should the field read "No" or "N"?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	What are the 3 thresholds for timeliness of cases in the various universes as noted in section I. Timeliness, 3.2?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Section IV. Dismissals** notes that 5 grievance dismissals will be selected for review against the listed criteria including sending the notice with IRE rights, etc. This process does not apply to grievances, as it applies to reconsiderations only as per the HPMS memo dated 9/10/2013. What CMS-published compliance standards will apply to grievance dismissals?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 14 - Part C Call Logs:** Are the calls to be included in this universe from members only? I.e., should we include logs from prospective member call centers as well? We believe this only applies to current members.
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 14 - Part C Call Logs:** We would like CMS to consider the volume of Part D call log universe. The volume could be very large based on plan sponsor size. We would recommend a shortened time frame, i.e. two weeks.
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	If there are not enough samples in a universe to select the CMS-stated sample size, how will the samples be chosen? For example, a universe may not contain 3 expedited grievances. Does that mean the sample size for grievances will be reduced or will the remainder be chosen from the standard grievance universe?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Tables 11 & 12, Column F:** The universe asks for us to indicate who made the request and included providers (contract and non-contract) as an option. CMS doesn't allow providers to file grievances on behalf of members unless they're authorized, at which point they would fall into the beneficiary's representative option that is included.
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	ODAG audit process and data request	To evaluate Organization Determinations, Appeals and Grievances for MA and Part D Sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**ODAG GRV-S and GRV-E tables** include a field labeled "Person who made the request". The instruction for this field contains values for grievances submitted by contract and non-contract providers. Please confirm that CMS does not intend on requesting provider complaints, since these complaints are not subject to the grievance requirements detailed in Chapter 13 of the Medicare Managed Care Manual. Rather, we believe the specification refers to member grievances filed by providers on behalf of the member.
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	Part C Organization Determinations, Appeals and Grievances (ODAG) Program - Claims Payment	Evaluate Organization Determinations-claim Payment for MAPD sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 3: Claims, Column M: Request Disposition** - Sponsors should note any requests that are untimely and not yet resolved (still outstanding) as denied. All untimely and pending cases should be treated as denials for the purposes of populating the rest of this record layout's fields. **Questions: 1.)** How will requests that are populated as a denial due to being still outstanding at the time that the record layout is populated be treated if selected as part of the audit sample and the final disposition is showing as approved? 2.) Will these be treated as a pass or a fail?
ODAG	Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request	Part C Organization Determinations, Appeals and Grievances (ODAG) Program - Claims Payment	Evaluate Organization Determinations-claim Payment for MAPD sponsors	508_Attachment_IV_ODAG_AuditProcess_DataRequest.pdf	**Table 4: DMR** **Column G: Comment:** Person who made the request - The beneficiary representative information is stored within our customer service repository when a member designates a representative. However, there is no distinction of who is submitting the request (B or BR) on the claim form, thus challenging to identify from a claim administration perspective. **Column O: Comment:** Was interest paid on the reimbursement - Please clarify the intent for LCI on Direct Requests for Member Reimbursements, our understanding that LCI does not apply. **Columns Q-S: Comment:** Direct Requests for Member Reimbursement in denied status are not auto-forwarded to IRE during claim administration. In addition, the AOR form is not a requirement for Direct Requests for Member Reimbursement during claim administration. These appear more aligned to appeals activity and not claim pay administration. **Question:** Would the appropriate response be N/A from a claim administration perspective?
SNP MOC	Special Needs Plan Model of Care (SNP MOC) Program Area Audit Process and Data Request	SNP MOC audit process and data request	Evaluate Special Needs Plan Model of Cares for MA and Part D Sponsors	508_Attachment_V_SNP-MOC_AuditProcessandDataRequest.pdf	**II. Coordination of Care Pages 10 & 11:** **2.5.4.** Did all members of the sponsor's staff that serve on the ICT receive training on the MOC? Does the sponsor have documentation of this training? **2.5.5.** Did the sponsor provide evidence of conducting outreach, training to educate network providers about the MOC? **Question:** Must the sponsor have documented evidence that Providers completed the training, or are the provider training materials sufficient for meeting this SNP compliance standard?
SNP-MOC	Special Needs Plan Model of Care (SNP-MOC) Audit Process and Data Request	Appendix A – Special Needs Plan Model of Care (SNP MOC) Record Layouts	Determine the correct date submission for initial HRA	508_Attachment_V_SNP-MOC_AuditProcessandDataRequest.pdf	**Table 1: SNPE;** Column L: Date Initial HRA was completed - In cases where an HRA did not occur within 90 days of the enrollment effective date should we: 1) Enter "NA" 2) Input the date that the first HRA was completed (even if past the 90 day period).
SNP-MOC	Special Needs Plan Model of Care (SNP-MOC) Audit Process and Data Request	Appendix A – Special Needs Plan Model of Care (SNP MOC) Record Layouts	Determine the correct date submission for most recent HRA	508_Attachment_V_SNP-MOC_AuditProcessandDataRequest.pdf	**Table 1: SNPE;** Column N: If HRA was not conducted during the current audit period, please enter the date of the most recently conducted HRA - If an HRA was not conducted during the audit period, do we enter the most recently conducted HRA at the time the universe is being completed or the most recent HRA prior to the audit period?
SNP-MOC	Special Needs Plan Model of Care (SNP-MOC) Audit Process and Data Request	Appendix A – Special Needs Plan Model of Care (SNP MOC) Record Layouts	SNP Tables require "N/A" all other sections require "NA" this may cause confusion when multiple areas must be	508_Attachment_V_SNP-MOC_AuditProcessandDataRequest.pdf	**The SNP Tables** utilize the abbreviation "N/A" for Not Applicable; however for other universes/tables the user is to enter "NA". This inconsistency in abbreviation may cause confusion when multiple universes/tables are being submitted by a plan.

PUBLIC SUBMISSION

As of: 9/1/16 2:17 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raf-9te3
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0024
CT

Submitter Information

Name: John Wells
Address:
Hartford, CT, 06156
Email: WellsJ4@AETNA.com

General Comment

Aetna appreciates CMS providing Medicare Advantage Organizations and Medicare Prescription Drug Plan Sponsors, such as Aetna, an opportunity to provide comments on the 2017 Draft Program Audit Protocols. As one of the market leaders in providing and managing benefits for Medicare beneficiaries, Aetna is committed to working with the Centers for Medicare & Medicaid Services (CMS) to finalize effective, efficient and consistent Program Audit protocols.

Aetna's comments as well as request for clarification for specific protocol items are included within the attached document, AET_CY2017 Draft Program Audit Protocol Comments.xlsx.

Attachments

AET_CY2017 Draft Program Audit Protocol Comments

PUBLIC SUBMISSION

As of: 9/1/16 2:16 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raf-gvy0
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0023
CA

Submitter Information

Name: Susan Ganick
Address:
Oakland, CA, 94612
Email: Susan.Ganick@kp.org
Organization: Kaiser Foundation Health Plan, Inc.

General Comment

Draft 2017 Medication Therapy Management Audit Protocols
General Comments
With respect to the new data fields CMS proposes to add to the Universe lists, we ask that CMS take into consideration the potential impact this may have on plans' current automated systems reporting capabilities. For new data fields that are outside the scope of the Part D MTM Reporting Requirements, plans will be required to conduct an assessment to determine if additional system coding is necessary and the level of impact. We recommend that CMS solicits comments to the proposed audit changes to the Universe lists at least one year in advance of when the protocols become effective to allow plans adequate time to conduct their system assessment and make any changes as applicable.
2015 Data Universe Comments
Contract ID is not included in the 2015 audit universe data requirements. Please clarify if this was an error or if it is CMS' intent to remove Contract ID.
2016 Data Universe Comments
Column ID AA asks for the delivery method for the first CMR administered in "CY 2015". We believe this should reference CY 2016.

Draft 2017 Special Needs Plan Model of Care Audit Protocols
We ask that CMS clarify the correct date in the example below. We believe in the example noted that the date of the engagement letter should be January 25, 2017 and not 2016.
The review period for SNPs that have been operational for at least a year, will be the (13) thirteen month period preceding the date of the audit engagement letter (for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017).

Draft ODAG / CDAG Call Log

Generating Call Log universes for Part C and D requests/inquiries/complaints may prove challenging, if not impossible, for plans that do not immediately categorize calls at point of intake as either Part C or Part D. In many instances, calls may be routed to customer service for follow-up, at which point the inquiry is classified/routed as appropriate. This helps to prevent cases from getting routed inappropriately, which ensures that appropriate processes are followed according to the details of each specific case--and ensures the plan is in a position to meet all associated processing timeframes.

2181 E. Aurora Road
Suite 201
Twinsburg, Ohio 44087

Regarding Agency collection number is CMS-10191, document number is 2016-13917 and document citation 81 FR 38187.

We request the following comments to be reviewed and taken into consideration before the audit protocols are finalized.

Reference	Section/Page	Comments/Questions
Supporting Statement Part A Medicare Parts C and D Universal Audit Guide CMS-10191, OMB 0938-1000	Wage Estimates/ Page 4	Although the information is helpful, it would be more useful it took into account the costs of creating an effective compliance team, rather than just the costs associated with particular actions.
508_Attachment_IV_ODAG_Audit_Process _DataRequest	#4 Sponsor Disclosed and Self-Identified Issues: Note/ Page 4	For timeliness tests, CMS will make allowances for corrected issues provided that after the reported correction date, at least 6 consecutive weeks of data remain in the audit review period. If at least 6 weeks are not available, the usual timeliness tests will be conducted on the entire universe and conditions will be cited based on the results. CMS will ensure correction of those timeliness conditions during audit validation. *Will there be an exception for high enrollment plans to have 4 consecutive weeks to consider the issue corrected as CMS is only requesting 4 weeks of data?*
508_Attachment_IV_ODAG_Audit_Process _DataRequest	Table 1: Standard Coverage Determinations (SCD) Record Layout/ Page 18	Include all requests processed as standard coverage determination. *How does CMS define processed in this scenario? We have cases identified as duplicates, therefore these cases are not "processed", would CMS require these to be included in the universe?*
508_Attachment_IV_ODAG_Audit_Process _DataRequest	Table 1: Standard Coverage Determinations (SCD) Record Layout/ Page 19 Column G	Patient Residence Codes - Under what circumstances would we use UNK, considering pharmacies submit 00 to indicate patient resident code is unknown?
508_Attachment_IV_ODAG_Audit_Process _DataRequest	Table 1: Standard Coverage Determinations (SCD) Record Layout/ Page 19 Column O	If our disposition is reopened approved or reopened denied, what date and time should be used in all of the date time fields? In the universe do we use the original date of the request considering it may be a duplicate and it will show untimely? Should both the original decision and the reopened decision be included in the universe?
508_Attachment_IV_ODAG_Audit_Process _DataRequest	Table 14: Standard Grievances part D (SGD) Record Layout/ Page 57 Column Q	Resolution Description: Why did the characters in the issue description and resolution description decrease? Resolution description is the one area that is difficult to reduce to 1500 characters.
508_Attachment_IV_ODAG_Audit_Process _DataRequest	Table 16 Call Logs Part D Records Layout/ Page 60	Regarding columns J-Description of the call and K-Description of the outcome of the call: Our system currently does not allow for separate documentation of the call

2181 E. Aurora Road
Suite 201
Twinsburg, Ohio 44087

		description and the outcome. The character limit may be insufficient. Oftentimes calls have several different layers to it so that you can see all elements of the call including the resolution to show the flow of the call. Therefore, it would be advantageous to have all the calls in one column.
508_Attachment_IV_ODAG_Audit_Process _DataRequest	Table 16 Call Logs Part D Records Layout/ Page 60	Would it be possible for CMS to provide an example of the type of description of the outcome that is being requested? The description of the outcome is less characters than the description of the outcome.
508_Attachment_II_FA_AuditProcess_Data Request	General question regarding blank fields	For cases in which the dispensing pharmacy submits data with information missing such that the member cannot be identified or the request cannot be processed due to missing information, do we include these in the audit universe, considering that blank fields are not permissible? If we do need to include them, should a "N/A" be entered or field left blank?

PUBLIC SUBMISSION

As of: 12/9/16 9:14 AM
Received: August 12, 2016
Status: Pending_Post
Tracking No. 1k0-8raf-xb9n
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0044
Comment on FR Doc # 2016-15014

Submitter Information

Name: Rosemary Benton
Address:
OH, 44241
Email: rbenton@envisionrx.com

General Comment

Regarding Agency collection number is CMS-10191, document number is 2016-13917 and document citation is 81 FR 38187.

Please see attached word document with comments related to the 2017 proposed audit protocols.

Attachments

2017 Draft Audit Protocol Comments

Universal American Comments to Draft 2017 Audit Protocols

ODAG - Claims

Table 3 -
Column J - Do see additional requests to pull in NDC Codes for "Drugs" - does this apply to Part D - or those medical claims where and NDC is used in pricing?
Column K - will not have information to answer "why it was requested - at present this is listed as (if known) - where is CMS expecting payers to gather this information from on claim?

Column J - Do see additional requests to pull in NDC Codes for "Drugs" - does this apply to Part D - or those medical claims where and NDC is used in pricing?

Column P (Was request denied for lack of medical necessity?) - Does this mean the claims denied for timely filing or consider a case that is still open as denied due to being untimely?

Appendix A – Table 1: SOD Record Layout

1) Section updated to include additional exclusions. Most are already excluded from SOD universe. However, might need to clarify "extension of previously approved service". Currently, extension of previously approved services for SNF or Home Health are excluded. However, extensions for outpatient services (i.e. dialysis, O2, wound care) are currently NOT excluded from the universe.
2) Column J - the 11 digit NDC should be provided for drugs
    a. This change will be difficult for plans to accommodate, consider providing feedback or requesting additional information from CMS. In the current process, Providers are not required to submit the NDC with the request so not all drugs on the universe will have this number. If this change is accepted in final 2017 protocols, the authorization request form will need to be updated to request NDC and the corresponding NDC field in AUM will need to be mandatory for all drugs.
    b. is this to be applied to the organization determination requests for Part B drugs?

PUBLIC SUBMISSION

As of: 9/1/16 2:20 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rag-njnt
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0025
TX

Submitter Information

Name: Anonymous Anonymous
Address:
Houston, TX, 77081
Email: nakis.urfi@universalamerican.com

General Comment

Universal American Comments to Draft 2017 Audit Protocols

ODAG - Claims
Table 3 -
Column J - Do see additional requests to pull in NDC Codes for "Drugs" - does this apply to Part D - or those medical claims where and NDC is used in pricing?
Column K - will not have information to answer "why it was requested - at present this is listed as (if known) - where is CMS expecting payers to gather this information from on claim?

Column J - Do see additional requests to pull in NDC Codes for "Drugs" - does this apply to Part D - or those medical claims where and NDC is used in pricing?

Column P (Was request denied for lack of medical necessity?) - Does this mean the claims denied for timely filing or consider a case that is still open as denied due to being untimely?

Appendix A - Table 1: SOD Record Layout
1) Section updated to include additional exclusions. Most are already excluded from SOD universe. However, might need to clarify "extension of previously approved service". Currently, extension of previously approved services for SNF or Home Health are excluded. However, extensions for outpatient services (i.e. dialysis, O2, wound care) are currently NOT excluded from the universe.
2) Column J - the 11 digit NDC should be provided for drugs
a. This change will be difficult for plans to accommodate, consider providing feedback or requesting additional information from CMS. In the current process, Providers are not required to submit the NDC with the request so not all drugs on the universe will have this number. If this change is accepted in final 2017 protocols, the authorization request form will need to be updated to request NDC and the

corresponding NDC field in AUM will need to be mandatory for all drugs.
b. is this to be applied to the organization determination requests for Part B drugs?

Attachments

Draft Protocol Comments

Comments
Draft 2017 Medicare Parts C and D Program Audit Protocols and Data Requests

Document	Page/Section	Topic	Comments
Attachment III: Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request	Page 5	Universe Preparation & Submission 2. Pull Universes The universes should be 1) all inclusive, regardless of whether the request was determined to be favorable, partially favorable, unfavorable, auto-forwarded, dismissed, withdrawn or reopened and 2) submitted in the appropriate record layout as described in Appendix A	Does CMS expect sponsors to include dismissed grievances within the grievance universes? If so, please define "dismissed grievance", the scenarios when one would occur and what sort of notice requirements are involved in grievance dismissals. Will CMS provide a model letter to plans for this purpose?
	Page 16	III. Grievances and Misclassification of Requests Section 2.1 For Grievances, bullet 4 Copy of all notices, letters, call logs, or other documentation showing when the sponsor sent acknowledgement of grievance receipt to the beneficiary and/or requested additional information from the beneficiary and/or their representative date/time stamp of the request. If request was made via phone call, copy of call log detailing what was communicated to the enrollee.	There does not appear to be existing guidance requiring an acknowledgement of grievance receipt. Please clarify the requirement for delivering an acknowledgement of grievance receipt including whether there are timeliness standards or a model letter for this acknowledgement.

	Page 17	Section 2.2 For Call Logs, bullet 5:
		• If the call was classified as a grievance:
		  ○ Copy of case file
		  ○ Copy of all notification sent to the beneficiary concerning the grievance
		  ○ Documentation of resolution of issue
			Please clarify whether the calls classified as a grievance will then be subject to the requirements in 2.1 or only be subject to the requirements in 2.2.

Document	Page/Section	Topic	Comments
	Page 18	Appendix A—Coverage Determinations, Appeals, and Grievances (CDAG) Record Layouts NOTE: There is a maximum of 4,000 characters per record row. Therefore, should additional characters be needed for a variable, enter this information on the next record at the appropriate start position.	Please clarify whether the 4,000 character limit is per cell/field or per row within the cell/field. Are cell/fields unlimited characters so long as the row does not exceed 4,000?
	Page 57	Table 14: Standard Grievances Part D (SGD) Record Layout Column ID Q, Field Name “Resolution Description”	The Field Length is decreased from 3000 to 1500. Plans are to provide a full description of the grievance resolution. Cutting the Field Length in half may result in CMS not getting a full (or closer to full) description.
	Page 58	Table 15, Expedited Grievances Part D (EGD) Record Layout Bullet 2: Submit cases based on date of resolution notification of the standard oral and written grievances (the date the grievance was received may fall outside of the review period).	It appears that “standard” is in error and should be changed to “expedited”.
	Page 59	Table 15, Expedited Grievances Part D (EGD) Record Layout Column ID P, Field Name “Resolution Description”	The Field Length is decreased from 2000 to 1500. Plans are to provide a full description of the grievance resolution. Cutting the Field Length may result in CMS not getting a full (or closer to full) description.
	Page 60	Table 16: Call Logs Part D Record Layout	We recommend that CMS only request call log information in cases where it appears the plan sponsor may be inappropriately categorizing calls vs adding a call log universe as a new requirement. This data is held with multiple vendors and would involve significant programming work to pull as a universe.

PUBLIC SUBMISSION

As of: 9/1/16 2:25 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rah-7nak
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0026
MN

Submitter Information

Name: Amy Luhmann
Address:
Eagan, MN, 55121
Email: amy.luhmann@clearstonesolutions.com

General Comment

See attached file(s)

Attachments

Comments 2017 audit protocols

BlueCross BlueShield
Illinois · Montana · New Mexico
Oklahoma · Texas

August 12, 2016

Submitted via: http://www.regulations.gov/

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10191 (OMB Control Number 0938-1000)

To Whom It May Concern:

Health Care Service Corporation (HCSC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to the "Medicare Parts C & D Program Audit Protocols and Data Requests," published in the Federal Register (81 FR 38187) on June 13, 2016.

HCSC is the largest customer-owned health insurance company in the United States. The company offers a wide variety of health and life insurance products and related services, through its operating divisions and subsidiaries including Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas. HCSC employs more than 23,000 people and serves more than 15 million members. HCSC has established Medicare Advantage (MA) plans and Part D Prescription Drug (Part D) stand-alone plans in all five of the HCSC states. In addition, HCSC operates a Medicare-Medicaid Plan (MMP) contract in the State of Illinois.

Our comments and related recommendations are provided below.

