CMS Responses to Industry Comments Received on the Federal Register Notice for Medicare Part C and Part D Universal Audit Guide

CMS received comments from three entities on the January 22, 2013 Federal Register, Information Collection Request: Medicare Parts C and D Universal Audit Guide 42 CFR parts 422 and 423 [[Form Number CMS-10191] OCN-0938-1000]. The commenters were Wellpoint, Commonwealth Care Alliance and Healthnet, Inc. Several of the comments were identical, therefore, CMS will respond to those comments together.

COMMENTS ON CMS' ENGAGEMENT LETTER

PUBLIC COMMENT:
Currently, CMS provides very short notice to plans that are selected for audit: however, CMS has an annual audit plan. With limited notice, plans incur increased expenses for travelling and are challenged to meet the increased need for staffing.

We request that CMS provide plans with advance notice of the yearly audit strategy for planning and scheduling purposes at the beginning of each audit year.

CMS RESPONSE:
The audit schedule is not usually confirmed at the beginning of the year. CMS creates a draft schedule that is subject to change based on several factors, one of which would be regional office audit referrals that are added when CMS is notified of issues of non-compliance throughout the year. Because of this, and in order to maintain audit integrity, CMS does not release the audit schedule to the public. CMS does however, provide the audit protocols and the audit process in advance of conducting audits and sponsors are given four weeks' notice before the start of each audit.

PUBLIC COMMENT:
CMS has increased audit activity from one week to two weeks which will require that more staffing be solely focused on the audit activity over a longer period of time. In addition, increasing the audit period from one week to two weeks creates a greater financial burden on plans: therefore, we request the audit period be returned to a one week period.

CMS RESPONSE:
Based on feedback that we have received from the industry, CMS extended the audit period from one week to two weeks so the sponsor's compliance team can focus on the performance areas being reviewed the first week. This allows the Compliance team the ability to focus on Compliance the second week. This also allows CMS to have the findings from the sponsor's operational areas before assessing the effectiveness of the compliance program. We have made every effort to decrease the financial burden by conducting the audit of the operational areas via webinar during the first week and having the compliance auditors onsite for the second week thus decreasing the burden on sponsor resources.

COMMENTS ON PROTOCOL ATTACHMENTS

ATTACHMENTS I, II, VII, X

PUBLIC COMMENT:
Finding threshold for Attachments I, II, VII, X indicate any sample cases that do not meet CMS requirements will fail and a finding will be documented. This implies the passing threshold is an unreasonable 100%.

We request that CMS re-examine these thresholds and identify a reasonable threshold plans can use to assess their performance and compliance. Without this reasonable threshold, plans are in essence held to an unknown compliance standard, which affords them little to no opportunity to take corrective measures to improve compliance because they don't know the standard they will be held to during an audit.

CMS RESPONSE:
For the 2013 audit season, CMS no longer utilizes pass/fail thresholds. Scoring is based on unique conditions identified in performance areas.

Please refer to the HPMS memo released on May 17, 2013, entitled, "Final Program Audit Scoring Methodology located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

ATTACHMENT I – FORMULARY – ELEMENT 1 FORMULARY ADMINISTRATION

PUBLIC COMMENT:
Sample Selection: CMS will select a sample of 30 claims from the 2013 rejected claims universe as follows: 15 claims for non-protected class drugs and 15 claims for protected class drugs. The sample will consist of rejections relating to formulary administration (e.g. prior authorization, step therapy, non-formulary drugs, and quantity limitations).

We request that CMS explain the process that will be used to determine the sample. Will it be a random sample, targeted, or some other sampling process? We request that CMS clarify. In addition, if the sampling is not random, it would be helpful for plans to understand the methodology or criteria that will be used to select the sample, so they can actively monitor and improve their own compliance in those instances where they are not being audited.

CMS RESPONSE:
As the program audit identifies issues that have direct beneficiary harm (i.e. beneficiaries not receiving access to care), CMS determined that it is appropriate to utilize a targeted sampling approach. This approach improves the health and safety of Medicare beneficiaries. For formulary administration, samples may be selected based on utilization management criteria applied to drugs that appear to be inconsistent with the sponsor's current formulary. Inconsistent rejection messaging may also be a reason for sample selection. Samples that are targeted typically require additional review or represent the highest risk to beneficiaries.

ATTACHMENT I – FORMULARY – ELEMENT II TRANSITION

PUBLIC COMMENT:
Sample Selection: For continuing beneficiaries with a cross year formulary change CMS will select a sample of 15 claims from the universe as follows: 7 claims for non-protected class drugs and 8 claims for protected class drugs from the 2013 rejected claims universe. CMS will analyze the universes and the CMS approved formulary to identify all beneficiaries and drug combinations where a drug changed formulary status between 2012 and 2013, using the following steps:
1) Identify all formulary changes between 2012 and 2013 (formulary deletions, addition of prior authorization, step therapy),
2) Identify beneficiaries who were taking a medication affected by a formulary change,
3) Identify all 2013 rejected claims for the affected beneficiary/drug combinations.

For new enrollees CMS will select a sample of 15 claims from the universe categories as follows: 7 claims for non-protected class drugs and 8 claims for protected class drugs from the 2013 rejected claims universe.

We request that CMS explain the process that will be used to choose the sample. Will this be a random, targeted or some other sampling process? If the sampling process will not be random, it would be helpful for plans to understand the methodology or criteria that will be used to select the sample, so they can actively monitor and improve their own compliance in those instances where they are not being audited.