Comments

Attachment I: Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request

Appendix A – Compliance Program Effectiveness (CPE) Record Layouts

- **Table 1 First-Tier Auditing and Monitoring (FTEAM) Record Layout (page 12).** CMS specifies that the universe for the first-tier entity auditing and monitoring record layout should include, among other data, audit and monitoring activities that are performed on a scheduled basis (e.g., daily, monthly, quarterly, annually), for each time the activity was performed. The agency further states that if an activity is conducted daily, it should only be

included once in the universe, although all deficiencies, corrective actions, etc. should be identified for all monitoring performed. We note that this information must be reported for all first-tier entities (FTEs) that are delegated a function on behalf of the sponsor (e.g., PBMs, claims processors, enrollment processors, call centers, independent provider groups that manage/oversee a network of physicians, etc.).

In our experience, inclusion in the data universe of daily and/or weekly monitoring activities (including deficiencies) for the full spectrum of our FTEs resulted in a very complex, resource intensive reporting process that entailed significant manual data input due to the volume, scope, scale and detailed nature of the information required. Further, we are concerned that the manual data input necessary to report some of these data significantly increases the likelihood for reporting errors, and also are concerned that the effort required to provide this information in this reporting format diverts critical administrative and other resources from other internal compliance efforts and functions.

While we recognize CMS' interest in requesting this information, it is unclear whether the value and benefit of including these data in the universe outweighs the resource and effort required for sponsors to report these data and for CMS to review and analyze the data. As a result, we strongly recommend that CMS revise the instructions for this record layout to exclude reporting of FTE audit and monitoring activity at the daily and weekly levels and only require reporting of monitoring activities performed on a monthly, quarterly or less frequent basis. We believe this revised approach will address the concerns outlined above, while providing the agency with the level of detail necessary to sufficiently and efficiently evaluate performance in this audit area.

- **Removal of Table 5 – Fraud Waste and Abuse Monitoring (FWAM).** CMS is proposing to delete from the CPE data request, Table 5: Fraud Waste and Abuse Monitoring (FWAM), in which Medicare Part C and/or Part D monitoring activities and investigations performed during the audit period to identify and address potential or suspected FWA, are reported. While we recognize that CMS also has removed references to FWA-related activities in a number of places throughout the CPE audit process and data request document, the agency also has added new FWA references. For example, on page 3, under the "Purpose" heading, CMS indicates that the purpose of the CPE audit is to "evaluate a sponsor's performance with adopting and implementing an effective compliance program to prevent, detect and correct Medicare Parts C or D program non-compliance and fraud, waste and abuse (FWA) in a timely and well-documented manner." In addition, on page 9, CMS proposes new compliance standards against which plans will be evaluated during the audit, one of which specifically focuses on whether the plan implemented an effective monitoring system to prevent FWA in the delivery of Medicare Parts C and D benefits (proposed standard 1.6).

  Given that CMS is proposing to delete the FWA-specific universe request, and since it does not appear that the remaining 4 universe requests have been revised to include fields that would capture data specific to FWA activities and monitoring, it is unclear how CMS will evaluate and determine sponsor compliance in this area. We recommend that CMS clarify the underlying information and data sponsors must report on audit for this purpose to ensure the audit process and data request document clearly articulates and aligns with the agency's expectations.

Attachments I-A – I-E: Questionnaires

- **Duplication.** CMS is proposing to implement a number of new questionnaires that must be populated by sponsors to assist the agency in better understanding the day-to-day operations of an organization related to a specific audit area. In an effort to further streamline the audit process, we recommend that CMS review questionnaires to ensure they are not duplicative and eliminate any identified areas of redundancy, as appropriate.

Attachment III: Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request

Appendix A – Coverage Determinations, Appeals and Grievances (CDAG) Record Layouts

- **Table 16: Call Logs Part D Record Layout (pages 16-17 & 60).** CMS is proposing to add a new data request to the CDAG audit area related to Part D call logs. Specifically, sponsors will be required to provide to CMS, detailed information and documentation related to plan call logs, including the initial call record; documentation explaining call issues; call log audio; documentation of how the call was processed/routed/handled; if the call was classified as a grievance; if the call was classified as a coverage determination or redetermination; and if the call was classified as an inquiry. In addition, CMS proposes that sponsors must include this information for all calls received (by the sponsor or another entity) related to the sponsor's Part D line of business. Based on the proposed record layout on page 60, it appears that the agency intends for this information to be provided only for calls received from beneficiaries (or their authorized representatives); however, the related instructions on pages 16-17 do not explicitly indicate or address this issue. We recommend that CMS revise the audit process and data request to clearly articulate this expectation.

Attachment IV: Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Audit Process and Data Request

Appendix A* – Organization Determinations, Appeals and Grievances (CDAG) *Record Layouts

- **Table 14 Call Logs Part C Record Layout (pages 15 & 53).** CMS is proposing to add a new data request to the ODAG audit area related to Part C call logs. Specifically, organizations will be required to provide to CMS, detailed information and documentation related to plan call logs, including the initial call record; documentation explaining call issues; call log audio; documentation of how the call was processed/routed/handled; if the call was classified as a grievance; if the call was classified as a coverage determination or redetermination; and if the call was classified as an inquiry. In addition, CMS proposes that organizations must include this information for all calls received (by the organization or another entity) related to the organization's Part C line of business. Based on the proposed record layout on page 53, it appears that the agency intends for this information to be provided only for calls received from beneficiaries (or their authorized representatives); however, the related instructions on page 15 do not explicitly indicate or address this issue. We recommend that CMS revise the audit process and data request document to clearly articulate this expectation.

We appreciate the opportunity to comment. If you would like additional information or have questions about our feedback, please contact me at 202-249-7222 or Sue_Rohan@hcsc.net.

Sincerely,

Sue Rohan
Vice President, Health Policy – Government Programs

PUBLIC SUBMISSION

As of: 12/9/16 8:55 AM
Received: August 12, 2016
Status: Pending_Post
Tracking No. 1k0-8rai-mn4n
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0045
DC

Submitter Information

Name: Anonymous Anonymous
Address:
DC, 20004
Email: Sue_Rohan@hcsc.net
Organization: NA

General Comment

See attached file(s)

Attachments

FINALHCSC Comments Draft C and D Audit Protocols8_12_16

CENTRAL HEALTH PLAN OF CALIFORNIA

August 11, 2016

RE: CMS–10191 (OMB Control Number: 0938–1000)

Dear Centers for Medicare and Medical Services,

Thank you for providing Central Health Plan of California ("CHPC") with the opportunity to comment on the proposed 2017 Draft Program Audit Protocols. As a Medicare Advantage Organization and Prescription Drug Plan that underwent CMS Program Audits in 2012 and 2015, the proposed audit requirements have a direct effect on our organization, and we are appreciative of the ability to seek clarity on some of the revisions. Please see the following chart of comments and questions regarding the various program areas:

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
CDAG, ODAG	Part D Coverage Determinations, Appeals, and Grievances (CDAG) AUDIT PROCESS AND DATA REQUEST Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST	Audit Purpose and General Guidelines	3	**Review Period**: The review period will be decided based on your organization's total enrollment. CMS reserves the right to expand the review period to ensure sufficient universe size. • Plans with <50,000 enrollees: The review period will be the 3 month period preceding and including the date of the audit engagement letter. • Plans with >50,000 but <250,000 enrollees: The review period will be the 2 month period preceding and including the date of the audit engagement letter. • Plans with >250,000 enrollees: The review period will be the 1	The review period should be shortened for ODAG Table 14: Call Logs Part C (CLC) and Table 16: Call Logs Part D (CLD). Requesting sponsors to compile a universe of up to 3 months of all calls received pertaining to the Sponsor's Part C and D businesses would pull extremely large universes.

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
				month period preceding and including the date of the audit engagement letter	
		Table 16: Call Logs Part D Record Layout	60	**Table 16: Call Logs Part D Record Layout** • Include all calls received by your organization (or another entity) that relate to your Medicare Part D line of business. • Exclude any calls not relating to your Part D business (i.e., Medicare advantage, commercial). • Submit all calls based on the date the call was received by your organization, PBM or other entity.	
		Table 14: Call Logs Part C (CLC) Record Layout	53	**Table 14: Call Logs Part C (CLC) Record Layout** • Include all calls received by your organization (or delegated entity) that relate to your Medicare Part C line of business.	
CDAG, CPE, FA, MTM, ODAG, SNP MOC	Part D Coverage Determinations, Appeals, and Grievances (CDAG) AUDIT PROCESS AND DATA REQUEST 2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I Formulary and	Audit Purpose and General Guidelines	3 3 4	**Sponsor Disclosed and Self-Identified Issues**: Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from the starting date of each universe period through the date of the audit start notice, which CMS may find in your data universes. A disclosed issue is	In regards to sponsor disclosed and self-identified issues, the protocol says to "not include all issues identified by your organization, just those that are relevant to the areas being audited." How would the sponsor know what issues are relevant to the areas being audited if the tracers and samples

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
	Benefit Administration (FA) AUDIT PROCESS AND DATA REQUEST Medication Therapy Management (MTM) PILOT AUDIT PROCESS AND DATA REQUEST Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST Special Needs Plan Model of Care (SNP-MOC) AUDIT PROCESS AND DATA REQUEST		3-4 3 3	one that has been reported to CMS prior to the date of the audit start notice (which is also known as the "engagement letter"). A self-identified issue is one that has been discovered by the sponsor for which no prior notification has been provided to CMS. If CMS identifies an issue through on-going monitoring or other account management/oversight activities during the plan year and reported that issue to the sponsor, the sponsor should list that issue as self-identified. Please do not include all issues identified by your organization, just those that are relevant to the areas being audited. Please identify if the issue is corrected, uncorrected and the date when correction occurred. Within 5 business days after receipt of the engagement letter, sponsors must provide a description of each issue as well as the remediation status using the Pre-Audit Issue Summary template (Attachment VIII).	have not yet been selected and communicated by CMS to the sponsor? Additionally, 5 business days is an insufficient amount of time for sponsors to compile the Pre-Audit Issue Summary. At that point, universes have not yet been compiled and the sponsor is unaware of what tracers and/or samples will be selected by CMS. This may result in duplicative work in preparing for universes. Furthermore, certain elements of the Pre-Audit Issue Summary appear to duplicate the Impact Analysis which is later requested if a condition is identified during the audit, so there does not appear to be any value added to the audit for the Pre-Audit Issue Summary. As an alternative, we would suggest that the deadline for the Pre-Audit Issue Summary is moved until after universes and tracers have been selected and communicated to the Sponsor. Or another alternative is to build in the process during the universe/sample request.
CDAG, ODAG	Part D Coverage Determinations, Appeals, and Grievances (CDAG) AUDIT PROCESS AND DATA	Universe Preparation & Submission	7-9	**4. Timeliness Tests:** CMS will run the tests indicated below on each universe except for Table 16: Call Logs Part D. For the	Please consider publishing CMS' percentage thresholds for timeliness in determining an overall compliance score

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
	REQUEST Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST			effectuation tests, auditors will determine percentage of timely cases from a sponsor's approvals (favorable cases). For the notification timeliness tests, auditors will determine the percentage of timely cases from a full universe of approvals and denials. If more than one universe tests the same compliance standard, multiple timeliness tests results will be merged for one overall score. *These universe may be combined with at least one other universe to determine an overall compliance score. **4. Timeliness Tests:** CMS will run the tests indicated below on each universe except for Table 14: Call Logs Part C. For the effectuation tests, auditors will determine percentage of timely cases from a sponsor's approvals (favorable cases). For the notification timeliness tests, auditors will determine the percentage of timely cases from a full universe of approvals and denials.	(other than ODAG Table 3: Claims, where a 95% standard is already provided). It is difficult for Sponsors to audit or monitor compliance on an ongoing basis if Sponsors are unaware of CMS' expectations in regards to timeliness. Furthermore, for self-disclosure purposes, Sponsor will be unable to determine whether to self-disclose untimeliness if CMS' thresholds for untimeliness are unknown.
CDAG, ODAG	Part D Coverage Determinations, Appeals, and	II. Appropriateness of Clinical	12	**Select Sample Cases:** CMS will select a targeted sample of 40	Please consider publishing CMS' criteria for determining

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
	Grievances (CDAG) AUDIT PROCESS AND DATA REQUEST Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST	Decision-Making & Compliance with CDA Processing Requirements II. Appropriateness of Clinical Decision-Making & Compliance with ODA Processing Requirements	 11	cases (30 denials and 10 approvals) that appear clinically significant. **Select Sample Cases:** CMS will select a targeted sample of 40 cases total that appear clinically significant from the pre-service and payment requests and IRE/ALJ/MAC reversal record layouts (Appendix A, Tables 1 through 10). CMS will attempt to ensure, to the extent possible, that the sample set is representative of various medical services (e.g., ER services, outpatient hospital, inpatient hospital, urgent care, etc.).	what types of cases are considered "clinically significant". This will assist sponsors in their own monitoring and auditing efforts.
CDAG, ODAG	Part D Coverage Determinations, Appeals, and Grievances (CDAG) AUDIT PROCESS AND DATA REQUEST Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST	III. Grievances and Misclassification of Requests	16 14-15	The sponsor will need access to the following documents or audio files during the live webinar and may be requested to produce screenshots or transcripts of any of the following: **2.2 For Call Logs:** • Call log audio files (recorded calls)	Is sponsor required to provide translation of audio files if call occurs in a language other than English, or can CMS auditors review an English call log as an alternative?
CDAG	Part D Coverage Determinations, Appeals, and Grievances (CDAG) AUDIT PROCESS AND DATA REQUEST	Formulary and Benefit Administration Audit and Data Request	17	3.1 Was the case or call correctly classified, and if not, was it quickly transferred to the appropriate process?	What is CMS' definition or standard of "quickly"?
CPE, FA	2017 Parts C and D	Audit Purpose	3	The screenshots must	Please clarify what

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
	Compliance Program Effectiveness ("CPE") Attachment I Formulary and Benefit Administration (FA) AUDIT PROCESS AND DATA REQUEST	and General Guidelines Audit Elements I. Formulary Administration, II. Transition	 7, 9	be provided to CMS via a Microsoft® Word or PDF document. The sponsor must provide a legend that directs CMS to the requested information on the screenshot. At a minimum, the first display of each screen type must clearly indicate where the requested information resides on the screen.	CMS means by "legend"?
CPE	2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I	Tracer Evaluation	7	**2.1. Tracer Summary:** For each selected case, sponsors should prepare a written document that provides the specific facts, rationales, and decisions and describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor in chronological order. The sponsor should ensure each tracer summary, at a minimum, addresses the following points: • Detailed explanation of the issue(s) (e.g., what the sponsor found, when the sponsor first learned about the issue, the root cause, and who or which personnel/operational area(s) were involved.) • Root cause analysis that determined what caused or allowed the compliance issue, problem or deficiency	Root cause is repeated twice under Tracer Summary.

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
				to occur	
CPE	2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I	Tracer Evaluation	8	**2.2. Supporting Documentation:** During the onsite portion of the audit, CMS will review documentation in support of tracer summaries to determine if applicable audit elements were effectively met. The sponsor will need access and provide screenshots only for the documents and data that are relevant to a particular case: Evidence of sponsor's monthly screening to identify employees and FDRs excluded by the Office of Inspector General (OIG) and General Services Administration (GSA).	Please explain how "Evidence of sponsor's monthly screening to identify employees and FDRs excluded by the OIG and GSA" will be tied in with the 6 tracer summaries. Will only employees and FDRs involved with the 6 tracer summaries be selected and/or required to provide proof of the OIG and GSA checks? What is the relationship between the tracer summary and the OIG and GSA checks for the involved employees and/or FDRs?
CPE	2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I	Correction Controls and Activities	11	III. Correction Controls and Activities This audit element evaluates the sponsor's escalation processes, timely response and appropriate actions to correct the underlying problems after compliance issues and deficiencies are identified. These compliance controls provide immediate and reasonable response to the detection of misconduct and violations of the	What is CMS' standard and how does CMS determine "timely response and appropriate actions", "immediate and reasonable response", "timely and reasonable corrective action", and "timely corrective actions"?

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
				Medicare program. 1.1. Did the sponsor undertake timely and reasonable corrective action in response to compliance issues, incidents, investigations, complaints or misconduct involving Medicare non-compliance or FWA? 1.2. Did the sponsor implement timely corrective actions for detected issues involving its FDRs' compliance performance?	
CPE	2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I	Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	14	**Column I: Activity Start Date** Date that the specific audit or monitoring activity was initiated, started or reopened by the sponsor. For example, if the sponsor started monitoring a function of the PBM to ensure it properly implemented its transition policy for new beneficiaries on January 1, 2017, that is the date that would be used for the date the audit or monitoring started. For an audit or monitoring activity conducted on a daily basis, only include the most recent start date.	It is difficult for sponsors to recall the exact date that a monitoring activity began, especially if the monitoring activity began years before the program audit process was released by CMS. We suggest removing this field from the FTEAM record layout as there does not appear to be any value added to the program audit. Furthermore, the instructions regarding how to populate a daily audit or monitoring activity is confusing. Are sponsors only to report the most recent daily activity, or all activities conducted throughout the universe period? If the former, how is the sponsor to report on deficiencies

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
					identified prior to the most recent daily audit or monitoring activity?
CPE	2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I	Table 2: Employees and Compliance Team (ECT) Record Layout	18	**Column G: Direct Phone Number** Contact phone number for employee's office or desk. Submit in 10-digit hyphenated number format (e.g., 410-555-5555).	Not all sponsors have direct phone numbers for every employee. We would suggest allowing flexibility to extend beyond the 15 character field length for entering extension numbers if directly reaching employees is CMS' intent.
CPE	2017 Parts C and D Compliance Program Effectiveness ("CPE") Attachment I	Table 2: Employees and Compliance Team (ECT) Record Layout	18	**Column J: Medicare Compliance Department Employee?** Note: Indicate Yes (Y) for any full-time compliance staff, as well as any staff from an operational area that serve as a primary compliance liaison between the Compliance Department and its operational area in any capacity.	Please clarify what CMS means by "any staff from an operational area that serves as a primary compliance liaison…in any capacity." What does CMS mean by "primary compliance liaison?" For example, Compliance receives responses from multiple staff within operational areas in regards to HPMS memos, auditing, or monitoring results, or provides assistance to Compliance with investigations within the operational areas or communicating with FDRs on Compliance's behalf. Would all staff responding to Compliance inquiries or communicating with Compliance on a regular basis be considered a "primary compliance liaison" for audit purposes? Or would those operational area staff just be responding to a compliance request? In the past, CMS would

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
					ask for a list of all employees involved with the selected tracers. Would that be a reasonable alternative to this data field instead of requesting this information up front in the universe?
CPE	Attachment I-A: Medicare Advantage and Prescription Drug Compliance Program Effectiveness Self-Assessment Questionnaire (SA-Q)	Directions for completing the self-assessment questionnaire	1	If the answer is "YES" to any question below, check the "YES" box and provide a BRIEF description of what documents support that response in the "Documentation" column. The Documentation description should also provide a cross reference (when applicable) to where this documentation can be located. For example, if your response is "YES" to the third question below *("Do your written Ps & Ps and/or Standards of Conduct articulate the organization's commitment to comply with all applicable Federal and State standards including but not limited to statutes, regulations and sub regulatory guidance")*, please indicate the section/page of the Standards of Conduct or policies and procedures where these compliance provisions are found. If the answer is "NO" to a question, check	The instructions do not allow for sponsors to answer "N/A" and only allows sponsors to enter "Yes" or "No." For example, if Sponsor's compliance officer does report directly, in-person to the CEO, how would Sponsor answer question 6: *If your compliance officer does not report directly, in-person to your CEO, are his/her reports routed through the President of the division that houses the Medicare and/or through the President of the organization rather than through operational management?* By the same logic, if Sponsor's compliance officer is not employed by the parent or corporate affiliate, how would Sponsor answer question 9? *If employed by your parent or corporate affiliate, does your compliance officer have detailed involvement in and*

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
				the "NO" box and document the rationale for the response in the "Documentation" column.	*familiarity with your Medicare operational and compliance activities?*
CPE	Attachment I-A: Medicare Advantage and Prescription Drug Compliance Program Effectiveness Self-Assessment Questionnaire (SA-Q)	Questionnaire	17	60. Do you conclude your investigations of FWA within a reasonable time after the activity is discovered?	What does CMS consider a "reasonable time" to conclude a FWA investigation after activity is discovered?
CPE	ATTACHMENT I-B: COMPLIANCE OFFICER QUESTIONNAIRE (CO-Q)	Questionnaire	3	11. Do you have sufficient support and resources to successfully perform your responsibilities as compliance officer over the Medicare Parts C and/or D program? Please explain.	Please explain what CMS' definition or expectation of "sufficient support and resources" is. This may vary by organization and is a subjective question.
CPE	ATTACHMENT I-D: SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER, DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)	Directions for Completing the FDR Oversight Questionnaire	1	This questionnaire will assist CMS with understanding how the individual who is responsible for the oversight of FDRs is vested in the day-to-day operations of the Medicare compliance program and the processes for working with key business operations and reporting to senior management and oversight bodies on the activities and status of the Medicare program.	Not all sponsors have one individual who is solely responsible for oversight of FDRs; rather, this practice is vested within multiple operational areas. For example, Claims Department may have an individual responsible for FDR oversight in that particular operational area; while Utilization Management has an individual responsible within that operational area. Please clarify how to address this issue and whether all departments/individuals responsible for FDR oversight must complete this questionnaire or only one individual on behalf of the Sponsor.

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
ODAG	Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST	Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout	14	I. Timeliness – Organizations Determinations and Appeals and Grievances (TODAG) 4. **Inform Sponsor of Results** CMS will inform the sponsor of the results of its analysis for each of the 13 universes supplied during the live audit portion of the review; including if any conditions will be cited, and if so which condition(s).	Is CMS no longer informing Plans whether a condition is categorized as CARs or ICARs? We noticed this was removed from the 2017 Draft Protocols but was present in the 2016 Audit Protocols.
ODAG	Part C Organization Determinations, Appeals, and Grievances (ODAG) AUDIT PROCESS AND DATA REQUEST	Audit Elements	11	II. Appropriateness of Clinical Decision-Making & Compliance with ODAGODA Processing Requirements 1. Select Sample Cases: CMS will select a targeted sample of 40 cases total that appear clinically significant from the pre-service and payment requests and IRE/ALJ/MAC reversal record layouts (Appendix A, Tables 1 through 10). CMS will attempt to ensure, to the extent possible, that the sample set is representative of various medical services (e.g., ER services, outpatient hospital, inpatient hospital, urgent care, etc.). CMS will select	Do partially favorable decisions need to be reported more than once (for example, once for the approval and once for the denial)?

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
				the sample set from the universe categories as follows: 10 organization determination denials (5 pre-service and 5 payment); 10 reconsideration denials (5 pre-service and 5 payment); 10 IRE, ALJ, or MAC overturns (5 pre-service and 5 payment); 5 organization determination approvals (standard and expedited); and 5 reconsideration approvals (standard and expedited). **Note:** For audit purposes, partially favorable decisions are treated as denials.	
SNP MOC	Special Needs Plan Model of Care (SNP-MOC) AUDIT PROCESS AND DATA REQUEST	Universe Preparation & Submission	6	**The sponsor will provide the following background information documentation that is applicable to the audit timeframe:** •Copies of all approved Models of Care (MOC) and any (red-lined) updates to the original submissions	Which version of the Models of Care (MOC) will the CMS auditors be reviewing the samples against? For example, we recently utilized the Off-Cycle MOC submission process for redlined updates to our MOCs, and NCQA took several months to approve our redlined changes. During those months in which we were awaiting CMS review, would CMS have audited us against the previously approved MOC, or the redlined updates made which were awaiting NCQA approval?

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
SNP MOC	Special Needs Plan Model of Care (SNP-MOC) AUDIT PROCESS AND DATA REQUEST	Universe Preparation & Submission	6	**The sponsor will provide the following background information documentation that is applicable to the audit timeframe:** Copies of the CMS-approved Health Risk Assessment Tool(s) (HRA) used by the SNP	The background information documentation request requires that Sponsors provide "CMS approved HRA used by the SNP." Based on our understanding, HRAs are only submitted for CMS approval as part of the SNP Application Process. However, if a SNP is approved for 3 years and no submissions are required within those 3 years, and the Sponsor updates it HRA format, there does not appear to be an off-cycle submission process for changes in HRA format. In other words, there is no off-cycle submission process for HRA approval other than the SNP Application process. The SNP & MMP Training on Off-cycle Submission of MOC Changes held on March 3, 2016 by NCQA stated on Slide 13 that "Changes to HRA format <u>are not</u> required for reporting as a revision. However, changes to HRA related to process <u>are</u> required as a revision." Therefore, if the Sponsor revised its HRA outside of the SNP Application process, how is this accounted for during a CMS audit?
SNP MOC	Special Needs Plan Model of Care (SNP-MOC) AUDIT PROCESS	Sample Selection	7	**<u>Select Sample Cases</u>**: CMS will select a sample of 30 beneficiaries from the	The proposed methodology for selecting the number of samples based on

PROGRAM AREA	DOCUMENT	SECTION	PAGE #	ORIGINAL TEXT	COMMENT
	AND DATA REQUEST			sponsor-submitted universe as follows: •% selected = % of D-SNP beneficiaries •% selected = % of I-SNP beneficiaries •% selected = % of C-SNP beneficiaries •% selected = % of MMP beneficiaries CMS will sample proportionally with a minimum of 5 for each existing SNP type to obtain a total sample size of 30. The same sample will be evaluated for the first two elements of the audit (referenced in the purpose section). The sample selection will be provided to the sponsor by the close of business on the Thursday before the Monday of the audit week.	percentile enrollment in each SNP type is very confusing. By what date is enrollment captured for purposes of determining the percentage of SNP categories to be selected for samples? In other words, how can Sponsor project what the percentile distribution will be? Is this based on a particular month/year of enrollment data? If so, which month/year would this determination be based upon?

We request that CMS please consider providing clarity to the questions and concerns listed above. We believe that they would benefit all affected MAOs and will help to clarify portions of the 2017 Draft Audit Protocols that are currently ambiguous.

Sincerely,

Central Health Plan of California

PUBLIC SUBMISSION

As of: 9/1/16 2:37 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raj-1o64
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0029
CA

Submitter Information

Name: Carli Suba
Address:
Diamond Bar, CA, 91765
Email: csuba@centralhealthplan.com

General Comment

See attached file.

Attachments

2017 Draft Audit Protocols Comments FINAL

America's Health
Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

August 12, 2016

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10191 (OMB No. 0938–1000)
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS–10191 (OMB No.: 0938–1000)

Dear Sir or Madam:

We are writing on behalf of America's Health Insurance Plans (AHIP) in response to the notice under the Paperwork Reduction Act concerning the "Medicare Parts C and D Program Audit Protocols and Data Requests" published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register (81 FR 38187) on June 13, 2016. The draft 2017 Medicare Parts C and D program audit protocols and data requests are of significant interest to AHIP's member organizations, many of which participate in the Medicare Advantage (MA) and Medicare Part D Prescription Drug Benefit (Part D) programs. Our comments appear below.

GENERAL COMMENT

Impact Analyses Submissions. CMS requires sponsors to produce impact analyses for issues discovered during the program audits. Preparing and completing these analyses takes time and resources. Moreover, the plan staff responsible for completing and providing this information may also need to participate in the webinar portion of the audits. We understand that the deadline for submitting impact analyses and the webinar may occur at the same time, which can inhibit the ability of plan personnel from responding effectively to CMS. In order to ensure for effective and complete responses to CMS, we recommend that the agency permit plans to submit impact analyses following the week of the webinar.

SPECIFIC COMMENTS

Attachment I – Part C and D Compliance Program Effectiveness (CPE) Program Area

- **Fraud, Waste and Abuse Monitoring.** For the 2016 program audits, sponsors are required to provide certain data universes and supporting documentation including those related to fraud, waste and abuse monitoring (FWAM). However, in the draft 2017 CPE Audit Process

and Data Request document, we see no reference to the FWAM data request. We request that CMS clarify whether it intends to remove the FWAM data universe submission requirement from 2017 program audits.

- **Frequency of Audit and Monitoring Activities (Table 1)**

  + On page 12 in Attachment I, CMS indicates that sponsors must include information in their data universe about their audit and monitoring activities "that are performed on a scheduled basis (e.g., daily, monthly, quarterly, annually)." The description under Column F (Activity Frequency) on page 13 includes additional examples of frequencies: weekly and ad-hoc. For consistency, we recommend that CMS add these two examples to the list on page 12 and to other applicable sections under Attachment I.
  + On page 14 in Attachment I, CMS is proposing to add an additional instruction for 2017 under Column I (Activity Start Date) and Column J (Activity Completion Date) which indicates that sponsors have to list audit or monitoring activities that are conducted on a daily basis only once in their data universe and include the most recent start date. We request that CMS clarify whether this instruction also applies to weekly activities. If it does, we recommend that the agency include this clarification under Table 1 and also in comparable sections under Tables 3 and 4 that reference frequencies.

Attachment III – Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area and Attachment IV – Part C Organization Determinations, Appeals, and Grievances (ODAG) Program Area

- **Call Logs** (CDAG – Table 16, ODAG – Table 14). For 2017 program audits, CMS is proposing a new requirement that sponsors produce data on all customer service calls related to MA and Part D lines of business. We understand that plans receive a significant number of calls from a variety of callers including current and prospective enrollees, providers and pharmacies. This proposed requirement could produce a voluminous amount of data that may not be useful to CMS. In addition, we believe that the agency is able to review call log data through other audit universe pulls and sample case reviews that are less burdensome to produce. CMS should continue to use a more targeted approach that is more likely to produce useful information. To have an efficient and effective audit process, we recommend that CMS not move forward with its proposal to require data on all calls.

- **Standardized Time Zone** (CDAG and ODAG – Appendices A). For 2017, CMS is requiring sponsors to ensure that all cases in their universes be "in one standardized time zone," which conflicts with the agency's current instructions for 2016 program audits that requires "all dates and times [to be] entered based on the time zone where the request was received." The rationale for this proposed change is unclear. This would likely require manual interventions and/or re-programming of systems and increase opportunity for errors. We therefore recommend that CMS retain its current approach.

Attachment V – Special Needs Plan Model of Care (SNP-MOC) Program Area

- **Review Period.** For 2017 program audits, CMS indicates that for special needs plans (SNPs) that have been operational for at least a year, the review period would be the thirteen-month period preceding the date of the CMS audit engagement letter. CMS further states that "for example, for an engagement letter sent on January 25, 2016, the universe review period would be December 1, 2015 through January 25, 2017." There appears to be one or more typographical errors in the date(s) cited in the example. We recommend that CMS revise the example.

- **Continuous Enrollment.** On page 5 in Attachment V under the section entitled "Universe Preparation & Submission," CMS indicates that sponsors must provide a universe that consists of "all SNP beneficiaries who have been continuously enrolled for a period of at least 13 months as of the engagement letter date." In addition, CMS notes that sponsors "should include all cases that match the description for that universe for all applicable SNP contracts and PBPs in its organization." We request that CMS clarify whether the note is intended to mean that continuous enrollment covers all beneficiaries under the parent organization.

Attachment VI – Part D Medication Therapy Management (MTM) Program Area PILOT

- On page 13 in Attachment VI, CMS is proposing that under Column N, sponsors include the MTM disenrollment reason. We understand that this data element may not be tracked in an easily reportable manner. We recommend that CMS solicit feedback from plans about reporting on this data element, as well as others, and consider the impact of the information being requested on plans' current system reporting capabilities.

We have appreciated the opportunity to comment. Please contact me if additional information would be helpful or if you have questions about the issues raised in this letter. I can be reached at (202) 778-3256 or mhamelburg@ahip.org.

Sincerely,

Mark Hamelburg
Senior Vice President, Federal Programs

PUBLIC SUBMISSION

As of: 9/1/16 2:46 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raj-atjp
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0030
DC

Submitter Information

Name: Anonymous Anonymous
Address:
DC, 20004
Organization: America's Health Insurance Plans

General Comment

See attached file(s)

Attachments

Draft2017AuditProtocols_FinalAHIPComnts_8_12_16

Jennifer O'Brien
Chief Compliance Officer
UnitedHealthcare
9800 Health Care lane
Minnetonka, MN 55343
952-931-5444

To: Centers for Medicare and Medicaid Services
Submitted electronically via: www.regulations.gov

From: Jennifer O'Brien
UnitedHealthcare
UnitedHealth Group

Date: August 12, 2016

Re: *Medicare Parts C and D Program Audit Protocols and Data Requests*

Attached are comments regarding CMS' Medicare Parts C and D Program Audit Protocols and Data Requests (CMS–10191).

Medicare Parts C and D Program Audit Protocols and Data Requests

Comments Submitted by
UnitedHealthcare
8/12/16

UnitedHealthcare (United) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments regarding the Medicare Parts C and D Program Audit Protocols and Data Requests.

Part C Organization Determinations, Appeals and Grievances (ODAG) Protocols
Audit Process and Data Request

United has concerns regarding the Audit Process and Data Request section of the ODAG Protocols. CMS indicates that all cases in the universes should be reported in one standardized time zone. However, we have members in multiple time zones and the times within each case are consistent with the applicable time zone that the cases are reported in. As one standardized time zone will not change the results of timeliness, we request that this requirement be removed.

In Table 1: Standard Pre-service Organization Determinations (SOD) Record Layout, CMS states, "If a standard pre-service organization determination requests more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination request."

> Reporting Organization Determinations at the case level could potentially impair the ability to track important details of individual cases needed for program audits with CMS, as well as important internal oversight performance. However, reporting cases at the service line level would allow for a detailed picture of the case and requested services. Service line reporting allows transparency and oversight into the individual elements of each case.
>
> Additionally, from a reporting perspective, decisions to approve or deny are made at the service line level. Reporting at the case level would not accurately reflect a health plan's timeliness in all situations based on the individual decisions.

Therefore, United respectfully requests the continuation of reporting Organization Determinations cases at a service line level.

United has concerns regarding two new fields, Diagnosis and Level of Service, that have been added to 10 tables in the Audit Process and Data Request. United processes Part C point of sale (POS) transactions similarly to Part D POS transactions. Under Part D guidance (chapter 18, section 30), it states that the plan is not required to treat the presentation of a prescription at a pharmacy as a coverage determination. Absent any specific Part C guidance, United is seeking clarification that the presentation of a prescription for a Part C item at a pharmacy is not an organization determination and therefore point of sale transaction would not be utilized to complete the level of service fields in the Part C universes. United is seeking further clarification on how to complete these two fields for Part C POS specifically giving the limitations noted above.

We also have several questions and concerns regarding Table 14: Call Logs Part C (CLC) Record Layout. First, we ask CMS to confirm that call logs should only include inbound member calls. Additionally, some member calls are warm transferred to business areas and would have separate recordings. In those cases, we respectfully request clarification on the following:

- Should the universe include the initial member call, the warm transferred calls or both?
- If warm transfers are in scope, which request types should be reported in call logs?
- Should return calls from a member to the health plan in response to a health plan call be reported in call logs?
- Are member calls to Delegated Entities that do not process ODs, payment requests or reconsiderations in scope for call logs?
- Are member calls to Delegated Entities that are referred to United excluded from call logs?

Finally, United asks that multiple requests be reported as separate call records when more than one request is made on a call. We believe that this would help ensure each call is correctly categorized.

Part D Coverage Determinations, Appeals and Grievances (CDAG)
Audit Process and Data Request

United has concerns regarding the Audit Process and Data Request section of the CDAG Protocols. CMS indicates that all cases in the universes should be reported in one standardized time zone. However, we have members in multiple time zones and the times within each case are consistent with the applicable time zone that the cases are reported in. As one standardized time zone will not change the results of timeliness, we request that this requirement be removed.

In both Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout, Row P and Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) Record Layout, Row T, CMS has changed the data field from date reimbursement mailed to date reimbursement provided. United requests clarification regarding the difference between mail date and provided date. Additionally, we request clarification on if this accounts for electronic notifications.

CMS added "re-opened approved, or re-opened denied" to several tables within the Audit Process and Data Request. Specifically, in:

- Table 1: Standard Coverage Determinations (SCD) Record Layout, Row O
- Table 2: Standard Coverage Determination Exception Requests (SCDER) Record Layout, Row T
- Table 3: Direct Member Reimbursement Request Coverage Determinations (DMRCD) Record Layout, Row M
- Table 4: Expedited Coverage Determinations (ECD) Record Layout, Row Q
- Table 5: Expedited Coverage Determination Exception Requests (ECDER) Record Layout, Row V

United requests CMS confirm that, in the event that a case was re-opened approved or re-opened denied, all fields including all date and time fields are to be populated based on the initial coverage determination prior to reopening.

For Tables 5, 7 and 8 (State of Request), we request that CMS update this field to 20 characters to align with other tables.

We have several questions and concerns regarding Table 16: Call Logs Part D Record Layout. First, we ask CMS to confirm that call logs should only include inbound member calls. Additionally, some member calls are warm transferred to business areas and would have separate recordings. In those cases, we respectfully request clarification on the following:

- Should the universe include the initial member call, the warm transferred calls or both?
- If warm transfers are in scope, which request types should be reported in call logs?
- Should return calls from a member to the health plan in response to a health plan call be reported in call logs?
- Are member calls to Delegated Entities, including Mail Order, that do not process CDs, payment requests or reconsiderations in scope for call logs?
- Are member calls to Delegated Entities that are referred to United excluded from call logs?

United also asks that multiple requests be reported as separate call records when more than one request is made on a call. We believe that this would help ensure each call is correctly categorized.

Finally, United believes that providing this documentation is a cumbersome task that would require considerable resources and time to produce due to the volume of areas that could potentially have contact with the members. We request that CMS reconsider the inclusion of Table 16 and remove it from the audit protocols.

Special Needs Plan Model of Care (SNP-MOC) Protocols
Audit Process and Data Request

CMS has made changes to the Universe Preparation & Submission's Pull Universes and Submit Background Information section. Specifically, it states, “The universes collected for this program area tests the sponsor’s performance in processing enrollments, care transitions, and plan performance monitoring and evaluation of the MOC.” We ask that CMS clarify whether "care transitions" should instead be “care coordination” to better align with the audit elements. CMS also included the bullet, “Copies of the CMS-approved Health Risk Assessment Tool(s) (HRA) used by the SNP.” Current CMS guidance does not appear to address how plans should seek approval for a new or updated HRA tool(s) outside of the annual SNP application process. We request clarification on if there will be an approval process put in place separate from the annual SNP application process.

We have concerns with some of the standards under Audit Element II: Care Coordination. Under Standard 2.2.2, the word "all" has been omitted from the question, as compared to the previous versions of the protocols. We request that CMS add the word “all” back to this standard. Additionally, CMS is asking for documentation that would demonstrate Standard 2.3.1. We request clarification and for examples of appropriate documentation.

United requests clarification regarding Table 2: Plan Performance Monitoring and Evaluation (PPME) Record Layout. Specifically, we ask that CMS clarify whether "N/A” is an acceptable response when no data is available for Rows E, L and Q. Furthermore, United requests that CMS modify the table to add a "comments" Row to allow for comment/clarification of N/A responses.

Medication Therapy Management (MTM) Protocols
Audit Process and Data Request

The Row for "contract ID" was removed from Table 1. CY 2015 Medication Therapy Management Program (MTM-2015) Record Layout. United requests clarification on whether this omission was intentional. Additionally, Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout, Row AA, states, "Indicate the delivery method for the first CMR administered in CY 2015…" We request clarification on the date and whether it should be "CY 2016."

Part D Formulary and Benefit Administration (FA) Protocols
Audit Process and Data Request

United has concerns that, for various tables, National Drug Code (NDC) fields in the Universe templates do not specify how to identify compounds. We request clarification on whether plans are expected to provide the highest cost Part D eligible NDC in these situations. Additionally, in multiple tables, quantity fields in the Universe templates do not specify if the unit of measure must be included in the same field as the quantity. We request clarification on whether plans are expected to populate this field with the quantity and unit of measure.

Compliance Program Effectiveness (CPE) Protocols

CMS has added three new questions (16, 17, 18) regarding POS transactions for Part B Drugs in the ODAG Supplemental Questionnaire. United processes Part C point of sale (POS) transactions similarly to Part D POS transactions. Under Part D guidance (chapter 18, section 30), it states that the plan is not required to treat the presentation of a prescription at a pharmacy as a coverage determination. Absent any specific Part C guidance, United is seeking clarification that the presentation of a prescription for a Part C item at a pharmacy is not an organization determination.

CMS removed the Fraud, Waste & Abuse Monitoring (FWAM) universe from Appendix A-Compliance Program Effectiveness (CPE) Record Layouts. United is seeking confirmation from CMS that this information is no longer in scope.

If you have any questions on these comments, please feel free to contact me at 952-931-5444.

Respectfully,

Jennifer O'Brien
Chief Compliance Officer
UnitedHealthcare

PUBLIC SUBMISSION

As of: 9/1/16 2:28 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raj-hrl5
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0027
MN

Submitter Information

Name: Jennifer O'Brien
Address:
Minnetonka, MN, 55343
Email: jesse_p_schoolnik@uhc.com
Organization: UnitedHealthcare

General Comment

See attached file(s)

Attachments

UHC Comments - Medicare Parts C and D Program Audit Protocols

PUBLIC SUBMISSION

As of: 9/1/16 2:34 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raj-nydh
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0028
New York

Submitter Information

Name: Kiomara Cirino Cirino
Address:
San Juan, New York, Puerto Rico, 00920
Email: kcirino@sssadvantage.com

General Comment

Document: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area Audit Process and
Data Request, Section 3.2 Calculate Universe Timeliness, page 11

1st Comment: We understand that CMS should provide these 3 timeliness thresholds, as it would help sponsors in their
internal monitoring /auditing efforts to ensure the timeliness measures used are more aligned with CMS's thresholds.

Document: Part D Coverage Determinations, Appeals, and Grievances (CDAG) Program Area Audit Process and
Data Request, Appendix A- Coverage Determinations, Appeals and Grievances(CDAG) Record Layouts. Page 18-20

2nd Comment: If a good faith effort was made to provide oral notification to the enrollee, but was unable to contact him/her,
should this field contain the date the unsuccessful/good faith attempt was made or should it indicate NA because although
there was a good faith attempt oral notification was not provided?

Document: Part D Formulary and Benefit Administration(FA). Review sample case documentation. section 2.2
Rejected and/ or paid claim information. Page 9-10

3rd Comment: For CY2016, would it include all rejected claims during the entire CY2016, or only

November and December?

Document: Medication Therapy Management(MTM) Program Pilot. Appendix A- Medication Therapy Management
Program(MTM-2015)Table 1. CY2015 Medication Therapy Management Program (MTM-2015) Record Layout(page 11-12)

4th Comment: We observed that column G (Contract ID) was not included in Table 1, the layout goes from Column F
(cardholder ID) to column H (MTM Eligibility Date); however Table 2 does have a Column G included. Was it inadvertently
removed or was it intentionally excluded only from table 1?

Draft 2017 CMS Audit Protocol Comments

OMB Document Number 2016-13917
Document citation: 81 FR 38187
Agency collection number is CMS-10191
PacificSource Community Health Plans, Inc
Contracts: H3864, H4753

Document	page #	Section/Table	Comment
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	13	Intro 3.2.4	Under Appropriateness of Clinical Decision, section 3.2.3 and section 3.2.4 seem duplicative. Please add further clarifying language to make a distinction between the two or remove one to resolve the duplication.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	17	Table 1 SOD, Table 2 EOD, Table 4 DMR, Table 5 SREC, Table 6 EREC	Clarification was added to table 3 and table 7 regrading the exclusion of reopenings. Please further specify whether reopenings should be included or excluded from other tables such as SOD, EOD, DMR, SREC or EREC.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	17 & 25	Table 1 SOD, Table 2 EOD	Does CMS consider referral requests to be organization determinations that should be included in the data for the SOD and EOD tables?
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	18	Table 1 SOD	Please clarify the language in the description for column N in table 1, SOD. We believe CMS is seeking to determine if the timeframe of a request was changed to expedited after the initial receipt of the request as standard and if so who made that request. However, the language is unclear. Column N creates confusion. The overall table instructions state to exclude requests that are processed as expedited. However, if there was a subsequent request to expedite the case and it was granted then the case would no longer be in this universe as it was not processed as standard. Please provide context and clarification for the inclusion of this field in the SOD universe.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	18	Table 1 SOD	
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	22	Table 2 EOC	Please clarify the language in the description for column O in table 2, EOD. We believe CMS is seeking to determine if the timeframe of a request was changed to expedited after the initial receipt of the request as standard and if so who made that request. However, the language is unclear. Additionally, the last sentence of the description in column O which provides for the use of the option of "NA" if the case was not expedited. This is the expedited universe and therefore every case in the universe was expedited by one of the previously given options of CP, NCP, B, BR, or S. This field could be made applicable to this table by removing the option of "S" since the sponsor does not make a request, rather they make a determination to expedite a case.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	22	Table 2 EOC	In Table 2, column O seems redundant to what is being asked and the output option in column N. They both provide information on whether the sponsor expedited the request. Suggest removing column N or removing the output option of "S" from column O.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	25	Table 3 Claims	Plans may have determined the clean or unclean status of a claim even if it is untimely. These two things are not necessarily dependent on one another. Suggest rephrasing to state "If the claims payment is untimely and clean status hasn't been determined then indicate NA"
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	26	Table 3 Claims	The option of NA needs to be added to Column O of Table 3 for untimely cases that are still open.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	28	Table 4 DMR	Direct Member Reimbursement is a term that is not used or defined in the regulatory space of ODAG. Can CMS provide general clarification on the term "Direct Member Reimbursement" as it applies to ODAG?
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	28	Table 4 DMR	Members have liability, and therefore appeal rights, in certain situations of denied claims submitted by contracted providers. Therefore, we ask CMS to consider whether the include/exclude language of this table should be modified to include theses types of reconsideration requests also.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	29	Table 4 DMR	Column O of the DMR table asks whether or not interest was paid on the reimbursement request. There are some types of requests included in this universe where the application of interest would not apply. Please provide clarification on what types of cases CMS is requesting this information for and how to populate the table in cases where an interest payment would not apply.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	32	Table 5 SREC	For column N in Table 5 please provide context for distinguishing the output response of BR from CP when the contract provider is requesting an expedited request on behalf of the member. Please clarify why this same output would not be desired for a non-contract provider acting on a member's behalf ? Additionally, it would seem that the designation of BR in these cases makes it difficult to validate the requirement that the plan automatically expedite a request if there is physician support.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	32	Table 5 SREC	In column N of Table 5 it seems that the output option of "S" is not a logical option for this table. If the sponsor determined to expedite the case then the case would no longer be in the standard timeframe universe.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	35	Table 6 EREC	As above for table 5, for column N in Table 6 please provide context for distinguishing the output response of BR from CP when the contract provider is requesting an expedited request on behalf of the member. Please clarify why this same output would not be desired for a non-contract provider acting on a member's behalf ? Additionally, it would seem that the designation of BR in these cases makes it difficult to validate the requirement that the plan automatically expedite a request if there is physician support.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	35	Table 6 EREC	In Table 6, column N seems redundant to what is being asked and the output option in column O. They both provide information on whether the sponsor expedited the request. Suggest removing column O or removing the output option of "S" from column N.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	40	Table 10 ALJ/MAC	In table 10, column J should have an output option of NA or other instructions on how to populate the response for payment cases which are also included in this table
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	46	Table 11 GRV	The right to file a grievance is given to members and their representatives. If a provider has valid authority to act on behalf of a member they would be acting as the beneficiaries representative and the output option in column F of Table 11 would be BR. The options of CP and NCP are not valid individual options as a provider cannot file a grievance unless they are a member's representative.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	48	Table 12 GRV-E	Same as immediately above, the right to file a grievance is given to members and their representatives. If a provider has valid authority to act on behalf of a member they would be acting as the beneficiaries representative and the output option in column F of Table 12 would be BR. The options of CP and NCP are not valid individual options as a provider cannot file a grievance unless they are a member's representative.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST	52	Table 13 DIS	In table 13 column O asks for the time the request was dismissed. Time is only relevant for expedited cases so the option of "NA" needs to be added for cases that were not expedited.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST & Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area AUDIT PROCESS AND DATA REQUEST	ODAG 53 CDAG 60	ODAG Table 14 CDAG Table 16	Please provide further clarification and refinement of the inclusion and exclusion criteria for these 2 new universes. The scope is currently very broad and there is concern that many non-relevant calls will be included in the universes which will make CMS objectives for use of this data difficult and will produce very large and cumbersome files. For example, as it is currently written, calls from providers inquiring on general member information for benefits, deductibles and out of pocket amounts would be included in this universe, also broker calls on general plan information, or calls from non-authorized representatives where no information is shared.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST & Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area AUDIT PROCESS AND DATA REQUEST	ODAG 53 CDAG 60	ODAG Table 14 CDAG Table 16	The universes for Call Logs in both CDAG and ODAG currently split the description of the call from the resolution of the call. Call notes are typically captured in systems all in one field. The call note includes all details of the call, including the description and resolution. From a customer service process, system and data standpoint, breaking these aspects out will be a significant burden on plans. It is suggested to make the description for column J in table 15 of CDAG consistent with corresponding column J of table 12 in ODAG. The member can only file an expedited grievance when the plan has taken an extension or denied the request for expedited processing. So all the other grievance categories in column J are not needed.
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area AUDIT PROCESS AND DATA REQUEST	58	Table 15 EGD	
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area AUDIT PROCESS AND DATA REQUEST		Various	For CDAG universes that will include reopened cases please clarify what the plans should populate as the receipt date for these types of cases. i.e. Does CMS want to see the date the request was reopened as the receipt date or the date the request was originally received?
Part C and D Compliance Program Effectiveness (CPE) Program Area AUDIT PROCESS AND DATA REQUEST	12	Table 1 FTEAM	We request that CMS consider changing the name of the FTEAM universe to FDRAM. This is more consistent with CMS language used throughout regulations related to this topic. It is also less confusing as organizations use the acronym of FTE to refer to employees and the CPE protocols contain a separate employee universe.
Part C and D Compliance Program Effectiveness (CPE) Program Area AUDIT PROCESS AND DATA REQUEST	25-29	Table 4 IM	Update page numbers within the document for accuracy.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area AUDIT PROCESS AND DATA REQUEST & Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area AUDIT PROCESS AND DATA REQUEST		Various	There is inconsistency in character length between common fields in the various program audit areas. For example the character length for the Issue Description fields in the grievance tables for CDAG and ODAG are drastically different. Please consider standardizing the number of characters allowed for common fields through out the tables for all program audit areas to ease programming requirements and ensure consistency from the plan sponsors.

PUBLIC SUBMISSION

As of: 9/1/16 2:52 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raj-saom
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0031
ID

Submitter Information

Name: Sarah Bishop
Address:
Boise, ID, 83706
Email: sarah.bishop@pacificsource.com

General Comment

Please see the attached file for your review and consideration.

Attachments

2017 CMS Draft Protocol Comments

PUBLIC SUBMISSION

As of: 9/1/16 2:54 PM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8raj-vg5x
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0032
FL

Submitter Information

Name: Anonymous Anonymous
Address:
Tampa, FL, 33611

General Comment

1. In the ODAG Standard Organization Determination (SOD) and Expedited Organization Determination (EOD) record layouts, for the "Request Disposition" field, we are seeking clarity on the following statements in the description of this field: 1) "Sponsors should note any requests that are untimely and not yet resolved (still outstanding) as denied" and 2) "All untimely and pending cases should be treated as denials for the purposes of populating the rest of this record layout's fields." To clarify, if a request was approved, but it was approved after the compliance timeframe passed, are we really to report the approval as a denial? If the answer is yes to that question, would we answer "NA" to the field "Date service authorization entered/effectuated in the sponsor's system" even if an approved authorization was entered, the service rendered, and later a claim paid?

PUBLIC SUBMISSION

As of: 12/9/16 8:32 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rak-4zwc
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0036
NJ

Submitter Information

Name: Mario Vargas
Address:
Newark, NJ, 07105
Email: mario_vargas@horizonblue.com

General Comment

Agency Collection Number: CMS-10191
Document Number: 2016-13917
Document Citation: 81 FR 38187

1. Requesting clarification regarding the changes made to the "Description" field of the Coverage Determinations Record Layout for the Patient Residence in the 2017 CMS Draft Audit Protocols.

Can the Plan Sponsor continue to capture the Patient Residence by utilizing the rejected or paid claim occurring within 3 days of the CD?

2. Medication Therapy Management (MTM) Pilot Audit protocols:
CY2016 universe Column ID: AJ

a. Follow up intervention criteria lists the reporting options as "Accepted" or "Denied" recommendations. Although many prescribers formally respond with an acceptance or a denial, not all prescribers respond.

b. Would an additional reporting option of "Adherence/Unknown" be appropriate to accurately identify, within the universe, instances when a prescriber does not respond?

HealthPartners®

Corporate Office:
8170 33rd Avenue South
Bloomington, MN 55425
healthpartners.com

Mailing Address:
P.O. Box 1309
Minneapolis, MN 55440-1309

August 12, 2016

Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-1850

Submitted Electronically to www.regulations.gov/comment?D=CMS-2016-0097-0001

RE: Comments on 2017 Draft CMS Program Audit Protocols (Agency collection number CMS-10191, OMB control number 0938-1000, Document number 2016-13917, and Document citation 81 FR 38187)

Dear Sir or Madam:

HealthPartners is a not-for-profit plan sponsor and holds three contracts with the Centers for Medicare & Medicaid Services (CMS). They are H2422 (MA SNP), H2462 (1876 Cost) and S1822 (Employer Group PDP). Our 1876 Cost contract is a 5-star plan, our SNP contract is a 4.5-star plan and our PDP is a 5-star plan.

In response to the release of the 2017 Draft Medicare Parts C and D Program Audit Protocols published on June 13, 2016, HealthPartners submits the comments below for consideration.

CMS 10191 - Supporting Statement Part A

1. Background Section (p. 1) – The second paragraph mentions that CMS utilizes seven protocols to audit sponsor performance, and that the data collected is detailed in each of the protocols and the exact fields are located in the record layouts, at the end of each protocol. The documents published on June 13, 2016, only contain the data collected and information for six protocols. The information for the Provider Network Adequacy protocol was not included in the draft protocols.

Recommendation: CMS should release the Provider Network Adequacy protocol as part of the final 2017 CMS Medicare Parts C and D Program Audit Protocols.

2. Burden Estimates (Hours and Wages) (p. 4-5) – The burden estimates for hours do not reflect our plan's experience during our CMS Program Audit in 2013. We had a minimum of 60 staff involved, including several Senior Leaders of our organization. We spent several hundred hours assembling and reviewing the requested information prior to submission; then spent several hundred hours during the actual administration of the audit (participating in the webinars and assembling the requested documentation after hours).

Recommendation: CMS should consider surveying Sponsors at the close of an audit to obtain a more accurate estimate of the hours the sponsor spent on audit activities. This information could be used to update the burden estimate as appropriate.

Attachment III – CDAG Audit Process Data Request

1. Universe Preparation & Submission, #2 Pull Universes (p. 5)– The third paragraph of this section states "The universes should be 1) all inclusive, regardless of whether the request was determined to be favorable, partially favorable, unfavorable, auto-forwarded, dismissed, withdrawn, or reopened". It is not clear where auto-forwarded determinations and appeals are to be included.

Recommendation: CMS should clarify if auto-forwarded determinations should be included in all universes as well as the auto-forward universe, or if they should only be in the auto-forward universes (Table 9 and 10).

2. Grievances and Misclassification of Requests, #2.2 For Call Logs (p. 16 & 60) – The supporting documentation requested under the call logs section does not align with current CMS guidance. There is not guidance that all calls to Member Service calls must be documented or tracked. There is also not a requirement to record calls, unless it is a telephonic enrollment. We do maintain documentation for all grievance calls. We document limited details on all calls received, however it would require a change to our current systems and would require increased staff time to document the full description of the call and a full description of the call outcome and resolution for all calls received.

Recommendation: CMS should align the scope of the protocol with current guidance. Consideration should be given to only request information on grievance calls.

Attachment IV- ODAG Audit Process Data Request

1. Universe Preparation & Submission, #2 Pull Universes (p. 5)– The third paragraph of this section states "The universes should be 1) all inclusive, regardless of whether the request was determined to be favorable, partially favorable, unfavorable, auto-forwarded, dismissed, withdrawn, or reopened". It is not clear where dismissed cased should be included.

Recommendation: CMS should clarify if dismissed cases should be included in all universes as well as the dismissals universe, or if they should only be in the dismissals universe (Table 13).

2. Grievances and Misclassification of Requests, #2.2 For Call Logs (p. 15 & 53) – The supporting documentation requested under the call logs section does not align with current CMS guidance. There is not guidance that all calls to Member Service calls must be documented or tracked. There is also not a requirement to record calls, unless it is a telephonic enrollment. We do maintain documentation for all grievance calls. We document limited details on all calls received, however it would require a change to our current systems and would require increased staff time to document the full description of the call and a full description of the call outcome and resolution for all calls received.

Recommendation: CMS should align the scope of their request with current guidance. Consideration should be given to only request information on grievance calls.

3. Table 9: IRE Payment Cases Requiring Effectuation (p. 42) – Column I – Level of Service lists an example of point of sale transaction. Can CMS provide a clarification of what is considered a Point of Sale Transaction for part C?

Recommendation: CMS should include examples of Point of Sale transactions for Part C as part of the data request.

Thank you for the consideration of our comments. If you have any questions regarding our comments, please feel free to contact me at 952-967-7650 or Laurena.S.Lockner@HealthPartners.com.

Sincerely,

Laurena Lockner
Sr. Manager, Monitoring and Compliance
HealthPartners

PUBLIC SUBMISSION

As of: 12/9/16 8:25 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rak-7owh
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0034
MN

Submitter Information

Name: Laurena Lockner
Address:
Bloomington, MN, 55425
Email: laurena.s.lockner@healthpartners.com

General Comment

In response to the release of the 2017 Draft Medicare Parts C and D Program Audit Protocols published on
June 13, 2016, HealthPartners submits the attached comments for consideration.

Attachments

HP Comments_Draft 2017 Program Audit Protocol

PUBLIC SUBMISSION

As of: 12/9/16 8:22 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rak-8ypa
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0033
FL

Submitter Information

Name: Anonymous Anonymous
Address:
Tampa, FL, 33611

General Comment

The question is in regards to the Part C Appeal universe. Member post-service appeals, universe specifies that it is only for non-contracted providers, is this correct?

2017 Draft Audit Protocol Comments

Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area

I. Change Noted:
   a. Added a call log universe

Clarifying Questions:

- What is meant when it says that "all calls" should be included in the universe? Is this intended to include provider calls or calls that do not come in via the member services line?
- If a call relates to both Part C and Part D, should the call be included in the call log universe for ODAG and CDAG?
- Was the Enrollment Effective Date intentionally left off the ODAG call log universe? It is on the CDAG call log universe.

Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area

I. Changes Noted:
   a. All universes now include reopened cases.
   b. CMS may select an additional 5 cases to review dismissals, withdrawals and/or re-openings to assess whether the request was appropriately classified and processed.

Clarifying Questions:

- Will CMS be providing a clear definition of re-openings? (i.e., should only re-openings with a revised decision be included in the universe?)
- Will CMS be providing a clear definition of dismissals?

II. Change Noted:
   a. Added a Call Log Universe

Clarifying Questions:

- Are all Medicare Part D provider calls (i.e. pharmacy calls) to be included in the Call Log Universe?
- The character lengths for Column ID's A, B & C are not consistent with all other universes. Was this intentional?

III. Change Noted (Grievances and Misclassification of Requests):
   a. CMS added requirements for the Sample Case Documentation for Call Logs

Clarifying Questions:

- Are audio recordings required, or only if available?
- Is a summary of the call (including all activity that occurred) sufficient for documentation of the call details, or are all notes required?

Part D Formulary and Benefit Administration (FA) Program Area

I. Change Noted:

a. New Rejected Claims Transition – Previous Contract Year (RCT-P) universe

Clarifying Question:

- In this universe, we are required to provide the pharmacy message associated with each rejected reason code. If our system cannot link individual pharmacy messages to individual rejected reason codes, is it acceptable to list, for each rejected reason code, all pharmacy messages associated with the rejected claim; OR is it acceptable to provide the NCPDP reject message associated with each rejected reason code?

PUBLIC SUBMISSION

As of: 12/9/16 8:29 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rak-z4ll
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0035
WI

Submitter Information

Name: Anonymous Anonymous
Address:
WI, 53717

General Comment

See attached file(s)

Attachments

2017 Draft Audit Protocol Comments

To: Department of Health and Human Services (DHS) and Centers for Medicare & Medicaid Services (CMS)

From: Stacey Puckett, Project Consultant, Program Oversight and Communication

Date: August 12, 2016

Re: 2017 Draft Program Audit Protocols

Thank you for the opportunity to provide feedback on the 2017 Draft Program Audit Protocols as outlined in your memo dated *June 16, 2016*.

Please see the below comments and recommendations sent on behalf of Blue Cross Blue Shield of Michigan (Contract H9572 and S5584) and Blue Care Network (H5883).

- **Compliance Program Effectiveness**
  - Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN) recommend the tracer sample selection from the universes remain at 5 cases instead of the proposed 6 cases. During our 2015 program audit, 5 tracer samples were sufficient for the auditors to evaluate whether our plan's compliance program functioned effectively.
  - BCBSM and BCN appreciate the record layout inclusions and exclusions additional clarification.
  - BCBSM and BCN requests CMS clarify if the information in the entrance meeting presentation is required or is this included in the draft protocols as an example. It is unclear if these are guidelines for the plan to use when developing their presentation or if they are required.
- **Coverage Determinations Appeals and Grievances**
  - BCBSM and BCN appreciate CMS outlining the timeliness tests per universe and including the compliance standard to apply. BCBSM and BCN recommend CMS add in the column titled "test" the fields from the universe that will be tested to confirm if the compliance standard was met. For example, Table 1 Standard CDs compliance standard to apply is "no later than 72 hours". Table 1 would state in "test" the columns compared from the record layout to determine whether or not the 72 hours was met.
  - BCBSM and BCN recommend CMS limits the scope of this table to include only member calls that are received via the Customer Service Current phone numbers listed in HPMS (Plan Bids - Bid Submission – Contact Data). Limiting the origin of

calls to the plan customer service line will promote greater reliability, consistency, and plan comparison.

- **Medication Therapy Management**

  - BCBSM and BCN requests CMS consider expanding the requirements for the annual data validation audit for Medication Therapy Management to eliminate the MTM Audit from the protocols.

- **Formulary Administration**

  - BCBSM and BCN request CMS clarify if a change from one Plan Benefit Package to another within the same contract is considered a new enrollment.

- **Organization Determinations, Appeals and Grievances**

  - BCBSM and BCN appreciate CMS clarifying the date written notification provided to the enrollee is when the letter left the organization. Often times obtaining exact mail dates can be complex when using batch processing. BCBSM and BCN recommend CMS consider allowing plans to utilize the last date in the batch processing system, when applicable.

  - BCBSM and BCN appreciate CMS outlining the timeliness tests per universe and including the compliance standard to apply. BCBSM and BCN recommend CMS add in the column titled "test" the fields from the universe that will be tested to confirm if the compliance standard was met. For example, Table 1 Standard Pre-Service ODs compliance standard to apply is "no later than 14 days, plus 14 days (totaling 28 days) if an extension is used". Table 1 would state in "test" the columns compared from the record layout to determine whether or not the 14 days or 28 days if an extension was used were met.

  - BCBSM and BCN appreciate the clarification of how to populate field titled "Who made the request?" as well as the inclusions and exclusions for record layouts.

  - BCBSM and BCN recommend CMS limits the scope of this table to include only member calls that are received via the Customer Service Current phone numbers listed in HPMS (Plan Bids - Bid Submission – Contact Data). Limiting the origin of calls to the plan customer service line will promote greater reliability, consistency, and plan comparison.

PUBLIC SUBMISSION

As of: 12/9/16 8:34 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8ral-9awh
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0037
MI

Submitter Information

Name: Stacey Puckett
Address:
Detroit, MI, 48226
Email: spuckett@bcbsm.com

General Comment

Blue Cross Blue Shield of Michigan (H9572 and S5584) and Blue Care Network (H5883) appreciate the opportunity to provide comments on the draft CY2017 audit protocols. Our comments are located in the attached document.

Thank you!

Attachments

Audit Protocols Comments FINAL

Health Partners Plans

Memorandum

To: Centers for Medicare and Medicaid Services (CMS)

From: Health Partners Plans

Date: 8/15/2016

Re: 2017 Draft Program Audit Protocols Comments and Feedback
Agency Collection Number: CMS-10191
Document Number: 2016-13917
Document Citation: 81 FR 38187

Health Partners Plans would like to thank the Centers for Medicare and Medicaid Services for the opportunity to provide feedback on the 2017 Draft Program Audit Protocols. Our various business units and subject matter experts have carefully examined the audit protocols and believe we have provided useful feedback. We welcome any questions or concerns should you need additional clarity.

2017 CMS SNP MOC Program Area – Universe Preparation & Submission – *2. Pull Universes and Submit Background Information*

The sponsor will provide the following background information documentation that is applicable to the audit timeframe:

- ***Listing of FDRs that assist with the MOC and their functions/deliverables***

Is this is FDRs as it relates to any aspect of the Model of Care from a claims, enrollment clinical perspective or only FDRs as it relates to key components of the clinical aspects of model of care?

2017 CMS SNP MOC Program Area - II Care Coordination - *1. Review Sample Case Documentation*

- ***Evidence that sponsor confirmation has occurred for MOC training of network providers and ICT members***

Will this include vendors if vendors own a core function of the MOC PPE/Table 1 function?

2017 CMS SNP MOC Program Area - II Care Coordination - *2.1.2. Did the sponsor conduct the initial HRA either 90 days before or after the enrollment effective date?*

The 2017 CMS SNP MOC draft audit protocol includes the following question "2.1.2 - Did the sponsor conduct the initial HRA either 90 days before or after the enrollment effective date?" We are unable to locate anything indicating regulations have been revised to now reflect "90 days before or after the enrollment effective date".

Revisions to the Medicare Managed Care Manual - Quality Assurance chapter do not appear to have been made to indicate the HRA may occur 90 days before or after the effective date. The manual indicates "The organization must complete the HRAT for each beneficiary, for initial assessment, and must complete an HRAT annually thereafter. At minimum, the organization must conduct initial assessment within 90 days of enrollment and must conduct annual reassessment within one year of the initial assessment."

The CFR reflects the following:

§422.112(b)(4)(i)

"The MA organization makes a "best-effort" attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment"

Per the 2016 Final Call Letter, "SNPs are required to perform a comprehensive initial HRA that includes assessment of each enrollee's physical, psychosocial, and functional needs within the first 90 days of enrollment and conduct reassessments annually thereafter".

Furthermore, in the 2016 Final Call Letter (page 90 of 190), CMS addressed concerns raised that related to the SNP Care Management measure. In that Call Letter, CMS indicated "During 2014 CMS issued a clarification to this measure to make it explicit that the initial Health Risk Assessment (HRA) must occur on or after the date of the member's initial enrollment in the plan. That is, the initial HRA must occur when members are already eligible to receive benefits. The reasoning behind this requirement is that in its absence, plans could base enrollment decisions on the results of the HRA. This is not the purpose of the HRA."

We have not come across anything other than the protocol and new reporting requirements indicating the HRA may be conducted 90 days before the enrollment effective date. If possible, please provide clarification as to whether or not regulations will be codified to include an HRA may be accepted 90 days before the enrollment effective date.

2017 CMS SNP MOC Program Area - II Care Coordination - *2. Apply Compliance Standard - 2.2.2. Did the ICP include specific interventions designed to meet the needs identified in the HRA?*

We ask that 2.2.2 read "Did the ICP include specific *measurable* interventions designed to meet the needs identified in the HRA."

2017 CMS SNP MOC Program Area - II Care Coordination - *2. Apply Compliance Standard - 2.4.1. Did the sponsor plan & implement care transition protocols to maintain member's continuity of care as defined in the MOC?*

This is a new MOC protocol. Do all MOCs need to be updated with this requirement?

2017 CMS SNP MOC Program Area - II Care Coordination - *2. Apply Compliance Standard - 2.5.2. Does the sponsor utilize a contracted vendor that administers the HRA? If so, does the vendor have Policies and Procedures that match the MOC goals and comply with CMS requirements?*

Does this apply to the initial HRA, the annual HRA, or both? We believe it should apply to both.

2017 CMS SNP MOC Program Area – III Plan Performance Monitoring and Evaluation of the MOC – *2. Apply Compliance Standard - 2.1. Did the sponsor collect, analyze, and evaluate the MOC (e.g., specific data sources, specific performance and outcome measures, etc.)?*

Is this in relation to PPE or overall model of care performance and outcome?

2017 CMS SNP MOC Program Area – III Plan Performance Monitoring and Evaluation of the MOC – *2. Apply Compliance Standard - 2.5. Are the appropriate personnel responsible for oversight of the MOC's evaluation and monitoring process?*

Does this refer to the appropriate personnel per the model of care or per CMS?

2017 CMS SNP MOC Program Area - Table 1: Special Needs Plan Enrollees (SNPE) Record Layout

Regarding *Column ID K: Was an initial HRA completed 90 days before or after the enrollment effective date?*:

We recommend that this read as two separate questions.

2017 CMS SNP MOC Program Area - Table 1: Special Needs Plan Enrollees (SNPE) Record Layout

Regarding *Column ID P: Was an ICP completed?*:

Is this an ICP that is related to the most previous HRA assessment/reassessment?

2017 Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area – Audit Elements III - *3.1. Was the case or call correctly classified, and if not, was it quickly transferred to the appropriate process?*

Please define "quickly."

2017 Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area – Table 16: Call Logs Part D Record Layout

1. **Table 16: Call Logs Part D Record Layout**

- Are the call logs from members and providers or members only?
- Does CMS want all audio files with the universe submission or will they want the audio files for the sample only?
- How do we save and submit the audio files? Is there a specific file type?
- Do calls in languages other than English need to be translated into English?
- This will be difficult for plans to operationalize and may require an entire overhaul of current processes, systems and a massive training initiative.

2. **Table 16: Call Logs Part D Record Layout**

K	Description of the outcome of the call	CHAR Always Required	1000	Full description of the call outcome and any resolution. This should include whether a subsequent action was started (CD, RD or grievance).

Please define what categories this pertains to and the exact outcomes we should use.

2017 Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area – Table 6: Standard Redeterminations (SRD) Layout, Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) Record Layout, and Table 8: Expedited Redeterminations (ERD) Record Layout

The character limit for the Request Disposition field was raised from 16 to 20 for CDAG Table 6 (Column ID O), but not for CDAG Tables 7 & 8 (Column IDs P and S, respectively)); however, all 3 tables provide the same options as answers: approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened approved, or re-opened denied. The longest option, re-opened approved, is over 16 characters. Will the character limit for CDAG Tables 7 & 8 also be raised to 20?

2017 Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area – Table 14: Standard Grievances Part D (SGD) Record Layout and Table 15: Expedited Grievances Part D (EGD) Record Layout

The character limit for Column ID H "How was the grievance/complaint received?" field was lowered from 40 to 7 for CDAG Table 14, but not for CDAG Table 15, Column ID I; however, the options were changed for both tables to either "Oral" or "Written".

2017 Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area – Table 3: Requests for Payment Organization Determinations (Claims) Record Layout

Regarding *Column ID N: Date the claim was paid or denied.*

We populated that field for the Universe with the day we decided to pay or deny the claim. There was conversation about whether that column should be the date the physical payment was sent to the provider. Populating it that way will make it identical to column ID S (Date written notification provided to provider) for electronic payments. CMS thought that for denials it should be different; the date we decided to deny the claim. Our concern is that we would be using different criteria depending upon if the claim was paid or denied. During the audit we asked for written clarification on Column N of ODAG Table 3 but never received it.

2017 Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area – Table 4: Direct Member Reimbursement (DMR) Requests Record Layout and Table 7: Requests for Payment Reconsiderations (PREC) Record Layout

Regarding *Column ID N: Date reimbursement issued or denied* (Table 4) and *Column ID L: Date the claim was paid or denied* (Table 7).

- Q 1: Do these dates refer to the mailing date of issuance/payment or denials were paid?
- Q 2: For the above fields is "N/A" an option (for scenarios of a credit balance with the provider and/or a $0.00 balance with provider/no member liability)? One scenario of concern is the where the member appeals a claims denial but the member does not have any financial liability for the claim (either the provider has waived the cost or the member cannot be billed for non-covered service). Currently the member receives a favorable decision on the appeal as the member has no further liability for the claim. However, the decision is only to the member's liability for the claim and not the claim itself, so the service remains uncovered. The appeal is favorable but there is no reimbursement/paid date.
- Q3: The description for ODAG Table 4 has been updated to add "reconsiderations and non-contract provider claim reconsiderations submitted by beneficiaries". Does this mean that this table now includes all Part C payment appeals from members, excluding those filed by non-par providers requiring a WOL?

2017 Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area Table 14: Call Logs Part C (CLC) Record Layout and 2017 Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Table 16: Call Logs Part D Record Layout

For the sample case documentation it asks for a copy of the CD, OD, Grievance or Appeal (if applicable). If identified, for this table review, are those case files being audited?

PUBLIC SUBMISSION

As of: 12/9/16 8:39 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8ral-667q
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0039
PA

Submitter Information

Name: Matt Reilly
Address:
Philadelphia, PA, 19107
Email: mreilly@hpplans.com

General Comment

2017 Draft Program Audit Protocols Comments and Feedback
Agency Collection Number: CMS-10191
Document Number: 2016-13917
Document Citation: 81 FR 38187

We would like to thank the Centers for Medicare and Medicaid Services for the opportunity to provide feedback on the 2017 Draft Program Audit Protocols. Our various business units and subject matter experts have carefully examined the audit protocols and believe we have provided useful feedback. We
welcome any questions or concerns should you need additional clarity.

Please refer to the attached document to review our comments.

Attachments

HPP Draft Program Audit Protocols Comments

PerformRx

200 Stevens Drive
Philadelphia, PA 19113-1570

www.performrx.com

August 12, 2016

VIA Electronic Submission: (www.regulations.gov)

Re: CMS 10191 Medicare Parts C and D Program Audit Protocols and Data Requests

To Whom It May Concern,

PerformRx is a pharmacy benefit manager (PBM) for Medicare Advantage Prescription Drug Plans (MAPDs) and Medicare-Medicaid Plans (MMPs) nationwide. We appreciate the opportunity to participate in the comment process for CMS 10191 Medicare Parts C and D Program Audit Protocols and Data Requests. Below are our comments/ recommendations.

Please contact me if you require additional information.

Cordially,

Michelle Juhanson, CHC, CHPC

Director, Compliance & Quality
mjuhanson@performrx.com
215-937-4108

PerformRx

200 Stevens Drive
Philadelphia, PA 19113-1570

www.performrx.com

Section/Title	Page No.	CMS Proposed Requirement	Comment
N/A	N/A	N/A	Would CMS please consider suspending any other audit (i.e., one-third financial, TMPA, MMP reporting) for any sponsor selected for a program audit until the program audit is complete? We have experienced a program audit that occurred at the same time that we were required to support the one-third financial audit and MMP 1.2 reporting process for the same health plan client. PerformRx is a small PBM with around 300 associates. We have consistently had to devote 30 FTEs to each program audit almost the entire 6-8 week audit cycle. The other CMS audits generally require action by the same departments/individuals whose sole focus needs to be the program audit, especially given the expectation for complete and accurate universes. The goal is for each audit to be successful. We also want to ensure a modicum of work-life balance for our associates. The program audit process is incredibly stressful because everyone wants to do well and there are so many moving parts that must be coordinated to meet CMS' expectations. To the extent that the audits are scheduled, any amount of coordination and amongst the other CMS audit vendors/schedulers would be greatly appreciated.
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request **3. Apply Compliance Standard**	11	CMS has determined 3 timeliness thresholds that apply to every test in each universe. Sponsors that fall at or above the first threshold will generally not be cited a condition.	Would CMS be willing to share these thresholds with the industry? CMS is in a position to identify this as a best practice and QA check for plan sponsors and their FDRs in their ongoing monitoring and auditing programs. Otherwise, would CMS be willing to share the methodology by which it determines the threshold? Similar to the transparency of the star ratings calculation and methodology, by sharing this information sponsors have an additional method to measure quality and compliance in their organization.

Section/Title	Page No.	CMS Proposed Requirement	Comment
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request **2. Review Sample Case Documentation**	13	If **rejection**, explanation for why drug rejected (i.e., refill too soon).	Would CMS change the word "rejection" to "denial"? A rejection happens at the point of sale (POS). Our organization does not consider POS rejections to be part of the coverage determination process, which is permissible according to Chapter 18. When we receive a coverage determination request we evaluate that request on its merit. While we will review the claim record, we are not specifically assigning a rejection to that request or assuming that a specific rejection caused the coverage determination request. Coverage determinations are processed in a different system and by a different department/company from the claims processing function. Our organization can be prepared to show previous rejections in the claim processing system, but the rejection does not cause PerformRx to initiate a coverage determination. The formulary administration portion of the audit evaluates the appropriateness of rejections.
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request **3.2 Clinical Appropriateness/Denials**	14	Was the **reconsideration** reviewed by a different physician with expertise in the field of medicine that is appropriate for the services at issue?	Would CMS revise the term "reconsideration" and replace it with "redetermination"? The reconsideration is processed by the independent review entity. The "redetermination" is processed by the plan sponsor. The requirement to have a different physician evaluate the case is only materially important (for the purpose of the audit) when comparing which clinician evaluated the coverage determination versus the physician that evaluated the "redetermination." This change will bring the audit test measure in line with the terms and conditions set forth in Chapter 18 for levels 0 and 1 in the coverage determination and appeals process.
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area Audit Process and Data Request **Appendix A**	19	Column ID G- Patient Residence	Would CMS consider retiring this field? Patient residence is not generally included on the coverage determination request. Likewise, as previously mentioned, we do not derive a one-to-one correlation between POS rejections and coverage determinations. Our prior authorization system is separate from the claims processing system. The prior authorization system is the sole source of data for the CDAG universes. It requires assumptions and manual work to identify and then allocate a specific residence code based on a POS rejection that is not captured in the PA system. Would CMS provide more

Section/Title	Page No.	CMS Proposed Requirement	Comment
			guidance on the utility and purpose of collecting this information? Again, to the extent that rejections do not always cause coverage determinations, would CMS consider limiting the universe elements to those things that are directly related to the processing of the coverage determination for all organizations?
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request **Appendix A**	12	Column ID A- Beneficiary HICN	Would CMS confirm in writing its intent that the only acceptable information in this field is the HICN number? We have been told by another organization that CMS accepted the cardholder ID in this field, but they could not produce written evidence that this was the case. If CMS is willing to allow sponsors to not report on this field, would CMS be willing to disclose general guidelines for exceptions when that substitution would be permissible?
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request Appendix A	13	Column ID R, S- Reject Reason Code and Pharmacy Message All pharmacy messages associated with a claim should be included	Would CMS please confirm in writing to the industry that the expectation is that plan sponsors report both the NCPDP reject reason codes/pharmacy message as well as any claim processor/plan-specific reject reason codes and pharmacy messages? In our CMS program audit experience, CMS has provided that level of specificity. Unfortunately, the statement "all pharmacy messages" has still resulted in differing interpretations. The impact goes beyond the CMS program audit, as consultants and health plans rely on their experience and interpretation of the CMS protocols to conduct their own audits. By providing a greater level of specificity the entire industry would benefit.
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request **2.2 Transition**	3	2.2 Transition 2.2.4 New Members (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs))	CMS has specified in this section that sponsors should include MMP and employer plan members. However, throughout the rest of the FA, CDAG, and MTM protocols we did not observe specific MMP plan instructions. In the event that CMS includes MMP contracts in the audit engagement letter, should sponsors include MMP plan data in all universes? If so, we would recommend that only the Part D claims and rules be in scope, as opposed to the Medicaid/ADD file claims as we are still operating under a demonstration. There is inconsistency in the rules and application thereof from one demonstration state to the next.

Section/Title	Page No.	CMS Proposed Requirement	Comment
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request **Sponsor Disclosed and Self-Identified Issues**	4	Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from the starting date of each universe period through the date of the audit start notice, which CMS may find in your data universes. A disclosed issue is one that has been reported to CMS prior to the date of the audit start notice (which is also known as the "engagement letter")	Would CMS consider leveraging the CMS Regional Office for the provision of this information? If the Part D Sponsors have already disclosed the issue to CMS, it stands to reason that the CMS plan managers have this information. Upon receipt of the audit engagement letter Plan Sponsors are under significant pressure to produce more than 20 universes, participate in audit meetings with CMS, and often coordinate with their FDRs, consulting firms, and CMS , all in a very compressed timeframe. Were CMS to consider using the Regional Office staff for this portion it would allow sponsors to focus their resources on producing accurate universes and information that CMS does not already have in its possession. If the concern is around formatting this information based on the proposed pre-audit issue summary templates, would CMS consider creating a self-disclosed issue module in HPMS for the sponsors and plan managers to report and manage those disclosures? CMS could have the HPMS developers create a module that collects the same information and in the same format as the audit template. This would allow the sponsor or CMS to quickly produce this information at the touch of a button, and be gathered and captured in real time, as the disclosures occur.
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request **Sponsor Disclosed and Self-Identified Issues**	4	Within 5 business days after receipt of the engagement letter, sponsors must provide a description of each issue as well as the remediation status using the Pre-Audit Issue Summary template (Attachment VIII).	We have had the opportunity to participate in several CMS program audits and have found the 5 business day turnaround time to be insufficient for sponsors to produce the self-identified issues because often those issues are identified during the course of the universe creation and validation process. If CMS allows plan sponsors 15 days to produce the applicable universes, would CMS consider allowing the sponsors that same amount of time to collect and report the self-identified issues? Likewise, often sponsors must work with their FDRs to obtain this information, since the FDR may be the organization producing the universes, and are likely to find different things in addition to what the sponsors may have identified. Sponsors tend to give FDRs much less time to produce the information to allow for plan executive, compliance, and or consultant review. As a result, the FDR may only have 2 or 3 business days to produce a report. At PerformRx, we practice self-disclosure as quickly as issues are discovered and or substantiated, and encourage our health plan clients to self-disclose to CMS. The concern is that the "Self-identified issues" are generally those issues that we

Section/Title	Page No.	CMS Proposed Requirement	Comment
			discoverer as a result of a rigorous evaluation of the universes and the claims/cases therein. It creates a significant burden to attempt to complete root cause analyses in less time than is afforded to produce the universe. As a result, it is possible that CMS is only receiving a fraction of what the plan sponsors "self-identify" and would be willing to disclose to CMS, but for the fact that they only have 5 business days to do so.
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request **Sponsor Disclosed and Self-Identified Issues**	4	If validation of correction is not feasible during the audit (e.g., would be time consuming or insufficient data exists) then the organization will be cited the applicable conditions related to the disclosed/self-identified issue in their audit report and **CMS will validate correction during audit validation.**	Would CMS consider revising the last sentence of the last paragraph of this section to reflect that the plan sponsors third-party auditor would validate correction during the audit validation or that CMS is relying on the evaluation of the plan sponsor's third-party auditor to validate correction? That language would more accurately describe the validation process as codified by CMS.
Part D Formulary and Benefit Administration Program Area Audit Process and Data Request 2.2 **Rejected and/or Paid Claims Information**	7	Requested information will include: 2.2: Whether prior authorization was used to process the claim.	Would CMS consider clarifying whether the term "prior authorization" is intended to mean coverage determination/redeterminations as set forth in Chapter 18, or if the intent is to capture any claim authorizations? A plan sponsor may place an override to authorize a claim for a myriad of reasons that fall outside of the scope of the coverage determination process. Likewise, our organization and many others to not process coverage determinations inside of the claims processing engine. When we place authorizations in the claims processing system there is no way to distinguish an authorization that is the result of a coverage determination or redetermination from an authorization that is the result of some other administrative override procedure, such as the Best Available Evidence process. We would recommend that CMS change the term "prior authorization" to "authorization" because the "prior authorization" is a legally significant term that suggests a coverage determination or redetermination occurred. Whereas the term

Section/Title	Page No.	CMS Proposed Requirement	Comment
			"authorization" and or "override" represent all situations in which the plan or PBM causes a claim that would otherwise reject to pay for administrative and clinical reasons.
MTM Impact Analysis	2	All columns	The current fields appear to ask for much of the same information that is available in the MTM universe (2015 and 2016). It also appears that these fields do not capture the types of information necessary to determine impact to beneficiaries in the event that CMS observes that immediate or other corrective action is required as a result of some issue of non-compliance in the MTM program. For example, if the CAR is related to a plan's failure to issue written CMR notices in the required timeframe, asking the plan to provide the Effective date of Contract Enrollment and MTM Program Eligibility Determination Date does not appear to be relevant or useful. Cognitive impairment, whether or not the member was continuing, LTC residence, etc., all of these are useful for the purpose of selecting samples, but once a CAR or ICAR condition is identified by CMS, there will be more relevant information that the plan sponsor should provide to demonstrate appropriate evaluation of impact. Given that this audit is still in the protocol phase, would CMS consider using the most common CAR and ICAR events from the pilot to determine which fields are most often needed to demonstrate impact? Another option is to use the Compliance Standards (3.1-3.6) and develop a limited data set of fields that could be used to address those issues, such that there may be a template for 3.1, 3.1, 3.3, etc. The auditor and sponsor can agree upon the fields that make sense for the CAR/ICAR condition. For example, in 3.1, was a CMR offered within 60 days of enrollment? If the CAR/ICAR is that the plan sponsor failed to offer a CMR to newly targeted beneficiaries within 60 days of enrollment, there would be questions around the specific beneficiaries, their MTM Program Enrollment date. The cognitive impairment status would not be required because in this example the CMS auditor did not observe non-compliance with handling of cognitively impaired beneficiaries.

Section/Title	Page No.	CMS Proposed Requirement	Comment
			Producing these impact reports can be labor intensive. During the course of an audit there are so many deliverables across multiple program areas, and plan sponsor, CMS, and PBM/MTM vendor time could be better utilized by gathering and reporting what is necessary and relevant. This will greatly improve the turnaround time to produce these impact reports.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request **Review Sample Case Documentation**	8	Documentation of notification to beneficiary regarding the comprehensive medication review Copy of the written summary of the comprehensive medication review	PerformRx conducted an internal audit of its MTM program using the 2016 pilot MTM protocols. During the course of the walkthrough we found it difficult to understand the distinction between "*Documentation of notification to beneficiary regarding the comprehensive medication review*" and "*Copy of the written summary of the comprehensive medication review*." By reviewing the CMR letter both of these steps are accomplished. Would CMS be willing to provide more detail on the difference between the two and what a sponsor would be physically expected to show during the walkthrough for each of these elements. QA information and reconcile incorrect information. Would CMS consider creating separate fields to capture multiple data elements currently collected in a single field? This will improve the clarity of information displayed.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request **Table 2. (MTM-2016) Record Layout**	16	**Column K- Did beneficiary Opt-out of the MTM Program?** Opt-out includes a request from the beneficiary or authorized representative to be disenrolled from the MTM program, beneficiary changing to a different contract not covered by the existing MTM program, or **death** **Column L- MTM Opt Out Date** **Column N MTM Disenrollment**	Would CMS consider changing the instruction "K" to remove reference to beneficiary death as a valid opt out reason? Death is a valid disenrollment reason, as explained in "N". We have observed that CMS treats death as a reason for both opting out of the MTM program and disenrolling from the MTM program with regard to the Part D reporting requirements and technical specifications. However, in Chapter 7 of the Medicare Prescription Drug Benefit Manual, opt out was explained to be based on the personal choice of the beneficiary and or their caregiver to not participate in the program while they still maintained other plan benefits. If we continue to report and consider death as an opt-out method and a method of disenrollment then we would always be required to over report to impact of a beneficiaries death. Was CMS' intent to capture *voluntary* removal from the program as opt out? If so, we would advocate striking death

Section/Title	Page No.	CMS Proposed Requirement	Comment
		Reason Reason for disenrollment by the organization from the first CY 2016 MTM program. Valid values are: **01 = Death**	from both column K of this table as well as from the Part D Reporting Requirements instructions. With regard to "L" and as a PBM, we rarely receive accurate information on the date of death for any beneficiary. Our client health plans routinely provide enrollment and disenrollment effective dates, the LIS effective dates, and birth dates. On the few occasions in which we have had occasion to call a beneficiary and are told by the respondent that the beneficiary passed away, our practice is to document the date we were told of the death. Out of respect for the person on the phone we do not ask them to confirm the date the beneficiary died. This means that we generally do not know and are not in a position to receive a date of death. That date is not integral to the administration of the MTM process. For all of these reasons we request that CMS remove death as an opt out reason.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request **Table 2. (MTM-2016) Record Layout**	17	**Column P,** Was the beneficiary residing in a long term care facility	Would CMS consider removing this element from the universe? CMS removed this element from the 2016 Part D Reporting Requirements. Beneficiary residence status is not always known, and beneficiaries can transfer from LTC to a home setting.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request **Table 2. (MTM-2016) Record Layout**	17	**Column P, Q, R,** Was the beneficiary residing in a long term care facility Cognitively Impaired Authorized Representative Answer NA if no CMRs were	Would CMS consider striking the instruction to answer NA? First, it would be operationally more difficult to produce this universe if we are required to retrospectively label fields with NA based on whether or not the CMR was administered or offered. There are other fields in the table that capture this information that CMS and its auditors could use to avoid sampling cases in which the CMR offer was not successful. Second, the provision or offer of the CMR does not directly impact the contents of these fields. Does

Section/Title	Page No.	CMS Proposed Requirement	Comment
		offered or administered in CY 2016.	CMS wish to only evaluate cases in which the CMR offer occurred? If so, would CMS consider instructing Part D sponsors to exclude those members from the universe organizations?
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request **Table 2. (MTM-2016) Record Layout**	21	Yes (Y) or No (N) indicator of whether the first CY 2016 TMR intervention(s) were delivered…If some but not all of the first CY 2016 TMR interventions were delivered, specify which interventions were and were not delivered and separate by a number as needed. Use a forward slash (/) to separate the intervention from the delivery status (e.g., 1. Dosage too high/N, 2. Adherence/Y, 3. Needs additional drug therapy/Y)…	Would CMS consider providing guidance on how to account for a TMR that result in multiple DTPs where each DTP is sent to multiple providers?

Section/Title	Page No.	CMS Proposed Requirement	Comment
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request **Table 2. (MTM-2016) Record Layout**	20-22	**Columns AH-AO – Interventions** Answer NA if no TMRs were performed in CY 2015, interventions were not necessary for any CY 2015 TMRs, or the first CY 2015 TMR intervention was declined	Would CMS consider striking the instruction to answer NA? First, it would be operationally more difficult to produce this universe if we are required to retrospectively label fields with NA based on whether or not a TMR intervention was declined. In our MTM system we capture the dates that we make outreach whether or intervention, TMR, or CMR. The universe development process would result in fewer errors if we were allowed to report the data based on our actions as opposed to the actions of the beneficiaries ore the prescribers. Does CMS wish to only evaluate cases in which the TMR intervention was accepted? If so, CMS could chose to use column AK "which TMR intervention type was declined" to filter out any case in which the answer is either Beneficiary (B), Prescriber (P), or Beneficiary and Prescriber (BP). This approach would result in fewer universe creation errors on the part of sponsors.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request	N/A	PerformRx is providing general comments regarding the terminology used in the proposed 2017 Audit Protocol as well as issues that arise from requiring multiple data elements to be reported in single fields.	Definitions within the audit protocol are utilizing different terminology from the CMS Part D MTM reporting requirements. Examples include "TMR interventions" versus "Drug Therapy Problems" or "TMR Interventions resolution" versus "Drug Therapy Problem resolutions". More consistency within this terminology would be helpful. To avoid duplicate reporting, and to clearly specify reporting requirements, PerformRx recommends that CMS align the 2017 Part D MTM audit universe fields with the existing 2016 Part D MTM reporting fields. The requirement that multiple issues be reported in one field makes it difficult to quality check information and reconcile incorrect information. Reporting on one instance on the universe and then a deeper dive into all during sample/on-site review will ensure issues do not arise from information not being displayed correctly within the universe.

Section/Title	Page No.	CMS Proposed Requirement	Comment
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Appendix A- **Table 1 2015 Universe**	11-14	Table 1 2015 Universe Column IDs A-T	Would CMS consider removing this table from the universe requirement because CMS collects a similarly detailed MTM report from Part D sponsors annually as part of the Part D Reporting Requirements? The contents of this report are almost identical to the contents of the universe and could be used by the auditors to draw samples. Producing a second report with the same information in a second layout is duplicative. The MTM detail report undergoes mandatory external data validation. As a result, unless CMS receives a data validation failure, it would be in a position to trust the accuracy of the report and use that report as the source of Table 1 MTM-2015 Record Layout. The same systems/resources that are used to produce the annual MTM detail report are the same resources that would be relied upon to create a duplicative universe. As the PBM for multiple health plans, PerformRx is often asked to participate in client "mock" program audits. For every CMS program audit there may be an additional four to five other health plan clients that request this same universe for their mock audits. Other MTM service providers face similar requests. Having to code and create a second report that captures the same information, but in different fields and a different order will present an avoidable burden and increase the programming and quality assurance resource need. One option for CMS is to amend its data validation protocols to include a universe validation requirement on the part of the data validation auditors (for the MTM detail report specifically. CMS may find this approach more operationally efficient as well.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Table 1. CY 2015 Medication Therapy Management	12	Continuing enrollee (CE) or New enrollee (NE). A continuing enrollee was auto-enrolled in the same contract's MTM program in CY 2014 and CY 2015. A new enrollee was not auto-enrolled in an MTM program during CY 2014 or was in a	PerformRx seeks clarification regarding the definition of continuing enrollee (CE). For example, if a beneficiary was enrolled from Q2 - Q3 of the previous contract year, and is reenrolled in Q1 of the new contract year, is this beneficiary considered CE or a new enrollee (NE)? If a beneficiary was enrolled in Q4 of the previous contract year but then does not meet criteria until Q2 in the new contract year, is this beneficiary considered CE or NE?

Section/Title	Page No.	CMS Proposed Requirement	Comment
Program (MTM-2015) Record Layout		different contract's MTM program in CY 2014 as compared to CY 2015.	
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout	18	Column T: Number of CMR Offers Declined Total number of CMR offers declined by the beneficiary or authorized representative in CY 2016. Answer NA if no CMRs were offered in CY 2016 or no CMR offers were declined in CY 2016.	PerformRx seeks clarification regarding how to properly account for a mailed CMR that was sent to a beneficiary (and was not returned) but was not acted upon by the beneficiary i.e., the beneficiary did not call in to complete a CMR? NA would not be appropriate since a CMR was offered.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout	19	Column AE: Number of TMRs Performed Total number of TMRs performed during CY 2016. Answer NA if no TMRs were performed in CY 2016.	Would CMS clarify that 'TMR performed' is a review of the medication profile either automated or manual and may or may not result in an intervention and follow up.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record	20	Column AI: TMR Intervention Recipient(s)	This information is captured in element AJ (TMR Intervention Description). PerformRx recommends removing Column AI to avoid duplication.

Section/Title	Page No.	CMS Proposed Requirement	Comment
Layout			
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout	20	**Column AJ: TMR Intervention Description** Include a description for every follow-up intervention identified for the first CY 2016 TMR requiring intervention(s). Include all interventions regardless of whether they were declined by the targeted recipient.	How do we account for interventions that may not have an accepted/declined outcome? How do we account for interventions that are still pending an outcome determination? For the outcome of the intervention, apart from Denied/Accepted , PerformRx recommends adding additional response choices, such as 'unknown' or 'pending' to account for these additional scenarios. Additionally, based on the fact that some members may have multiple TMRs, PerformRx recommends that the field length account for this.
Part D Medication Therapy Management (MTM) Program Area PILOT Audit Process and Data Request Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout	21	Column AL: TMR Intervention Delivery Date? Date(s) the first CY 2016 TMR intervention(s) were delivered to the targeted recipient(s). Submit in CCYY/MM/DD and separate by a number as needed for multiple dates (e.g., 1. 2016/03/05, 2. 2016/03/05, 3. 2016/03/09).	Per CMS guidelines, a TMR is considered a complete drug review which can result in multiple DTPs (follow-up interventions) or no DTPs (educational support, no interventions, etc...); How is CMS defining the first TMR intervention? Is it the date the first TMR was performed or is it the date of the first DTP sent to the recipient? Should we document the date of each individual DTP or the singular TMR incorporating all DTPs?
Supplemental Questionnaires: Attachment III-A- CDAG Attachment II FA	n/a	Complete the supplemental questionnaire	This is information that the plan sponsors could provide to CMS via HPMS as part of the annual Part D Reporting Requirement or similar to how the Plan Sponsors report the information about the P*T Committee and important plan contacts. Would CMS consider collecting this information annually outside of the program audit process? This would result in additional time saved during the short time between the audit engagement letter and the universe due date and free up resources to focus on the many other audit requirements. Also, we did not observe a supplemental questionnaire for the MTM program. Does CMS

Section/Title	Page No.	CMS Proposed Requirement	Comment
			intend to create an MTM questionnaire? If so, would CMS consider doing so in HPMS to coincide with the annual reporting requirement, or to be updated by the plan during the course of the year in the event that there are any changes to how the MTM process is delegated?

GPI 14 or GCN	NDC (11 digits; no hyphens or spaces)	RxCUI	Drug Name	Number of Impacted Members	Protected Class (Y/N)

Cardholder ID	Contract ID	Plan ID	Effective Date of Enrollment (MM/DD/YY)	Is beneficiary currently enrolled? (Y/N)	GPI 14 or GCN	NDC (11 digits; no hyphens or spaces)	Drug Name	Request type - CD or RD	Expedited CD or RD? (Y/N)	Date request was received (MM/DD/YY)	Time request was received (HHMMSS- Military time)	Was the request approved or denied?	Date request was approved/denied (MM/DD/YY)	Date of written notification (MM/DD/YY)	Time of written notification (HHMMSS- Military time)	If decision or notification was untimely, was the case forwarded to the IRE? (Y/N)	Number of hours decision/effectuation untimely (N/A if not applicable)	Number of hours notification untimely (N/A if not applicable)	Dates of adjudicated claims after decision date (MM/DD/YY)	Did beneficiary ever receive the originally requested medication as evidenced by a paid claim? (Y/N)	If yes in column V, indicate number of elapsed days from date of receipt of request.	Date issue was resolved or remediated (MM/DD/YY)	Brief summary of issue resolution (e.g. new notification letter and reason, prescriber contact and outcome, beneficiary received medication)	If approval was not granted, provide brief explanation (ex: outreach to MD showed member is on similar medication and no longer needs the medication)	Request type (e.g., tiering exception; non-formulary exception; Part B vs. Part D; DMR; Other)	<Other requested data>	<Other requested data>

PUBLIC SUBMISSION

As of: 12/9/16 8:36 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8ral-hn6w
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0038
PA

Submitter Information

Name: Jonathan Larsen
Address:
Philadelphia, PA, 19113
Email: jlarsen@performrx.com

General Comment

Good afternoon,

Please find comments from PerformRx attached.

Thank you.

Attachments

PerformRx 2017 Part D Program Audit Comment Document 8.12.16

PUBLIC SUBMISSION

As of: 12/9/16 8:41 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8ral-us3y
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0040
San Juan

Submitter Information

Name: Cynthia Falcon
Address:
San Juan, San Juan, Puerto Rico, 00936
Email: Cynthia.Falcon-Mejias@mmmhc.com

General Comment

Comments: 2017 Draft Program Audit Protocols Now Posted in the Federal Register
Audit Protocol: Part D Medication Therapy Management (MTM) Program Area PILOT AUDIT PROCESS AND DATA REQUEST
Comment 1: Some of the audit universe elements are not currently required in annual CMS MTMP reporting and Technical Specification documentation therefore they are not currently captured in MTM software programs; please take into consideration for future layout changes that these types of changes require additional programming challenges. Examples include TMR Intervention Description(s).
Comment 2: Appendix A, Table 1. CY 2015 Medication Therapy Management Program (MTM-2015) Record Layout is missing Column ID "G".
Comment 3: Appendix A, Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout might contain a typo in the description of the 1st CMR Delivery method (Column ID "AA"). Criteria states "Indicate the delivery method for the first CMR administered in CY 2015. Valid values include: Face-to-face (FF), Telephone (T), Telehealth Consultation (TH) (e.g., video-conference) or Other (O). Answer NA if no CMRs were administered in CY 2016 or the beneficiary/authorized representative declined CY 2016 CMR services." Is the year in the description accurate?
Comment 4: Appendix A, Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout, Column ID: AJ does not provide an alternative for when the prescriber does not respond to the intervention. What value should be used?

Audit Protocol: Part D Formulary and Benefit Administration (FA) Program Area; Appendix A: Part D Formulary and Benefit Administration Record Layouts
Comment 1: Tables 1-3, 5 Field Name: Effective Disenrollment Date
This is a new field and would appreciate CMS provide some context for its inclusion on these universes. In addition could CMS provide clarification what is expected to be included when beneficiaries have multiple disenrollment dates during the year; what disenrollment date should be use and at what level (i.e., contract, carrier, plan).
Comment 2: Tables 1-4 Field Name: Claim Quantity
Please confirm if it expected that plans enter fractional values in this field when appropriate.
Comment 3: Tables 1-4 Field Name: Claim Days' Supply
We respectfully request that this character be removed from this field name; this change will require considerable resources to modify universe queries, record layouts, and quality monitoring processes.
Comment 4: Tables 1-3 Field Name: Patient Residence
Can CMS please confirm that it is still expected for plans to use NCPDP values in this field and that if there are no data for this field, CMS expects an entry of "UNK" and not "00"?
Comment 5: Tables 1-3 Field Name: Pharmacy Service Type
Can CMS please confirm that it is still expected for plans to use valid NCPDP values in this field and that if a pharmacy passes an unknown value, such as 00, how would CMS like that coded?
Comment 6: Tables 1-3 Field Name: CMS Part D Defined Qualified Facility
Can CMS please confirm that this field has been removed from the universes?

Audit Protocol: Part D Coverage Determinations, Appeals, and Grievances (CDAG); Appendix AOrganization Determinations and Appeals and Grievances (ODAG) Record Layout
Comment: Table 11: GRV_S Record Layout and Table 12: GRV_E Record Layout only provide 300 characters for the issue description "Column J" and "Column "K" respectively; could this field be expanded to 1,500 characters in order to provide an accurate description of the grievance?

Attachments

Comments- 2017 Draft Program Audit Protocols Now Posted in the Federal Register

Comments: 2017 Draft Program Audit Protocols Now Posted in the Federal Register

Audit Protocol: Part D Medication Therapy Management (MTM) Program Area PILOT AUDIT PROCESS AND DATA REQUEST

Comment 1: Some of the audit universe elements are not currently required in annual CMS MTMP reporting and Technical Specification documentation therefore they are not currently captured in MTM software programs; please take into consideration for future layout changes that these types of changes require additional programming challenges. Examples include TMR Intervention Description(s).

Comment 2: Appendix A, Table 1. CY 2015 Medication Therapy Management Program (MTM-2015) Record Layout is missing Column ID "G".

Comment 3: Appendix A, Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout might contain a typo in the description of the 1st CMR Delivery method (Column ID "AA"). Criteria states "*Indicate the delivery method for the first CMR administered in CY **2015**. Valid values include: Face-to-face (FF), Telephone (T), Telehealth Consultation (TH) (e.g., video-conference) or Other (O). Answer NA if no CMRs were administered in CY **2016** or the beneficiary/authorized representative declined CY **2016** CMR services."* Is the year in the description accurate?

Comment 4: Appendix A, Table 2. CY 2016 Medication Therapy Management Program (MTM-2016) Record Layout, Column ID: AJ does not provide an alternative for when the prescriber does not respond to the intervention. What value should be used?

Audit Protocol: Part D Formulary and Benefit Administration (FA) Program Area; Appendix A: Part D Formulary and Benefit Administration Record Layouts

Comment 1: Tables 1-3, 5 Field Name: Effective Disenrollment Date

This is a new field and would appreciate CMS provide some context for its inclusion on these universes. In addition could CMS provide clarification what is expected to be included when beneficiaries have multiple disenrollment dates during the year; what disenrollment date should be use and at what level (i.e., contract, carrier, plan).

Comment 2: Tables 1-4 Field Name: Claim Quantity

Please confirm if it expected that plans enter fractional values in this field when appropriate.

Comment 3: Tables 1-4 Field Name: Claim Days' Supply

We respectfully request that this character be removed from this field name; this change will require considerable resources to modify universe queries, record layouts, and quality monitoring processes.

Comment 4: Tables 1-3 Field Name: Patient Residence

Can CMS please confirm that it is still expected for plans to use NCPDP values in this field and that if there are no data for this field, CMS expects an entry of "UNK" and not "00"?

Comment 5: Tables 1-3 Field Name: Pharmacy Service Type

Can CMS please confirm that it is still expected for plans to use valid NCPDP values in this field and that if a pharmacy passes an unknown value, such as 00, how would CMS like that coded?

Comment 6: Tables 1-3 Field Name: CMS Part D Defined Qualified Facility

Can CMS please confirm that this field has been removed from the universes?

Audit Protocol: Part D Coverage Determinations, Appeals, and Grievances (CDAG); Appendix A—Organization Determinations and Appeals and Grievances (ODAG) Record Layout

Comment: Table 11: GRV_S Record Layout and Table 12: GRV_E Record Layout only provide 300 characters for the issue description "Column J" and "Column "K" respectively; could this field be expanded to 1,500 characters in order to provide an accurate description of the grievance?

TUFTS Health Plan

August 12, 2016

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Tufts Health Plans, Inc. Comments for 2017 DRAFT Program Audit Protocols

To Whom It May Concern:

On behalf of Tufts Health Plans, Inc. ("Tufts Health Plan" / "THP"), we appreciate the opportunity to provide the Centers for Medicare and Medicaid Services ("CMS") comments on the 2017 DRAFT Program Audit Protocols.

We support CMS' efforts in collecting feedback from the industry as it develops the 2017 Program Audit Protocols and offer the following comments:

Document Title	Page #	Section Title	Section THP Providing Comments	Comments to CMS
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area	24	Table 2: Standard Coverage Determination Exception Requests (SCDER) Record Layout	Table 2: Column ID U: Was the request denied for lack of medical necessity?	Is CMS able to clarify what types of requests CMS would not consider medical necessity as it relates to a coverage determination exception request?
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area	30	Table 4: Expedited Coverage Determinations (ECD) Record Layout	Table 4: Column ID R: Was the request denied for lack of medical necessity?	Is CMS able to clarify what types of requests CMS would not consider medical necessity as it relates to a coverage determination exception request?
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area	37	Table 6: Standard Redeterminations (SRD) Record Layout	Table 6: Column ID P: Request Disposition Description: Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed.	Is CMS able to provide clarification on the use of the valid value response of "N/A for a request that was never resolved/processed" if we are only to include all requests processed as standard pre-service redetermination requests for Table 6.
Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area	40	Table 7: Direct Member Reimbursement Request Redeterminations (DMRRD) Record Layout	Table 7: Column ID O: Request Disposition Description: Status of the request. Valid values are: approved, denied, IRE auto-forward, dismissed, withdrawn, re-opened approved, or re-opened denied. Answer NA if the request was never resolved/processed.	Is CMS able to provide clarification on the use of the valid value response of "N/A for a request that was never resolved/processed" if we are only to include all requests processed as Direct Member Reimbursement for Table 7.

Part D Coverage Determinations, Appeals and Grievances (CDAG) Program Area	60	Table 16: Call Logs Part D Record Layout	• Include all calls received by your organization (or another entity) that relate to your Medicare Part D line of business. • Exclude any calls not relating to your Part D business (i.e., Medicare advantage, commercial). • Submit all calls based on the date the call was received by your organization, PBM or other entity.	Is CMS able to provide clarification on its expectations that Table 16 be populated with calls from every vendor that would speak to a member? Is CMS able to provide clarity on how calls that are not clearly a C or D specific calls be classified? THP's initial thinking is that we would follow the same logic as in Data Validation for grievances (if there is a question about whether it is C or D, it is always counted as C). Is CMS able to confirm our logic? Is CMS able to provide scenarios to get a better understanding of CMS expectations of how calls should be classified? Is CMS able to provide clarification on calls handled entirely through the IVR process? If the call is handled entirely through the IVR process and never reaches a Customer Service representative, should these calls be excluded from Table 16?
Document Title	**Page #**	**Section Title**	**Section THP Providing Comments**	**Comments to CMS**
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	17, 21, 31, 34, 38	Table 1, 2, 5, 6, 7	Include/Exclude Criteria	Is CMS able to provide clarification on how dismissals should be treated for Table 1, 2, 5, 6, 7; should they be included or excluded from the table?
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	18, 22, 25, 28, 31, 35, 38, 40, 42, 44	Tables 1 – 10 Field Name: Diagnosis	Description: Provide the enrollee diagnosis/diagnoses ICD-10 codes related to this request. If the ICD codes are unavailable, provide a description of the diagnosis, or for drugs provide the 11 digit National Drug Code (NDC).	Is CMS able to provide clarification on how to populate this field for drugs (provide the 11 digit NDC)? Physicians only bill J codes and not NDC's.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	19, 22	Table 1, 2	Status of the request. Valid values are: approved, or denied. Sponsors should note any requests that are untimely and not yet resolved (still outstanding) as denied. All untimely and pending cases should be treated as denials for the purposes of populating the rest of this record layout's fields.	CMS please provide clarification on the term "all untimely and pending cases should be treated as denials for the purposes of populating the rest of this record layout's fields". Does this statement apply to "approved and untimely"; "pending and timely"; "pending and untimely"; or simply "untimely and pending".
Part C Organization	29	Table 4: Direct Member	Table 4: Column ID O: Was interest paid	Is CMS able to provide

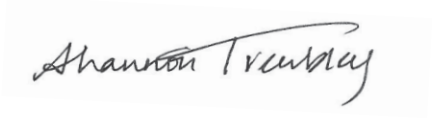
Determinations, Appeals and Grievances (ODAG) Program Area		Reimbursement (DMR) Requests Record Layout	on the reimbursement request?	clarification on the intent of this field for Table 4? This field was previously removed from the Audit Protocols and CMS provided guidance at a recent conference that interest should not be paid on direct member reimbursement requests.
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	32, 35	Table 5& 6	Field Name: Request for expedited timeframe Description: If an expedited timeframe was requested, indicate who requested the expedited reconsideration timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested. Answer BR if a contract provider submitted an expedited reconsideration request as the enrollee's representative.	Is CMS able to provide guidance on when the response "BR" or "CP" would be used as CMS has instructed to answer BR if a contract provider submitted an expedited reconsideration request as the enrollee's representative?
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	34	Table 6: Expedited Pre-service Reconsiderations (EREC) Record Layout	Table 6: Column ID G: Who made the request? Description: Indicate whether the reconsideration request was made by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR). Note, the term "provider" encompasses physicians and facilities.	CMS please clarify if facilities should be considered a valid requestor without an AOR? If they had a valid AOR, the facility would be acting as the beneficiary's representative (BR).
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	46	Table 11: Part C Oral & Written Standard Grievances (GRV_S) Record Layout	Table 11: Column ID F: Person who made the request Description: Indicate whether the grievance was submitted by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR).	CMS please provide clarification on when a contract provider (CP) or non-contract provider (NCP) would be a valid response. If a CP or NCP with a valid AOR submits the request, shouldn't the field be populated as beneficiary's representative (BR)?
Part C Organization Determinations, Appeals and Grievances (ODAG) Program Area	53	Table 14: Call Logs Part C (CLC) Record Layout	• Include all calls received by your organization (or delegated entity) that relate to your Medicare Part C line of business. • Exclude any calls not relating to your Part C business (e.g., Medicare Part D, commercial) • Submit calls by the date the call was received by either your organization or another entity.	Is CMS able to provide clarification on its expectations that Table 14 be populated with calls from every vendor that would speak to a member? Is CMS able to provide clarity on how calls that are not clearly a C or D specific calls be classified? THP's initial thinking is that we would follow the same logic as in Data Validation for grievances (if there is a question about whether it is C or D, it is always counted as C). Is CMS able to confirm our logic? Is CMS able to provide scenarios to get a better understanding of CMS

				expectations of how calls should be classified? Is CMS able to provide clarification on calls handled entirely through the IVR process? If the call is handled entirely through the IVR process and never reaches a Customer Service representative, should these calls be excluded from Table 14?
Document Title	**Page #**	**Section Title**	**Section THP Providing Comments**	**Comments to CMS**
Part D Formulary and Benefit Administration (FA) Program Area	9	II. Transition	2.2. Rejected and/or Paid Claim Information • The comment log associated with the rejected claim	Is CMS able to provide more clarification on its expectations for what it would consider a "comment log"?
Part D Formulary and Benefit Administration (FA) Program Area	18	Table 4: Prescription Drug Event (PDE) Data Record Layout	• Include all final action PDEs accepted by CMS with dates of service in September – December of 2016. • Include PDEs only for beneficiaries in the Rejected Claims Transition Universes (RCT-N and RCT-P).	Is CMS able to provide additional clarification on the include requirements for Table 4? Should this table be populated with PDEs in the Rejected Claims Transition Universes (RCT-N and RCT-P) **AND** all final action PDEs with dates of service in September - December 2016?
Document Title	**Page #**	**Section Title**	**Section THP Providing Comments**	**Comments to CMS**
Special Needs Plan Model of Care (SNP-MOC) Program Area	10	II. Care Coordination	2.1.2. Did the sponsor conduct the initial HRA either 90 days before or after the enrollment effective date?	CMS please provide guidance on 2.1.2, have regulations changed that have allowed the sponsor to now conduct the initial HRA 90 days before the enrollment effective date?
Special Needs Plan Model of Care (SNP-MOC) Program Area	17	Table 1: Special Needs Plan Enrollees (SNPE) Record Layout	Table 1: Column ID O: Date of previous HRA/reassessment? Description: Submit in CCYY/MM/format (e.g. 2016/01/01) If previous HRA/reassessment was not conducted please enter N/A	CMS please clarify how to populate this field if the previous HRA/reassessment date falls **OUTSIDE** of the audit period?
Special Needs Plan Model of Care (SNP-MOC) Program Area	18	Table 2: Plan Performance Monitoring and Evaluation (PPME) Record Layout	Table 2: Column ID O: Goal Met/Not Met	On behalf of Tufts Health Plan, we appreciate the addition of Column ID O; Field: Goal Met/Not Met for Table 2 as it adds clarity and consistency.
Document Title	**Page #**	**Section Title**	**Section THP Providing Comments**	**Comments to CMS**
Part D Medication Therapy Management (MTM) Program Area PILOT	11	Table 1. CY 2015 Medication Therapy Management Program (MTM-2015) Record Layout	Field Name: Contract ID	Tufts Health Plan has noted Table 1 does not contain a field for Contract ID, was this field omitted in error?
Document Title	**Page #**	**Section Title**	**Section THP Providing Comments**	**Comments to CMS**
Part C and D Compliance Program Effectiveness (CPE) Program Area	3	Audit Purposes & General Guidelines	4. Sponsor Disclosed and Self-Identified Issues	Tufts Health Plan has noted the removal of previous language in all Program Areas: "Issues that are reported as corrected prior to the audit universe review period will be assumed to

				be corrected. However, if the issue is identified during the course of the audit, CMS will cite the applicable conditions in the audit report. CMS will not otherwise validate correction of issues identified as corrected." Is CMS able to provide clarification on how it intends to consider issues that are reported as corrected prior to the audit universe review period?
Part C and D Compliance Program Effectiveness (CPE) Program Area	7	Tracer Evaluation	1. Sample Selection In order to be effective, a sponsor's compliance program must be fully implemented and tailored to the sponsor's unique organization, operations, and circumstances. CMS will use a tracer method to evaluate implementation of applicable compliance elements and determine whether the sponsor's compliance program, as a whole system, functions in a way that is effective to address compliance and FWA issues in a timely and well-documented manner. CMS will select a sample of six (6) cases from the universes to trace the sponsor's response to compliance issues. It is not required that each case in the sample will cover all elements of a compliance program.	With the removal of Table 5: Fraud Waste and Abuse Monitoring (FWAM), does CMS intend to select an FWA sample for a tracer evaluation? Is so, how does it intend to make this selection?

We thank you for consideration of our comments and look forward to continuing to work with CMS on these important issues.

Sincerely,



Shannon Trembley
Medicare Compliance Officer
Director, Medicare Compliance

PUBLIC SUBMISSION

As of: 12/9/16 8:44 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8ram-9ik8
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0041
MA

Submitter Information

Name: Shannon Trembley
Address:
Watertown, MA, 02472
Email: shannon_trembley@tufts-health.com

General Comment

See attached file(s)

Attachments

THP Comments - 2017 DRAFT Audit Protocols 8.12.16

Key Changes and Associated Questions & Comments Related to CMS-10191 (Draft 2017 Program Audit Protocols)

Sponsor: Essence Group Health Care (EGHC)

Contact Name(s):

- Erin Venable, Chief Compliance Officer, evanable@essencehealthcare.com
- Tim Noonan, Compliance Director, tnoonan@essencehealthcare.com
- Britton Whitbeck, Compliance Director, bwhitbeck@essencehealthcare.com

Program Area	Table / Universe	Protocol Language	Comment / Question
Part C Organization Determinations, Appeals and Grievances (ODAG)	Standard Pre-service Organization Determinations (SOD) & Expedited (EOD)	Include all requests processed as standard pre-service organization determinations, including all supplemental services, such as dental and vision, and include all approvals and denials.	Should partial approvals be included in SOD & EOD? Should they be classified as approvals, denials, or another combination (i.e., one row for the approved portion, another row denial portion)?
ODAG	SOD, Column 'N' & EOD, Column 'O' Field: Subsequent Expedited Request	If a request was made after the organization determination to expedite the request, indicate who made the subsequent request to expedite the request: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested.	Is this a request to expedite after beginning as a standard request? The area needs clarification, overall. Please provide a scenario where this would be applicable. A request to expedite after an organization determination seems illogical in the sequence of events. Additionally, in the 2016 audit protocols, field "Request for expedited timeframe" asked who requested the expedited that was later de-prioritized to a standard. The 2017 change to the new language of "who made the subsequent request to expedite the request", seems to remove the de-escalation component and introduce a new component that is unclear of what the intent is.
ODAG	SOD, Column 'S' Field: Was the request denied for lack of medical necessity?	Yes (Y)/No (N) indicator of whether the request was denied for lack of medical necessity. Answer NA if the request was approved. Answer No if the request was denied because it was untimely.	Should NA be populated for pended cases?

Program Area	Table / Universe	Protocol Language	Comment / Question
ODAG	Call Logs Part C (CLC)	All calls received by your organization (or delegated entity) that relate to your Medicare Part C line of business.	Questions: Are the call logs inclusive of all calls received and handled during the universe period. Please confirm the purpose of providing these calls logs; i.e. will they be picked as samples to see if the Plan handled appropriately as inquiry or we should have sent through as an appeal or grievance? Is a summary of the call (including all activity that occurred) sufficient for documentation of the call details, or are all notes required? Comments: The volume of calls received are quite large. As a result, gathering the data for this universe is administratively burdensome for plans. We request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the current universe and sample reviews.
ODAG	Oral & Written Standard Grievances (GRV_S), Column I & Expedited Grievances (GRV_E), Column J Field: Category of the grievance/complaints	GRV_S, Column I: Category of the grievance/complaint. At a minimum categories must include each of the following: Enrollment/Disenrollment, Benefit Package, Access, Marketing, Customer Service, Organization Determination and Reconsideration Process, Quality of Care, Grievances Related to "CMS" Issues, and Other. GRV_E, Column J: Category of the grievance/complaint. Indicate whether the expedited grievance was submitted by the enrollee because the plan declined to process a case on the expedited timeframe (ETD) or whether it was submitted due to the enrollee's dissatisfaction with the plan taking a processing timeframe extension (PTE).	In GRV_S, Column I, CMS provided specific guidance, but in GRV_E, Column J, it doesn't appear to be similar or in line with the topic. Please clarify GRV_E, Column J.

Program Area	Table / Universe	Protocol Language	Comment / Question
ODAG	EREC, Column 'N', Field: Request for expedited timeframe	If an expedited timeframe was requested, indicate who requested the expedited reconsideration timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B), beneficiary's representative (BR) or sponsor (S). Answer NA if no expedited timeframe was requested. Answer BR if a contract provider submitted the expedited reconsideration request on behalf of an enrollee.	Should that indicate "CP", not "BR" in the last sentence?
ODAG	Requests for Payment Organization Determinations (Claims)	3rd bullet: Submit payment organization determinations (claims) based on the date the claim was paid or denied, or should have been paid or denied (the date the request was initiated may fall outside of the review period).	Language says submit payment organization determinations based on the date the claim was paid or denied, or should have been paid or denied. In the 2016 protocols it said submit claims based on the date the sponsor's decision was rendered, or should have been rendered. Can you confirm this change, and offer up additional clarity around the intent of the change?
Part D Coverage Determinations, Appeals and Grievances (CDAG)	Call Logs Part D	(new section)	Questions: Are the call logs inclusive of all calls received and handled during the universe period. Please confirm the purpose of providing these calls logs; i.e. will they be picked as samples to see if the Plan handled appropriately as inquiry or we should have sent through as an appeal or grievance? Is a summary of the call (including all activity that occurred) sufficient for documentation of the call details, or are all notes required? Comments: The volume of calls received are quite large. As a result, gathering the data for this universe is administratively burdensome for plans. We request the universe not be included in the 2017 protocols, as CMS is able to effectively review coverage determinations, appeals and grievances through the current universe and sample reviews.
CDAG & ODAG	Pull Universes	(general comment)	This area no longer indicates how to determine which cases fall within the audit period. In previous protocols, universes were specified to pull based on decision date, receipt date, date auto forwarded, or IRE receipt date. Will the Pull Universes section be amended to include this clarifying and helpful information that was on prior protocols?

PUBLIC SUBMISSION

As of: 12/9/16 8:46 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rap-5h1l
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0042
MO

Submitter Information

Name: Tim Noonan
Address:
MO, 63105
Email: tnoonan@essencehealthcare.com

General Comment

Attached are comments/questions from Essence (EGHC).

Attachments

Essence comments for CMS-10191 - Draft 2017 Program Audit Protocol Changes

GORMAN
HEALTH GROUP

We are your partner in **government-sponsored health programs**

August 12, 2016

Regan Pennypacker
Senior Vice President, Compliance Solutions
Gorman Health Group, LLC
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015

Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
Room C4-26-05, 7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Docket ID CMS-2016-0097 (CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Greetings,

Thank you for providing industry opportunity to comment on the draft 2017 Parts C and D Program Audit Protocols and Data Requests. Gorman Health Group, LLC supports many Sponsors subject to these protocols in a variety of ways. We support the industry in an advisory capacity and with systems and tools to help Sponsors capture data, effectively monitor, perform audits, and report on results. By partnering with Sponsors in these capacities, we believe decision-makers can be best informed on the performance of their operations and make well-informed decisions in efforts to adhere to agency requirements.

We appreciate the agency's goals to strive for consistency, accuracy, efficiency, and objectivity within the protocols and process. We respectfully submit the following comments in an effort to aid in these efforts.

Sincerely,

/S/

Regan Pennypacker

General
Please enhance instructions to include the steps to take if the Sponsor identifies issues of non-compliance as they are developing the universes for submission. Please clarify whether this information should be included in Attachment VIII or if that information only needs to be brought to the attention of the Audit Lead and the Plan Manager prior to Audit Week 1.

CMS states the Sponsor should include all cases that match the description for that universe for all contracts and PBPs. Please confirm/clarify whether or not 800 series PBPs should be included in each universe and whether or not 800 series PBPs will be tested for each applicable protocol.

CDAG AND ODAG
Additional clarification from CMS would be helpful in determining if the AOR date is used to calculate timeliness.

Only ODAG has an AOR date field in the universe. For consistency purposes, this should be added to CDAG.

Only ODAG has an FDR field in the universe. For consistency purposes, this should be added to CDAG.

Only CDAG has an Enrollment Effective Date field in the universe. For consistency purposes, this should be added to ODAG.

ODAG grievances have a "Person who made the request" field. For consistency purposes, this should be added to CDAG grievances.

CDAG grievances have a "How was the grievance/complaint received?" field that allows for two valid responses only: Oral or Written. ODAG grievances allow 40 characters as freeform. The choice of two options as illustrated in CDAG grievance layouts is much easier to capture. For consistency purposes, this should be updated on ODAG.

ODAG grievances "Issue Description" field only allows for 300 characters; CDAG grievance layouts allow for 1,500. For consistency purposes, one should be updated.

CDAG grievances "Resolution Description" field only allows for 1,500 characters; ODAG grievance layouts allow 3,000. Also, the Resolution Description field in CDAG should be moved to be before Oral Notification similar to the ODAG layout. For consistency purposes, one should be updated.

ODAG expedited grievance "Category of the grievance/complaint" field allows for two valid responses only. CDAG expedited grievance options are incorrect and should be updated. There are only two instances when a beneficiary may request an expedited grievance on Part D: because the Sponsor denied a request to expedite the initial request for a Part D drug or denied a request to expedite the appeal of a Part D drug. In the Part C layout, this option is listed as ETD. It is recommended CMS consider using something similar.

We have received CMS guidance that it is not permissible to take a time frame extension on an expedited grievance, but CMS noted in the response it can still sometimes happen in error. We do not believe accommodation should be made for a potential "in error" option currently allowed

GORMAN HEALTH GROUP
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015
P 202.364.8283 F 202.315.4483

in the CDAG and ODAG expedited grievance layouts. From an industry perspective, having seen the small size universes for expedited grievances, the evaluation of whether or not an extension was inappropriately taken can be evaluated in the timeliness of the universe. Therefore, it is recommended the column for "time frame extension" be removed. This will streamline for Sponsors and eliminate the need to incorporate the additional data field.

On ODAG Call Log, the last field is Resolution Description. On CDAG Call Log, the last field is Description of the outcome of the call. CDAG allows for 1,000 characters; ODAG allows 3,000. It would be ideal to be consistent in both naming convention and character limitation.

In CDAG Call Log, Beneficiary First Name, Last name, and Effective date character limitations are 30, 30, and 8, respectively. Effective date should have a character limitation of 10 to allow for the described format (CCYY/MM/DD). In ODAG Call Log, First Name and Last Name are 50 and 50, and there is no field for Effective Date. Furthermore, ODAG Call Log Description of the call allows for 750 characters, whereas CDAG Call Log allows 2,000. It would be ideal to be consistent in fields and character limitations where possible, as industry experience has shown most plans capture these calls in the same system, and consistency would reduce the burden on Sponsors responsible for pulling this data.

We have identified opportunities for additional consistency between SREC (ODAG Standard Pre-service Reconsiderations) and SRD (CDAG Standard Redeterminations). SREC calls for the exclusion of claims denied for a variety of reasons, including denials for duplicate claims, adjustments, invalid billing codes, billing errors, and denials for beneficiaries not enrolled on the date of service. Unless the CDAG team wants these administrative denials included in the universe, it is recommended SRD also provide similar guidance in terms of what case types should be excluded.

It is also requested CMS review the values for Status of the Request in both SREC and SRD. In SREC, the valid values are: "approved, denied, denied with IRE auto-forward, or IRE auto-forward due to untimely decision." In SRD, the valid values are: "approved, denied, IRE auto-forward, dismissed, and withdrawn. Answer NA if the request was never resolved/processed." Understandably, there are two types of auto-forward in Part C, requiring the two options for IRE. However, SRD allows for dismissed, withdrawn, and N/A for requests that were never resolved/processed. It is suggested CMS review and make any updates to allow for consistency where possible.

ODAG DMR valid values for Request Disposition include: approved, denied, denied with IRE auto-forward, or IRE auto-forward due to untimely decision. Similar to the comment made previously regarding SRD, will CMS also want dismissed, withdrawn, or NA (case never resolved/processed)? If those will be appropriate values, please include. If CMS would like Sponsors to exclude those cases from ODAG DMR, then it is suggested the table instructions be updated to clarify.

It is recommended Rows Q and R in ODAG DMR be clarified to note these rows are NA for DMR organization determinations. Only reconsiderations are forwarded to the IRE if denied or untimely. One method to clarify this is to update the last sentence in Q and R Description to read: Answer NA if approved, not forwarded to IRE, or if case is an organization determination.

GORMAN HEALTH GROUP
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015
P 202.364.8283 F 202.315.4483

For ODAG IREEFF, please update description of Fields L and N (which are time fields) to include instruction to populate the fields with NA if the case is a standard case. This is consistent with CMS instruction provided to us, as there is no other flag in the Table to indicate whether the case is standard or expedited.

For ODAG Dismissals, it is recommended CMS clarify the timeliness tests table (currently page 7) under COMPLIANCE STANDARDS TO APPLY to account for guidance received by Sponsors and us regarding Dismissal expectations. Specifically, CMS clarified they allow Dismissals on ODAG requests to be sent on the next business day following any holidays or weekends if the last day of the processing or appeal time frame is on a weekend, holiday, or other day the U.S. Post Office is closed. Furthermore, the record layout does not contain a field to identify if an extension was used; this field is needed to determine timeliness of the dismissal notification.

The CDAG audit protocol (p. 7, #4) states for the timeliness test, if more than one universe tests the same compliance standard, multiple timeliness tests will be merged for one overall score. 1) The universes that are to be merged are identified at the end of the table. Recommend moving this section up, prior to the table, to add clarification on CMS' intent. 2) Merging the overall scores does not allow sponsors to identify potential problem areas (e.g., issue with the universe and/or data itself, trends) in single universes. 3) Are there areas of the ODAG protocol for which CMS might apply this same strategy?

For both the ODAG/CDAG audit protocols (Section I, Timeliness, #3.2), will CMS provide the three timeliness thresholds that apply? The compliance standard indicates CMS will test timeliness in accordance with the CMS compliance standards referenced in the table. One would assume if the Sponsor met the compliance standards referenced in the table, they would be considered timely, but it is not clear what threshold would be considered a CAR or ICAR.

For the CDAG audit protocol (Section II, CDM/Compliance with CDA, p. 12, #1), CMS states it will select 40 cases: 30 denials and 10 approvals. Based on these numbers and how the samples are categorized, it appears CMS is considering the IRE, ALJ, and MAC overturns to be denials. However, our understanding is that an overturn is considered favorable to the member and therefore an approval. Can CMS clarify what bucket IRE, ALJ, and MAC overturns should fall into – denials or approvals? The ODAG protocol does not specify the number of denials and approvals that will be selected, but this would also be helpful, and the same comment would apply.

For the CDAG protocol (Section II, CDM/Compliance with CDA, p. 15, #4), the sample results section states CMS will test each of the 40 – 45 cases. However, in the sampling section (p. 12, #1), CMS references 40 cases only. When would CMS test 45 cases?

For both the ODAG and CDAG audit protocols (sampling sections), could CMS identify the intended tables from which the samples are to be selected? For example, ODAG, 10 organization determination denials would come from Tables 1, 2.

For both the ODAG and CDAG protocols, Section III, Grievances, please confirm the only applicable compliance standard for calls is correct categorization (i.e., not fully addressing all issues, either during or after the call, would not be a compliance standard). Understandably, CMS notes in the section the agency may review factors not specifically addressed in the questions, but it would be preferable if CMS did enhance these questions to make it clear that fully addressing an issue would be an expectation.

GORMAN HEALTH GROUP
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015
P 202.364.8283 F 202.315.4483

For the CDAG audit protocol, Section III, Grievances, Compliance Standard 3.1 (p. 17, item #3) asks if the mis-categorized call or case was transferred "quickly" to the appropriate process. What does CMS consider to be "quickly?"

For both the ODAG and CDAG audit protocols, the new section relating to call logs asks if the call was classified as a grievance. Please confirm whether or not these cases should appear in both the call log and grievances universes.

For both the ODAG and CDAG direct member reimbursement universes, the responses for date reimbursement provided does not allow for a situation where no payment is due (i.e., the cost is less than the copayment). The CDAG universe directs the sponsor to answer NA if the check was not provided but is not specific as to the possible reasons the check might not be provided (e.g., the check was never mailed). The ODAG universe directs sponsors to answer NA for untimely cases that are still open. Recommend providing a response for no payment due/required in both protocols for all applicable direct member reimbursement universes.

For both the ODAG and CDAG timeliness tests, please clarify in the documents how CMS intends to test timeliness for the direct member reimbursement universe cases in which a reimbursement is not issued and/or not required to be issued.

For both the ODAG and CDAG direct member reimbursement universes, please clarify whether or not administrative denials (e.g., duplicate requests) should be excluded from the universes.

For both the ODAG and CDAG audit protocols, the compliance standard related to IRE, ALJ, and MAC overturns (Section 3.3) states if a reviewer determines the IRE, ALJ, or MAC reversal was in error, the sponsor will receive a score of pass for the case. Please clarify how a reviewer would determine the IRE, ALJ, or MAC reversal is in error.

For both the ODAG and CDAG supplemental questions, please provide instructions to clarify whether or not these should be completed only by the plan sponsor, for its organization, or if the plan sponsor should also have applicable FDRs complete the questionnaires or include information from their FDRs on the questionnaires. While it may be assumed CMS is looking for the responses as they pertain to the functions (regardless of whether it is the Sponsor or FDR performing), it is not clear in the instructions.

For both the ODAG and CDAG audit protocols, SOD and SCD tables respectively, Column ID J, Issue Description, we recommend separating the denial reason (when applicable) into a separate column and providing categories for plan sponsors to select the denial reasons.

For the ODAG protocol, Section II, Compliance Standard 3.2.11 asks if the enrollee received a clinically equivalent or alternative service. There are circumstances where it would not be appropriate to provide an equivalent or alternative service (e.g., not a covered benefit). Recommend clarifying this compliance standard.

CPE

For CPE, CMS proposes requesting documentation as well as four data universes. It is noted in the instructions after the third failed attempt to provide a universe, or when the sponsor determines after fewer attempts they are unable to provide an accurate universe within the time frame

GORMAN HEALTH GROUP
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015
P 202.364.8283 F 202.315.4483

specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case. Since samples may or may not be selected from a given universe, please clarify in the instructions how an IDS for a CPE universe would be applied to the three proposed CPE elements (prevention, detection, correction).

For the evaluation of Prevention Controls and Activities and Detection Controls and Activities, there are questions outlined in the Compliance Standard which appear to be global questions, not necessarily pertinent to the tracer selected, but instead a description of what was in place. For example, CMS asks if the sponsor updated and distributed Standards of Conduct and P&Ps to employees/FDRs where appropriate and within time frames. While each sample tracer could describe the global process, it is understood CMS may request documentation of distribution for the pertinent parties within the tracer, such as employees or FDRs.

Please outline the threshold for passing the three elements evaluated for CPE. CMS has noted cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may be associated with a single condition or multiple conditions of non-compliance. It would be helpful for Sponsors to understand the additional details in the methodology used in order to incorporate into self-tests and audits.

Please incorporate additional instruction for CPE ECT layout Field G, which is for the Direct Phone Number of employee for when there is no direct phone number but instead a phone number plus extension.

Please provide additional instruction for CPE ECT layout Field L, which is for Compliance Committee member. Many Sponsors have more than one Compliance Committee where Medicare Compliance issues are addressed and discussed. For example, there may be a Corporate Compliance Committee, a Medicare Operations Compliance Committee, a Delegation Oversight Compliance Committee, etc. Therefore, it is recommended CMS clarify if members of various committees should be indicated here.

In all protocols, CMS requests the plan sponsor provide a list of previously disclosed and self-identified issues CMS may find in the universe. For CPE, please clarify if plan sponsors should include FA, CDAG, ODAG, SNP MOC issues identified through auditing and monitoring efforts of operational areas over the past year (the CPE universe period), even though the issue may fall outside of the scope of the universe period for that applicable audit protocol. If so, please describe how CMS would validate corrected issues in these situations.

For the CPE protocol, there are several compliance standards identified under Section II, Detection, which could apply or have aspects that apply to Section I, Prevention. For example, initial OIG/GSA screening of employees/FDRs could be considered preventive, as could implementing FWA prevention activities.

In the CPE audit protocol, CPE FTEAM universe, the first bullet appears incomplete – did CMS intend to include first tier entities (FTEs) that are delegated to provide administrative or healthcare services, or any FTE delegated to perform any function?

In the CPE audit protocol, FTEAM universe, Column O, Corrective Action Description allows a response of NA if corrective action was not taken or determined necessary. However, Column N,

GORMAN HEALTH GROUP
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015
P 202.364.8283 F 202.315.4483

Corrective Action Required, does not allow a response of NA. Same comment applies to IA universe, Columns L and M, and IM universe, Columns L and M. Response options should be consistent/parallel.

In the CPE audit protocol, ECT universe, Column H, Date of Hire, please consider revising to Date of Hire/Appointment (for governing body members).

In the CPE audit protocol, ECT universe, Column I, Employee Type does not include governing body members. Recommend including governing body member as a permitted response option.

In relation to the proposed CPE questionnaires (Compliance Officer, FDR Oversight, SIU/FWA Prevention and Detection), will these be used in lieu of interviews, or to supplement interviews? Will CMS provide the documents in a format other than pdf for completion? If the plan sponsor has multiple individuals responsible for the areas, is the plan sponsor expected to have each individual complete the questionnaire, or provide one questionnaire incorporating responses from multiple individuals? Recommend providing additional instructions and clarification as to the purpose of the questionnaires.

CMS is proposing to have plan sponsors complete both the new Compliance Officer, FDR Oversight, SIU/FWA Prevention and Detection questionnaires and the Self-Assessment Questionnaire (SAQ). Some of the information in the new questionnaires is somewhat duplicative of the information in the applicable sections of the SAQ. Recommend revising the SAQ to remove duplicate or unnecessary information, or removing it from the protocol altogether.

GORMAN HEALTH GROUP
5335 Wisconsin Ave. NW, Suite 340
Washington, DC 20015
P 202.364.8283 F 202.315.4483

PUBLIC SUBMISSION

As of: 12/9/16 8:49 AM
Received: August 12, 2016
Status: Draft
Tracking No. 1k0-8rar-m5hc
Comments Due: August 12, 2016
Submission Type: Web

Docket: CMS-2016-0097
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Comment On: CMS-2016-0097-0001
(CMS-10191) Medicare Parts C and D Program Audit Protocols and Data Requests

Document: CMS-2016-0097-DRAFT-0043
DC

Submitter Information

Name: Anonymous Anonymous
Address:
DC, 20015

General Comment

Kindly review the attached comments being submitted for your consideration as they pertain to the 2017 Part C and Part D Program Audit Protocols and Data Requests.

Attachments

90 Day Comments 081216