CMS RESPONSE:
As the program audit identifies issues that have direct beneficiary harm (i.e. beneficiaries not receiving access to care), CMS determined that it is appropriate to utilize a targeted sampling approach. This approach improves the health and safety of Medicare beneficiaries. For transition, samples are selected to ensure new and eligible continuing beneficiaries are appropriately afforded their transition fills in accordance with CMS guidance. Samples that are targeted typically require additional review or represent the highest risk to beneficiaries.

PUBLIC COMMENT:
Sample Case Results: CMS will test each of the 30 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

We request that CMS explain which "requirements" will be examined during testing. Will CMS update the manual to include all instructions to date and reflect those changes in the Audit Guide?

CMS RESPONSE:
These requirements refer to the CMS requirements listed in Chapter 6 of the Medicare Prescription Drug Benefit Manual. The manual chapter contains CMS requirements while our Audit Protocols identify what CMS will review during an audit.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Formulary and Benefit Administration protocols.

ATTACHMENT I – FORMULARY – ELEMENT III - WEBSITE REVIEW

PUBLIC COMMENT:
Sample Selection: CMS will select one contract per formulary ID to review. Contract selection will be made in the following order: PDP: MAPD: and EGWP. CMS will select a sample of:

i) PA criteria: 5 drugs per contract to compare to the posted PA criteria.
ii) Formulary information: 10 drugs per contract to compare to the posted formulary to verify the info is correct. (e.g., tier, UM, etc.)

We request that CMS explain the process that will be used to determine the sample. Will it be a random, targeted or some other sampling process? If the sampling process will not be random, it would be helpful for plans to understand the methodology or criteria that will be used to select the sample, so they can actively monitor and improve their own compliance in those instances where they are not being audited.

CMS RESPONSE:
As the program audit identifies issues that have direct beneficiary harm (i.e. beneficiaries not receiving access to care), CMS determined that it is appropriate to utilize a targeted sampling approach. This approach improves the health and safety of Medicare beneficiaries. For the website review, samples are selected to review posted prior authorization and formulary criteria on the sponsor's website.

COMMENT ON PROTOCOL ATTACHMENT I – FORMULARY – ELEMENT IV P & T COMMITTEE

PUBLIC COMMENT:
Sample Selection: CMS will identify all formulary changes between CY 2012 and CY 2013. From this universe, CMS will select a sample of 15 drugs that were either added to the formulary for 2013, deleted from the formulary for 2013, or changed formulary status between 2012 and 2013 from the universe categories as follows:

(1) 10 drugs subject to utilization management:
(2) 5 protected class drugs.

Documentation: CMS will review the submitted P&T committee minutes for evidence documenting the formulary change.

Sample Case Results: CMS will test each of the 15 cases. If changes are not documented in the P&T committee minutes, a sample case fails and a condition (finding) is documented. If changes are documented in the P&T Committee minutes, a sample case passes and no conditions (findings) is documented.

We request that CMS explain the process that will be used to choose the sample. Will the sample be a random sample, targeted, or some other sampling process? If the sampling process will not be random, it would be helpful for plans to understand the methodology or criteria that will be used to select the sample, so they can actively monitor and improve their own compliance in those instances where they are not being audited.

CMS RESPONSE:
As the program audit identifies issues that have direct beneficiary harm (i.e. beneficiaries not receiving access to care), CMS determined that it is appropriate to utilize a targeted sampling approach. This approach improves the health and safety of Medicare beneficiaries. For P&T committee, samples are selected for drugs that were added to the formulary, deleted from the formulary or a utilization management control (e.g., prior authorization, step therapy or quantity limits) was changed. Samples are targeted based on possibly representing a high-risk to beneficiaries.

ATTACHMENT II – PART D CDAG

PUBLIC COMMENT:
Select 15 Cases: CMS will select a targeted sample of 15 grievances from the universe which focus on grievances related to drug access or pricing issues. Please note that if the grievances universe contains less than 15 cases, CMS may request a universe of Customer Service Member Calls consisting of all member phone calls received for the review period. CMS will provide instructions for submission of the Customer Service Member Calls universe to the sponsor if it is deemed appropriate.

CMS indicates that "if the grievances universe contains less than 15 cases, CMS may request a universe of Customer Service Member Calls consisting of all member phone calls received for the review period. CMS will provide instructions for submission of the Customer Service Member Calls universe to the sponsor if it is deemed appropriate." We wish CMS to elaborate on this, since this statement is rather vague. CMS indicates they "will provide instructions for this submission if it is deemed appropriate,"

We request that CMS explain the timing in which instructions will be provided, given that plans would like to ensure that they are audit ready. Also, we request that CMS explain what is meant by "deemed appropriate".

We request CMS to describe a situation in which they will request all Customer Service Member calls during that period or is CMS asking plans to separate out those plans identified as a grievance? What is the format for the universe template? What elements would CMS want to

see? It would be helpful to know these things so plans can ensure they are able to pull the information in the format CMS would expect before they are audited. This will ensure that plans are prepared if they need to make changes to reports, etc.

CMS RESPONSE:
Generally, it is not necessary to request call logs. In the rare instance when CMS receives an insufficient grievance universe, CMS will request the call logs. CMS will provide detailed instructions at the time of the request. For example, CMS will request the contract ID, the plan ID, the date the call was received, category of call, description of call and description of the outcome of the call. CMS will work with the sponsor to determine a reasonable deadline to provide this information to CMS.

ATTACHMENT III-A – COMPLIANCE PROGRAM – SAMPLE CASE FILE DOCUMENTATION REQUEST

PUBLIC COMMENT:
Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks
Sample Requested: First Tier Entity Records
For each identified first tier entity, provide the following documentation, including the date of receipt (signed certifications, attestations, training logs, etc.):
Training, Education and Exclusion List Checking
• Evidence that general compliance training was timely provided to your FDRs.
• Evidence that sampled non-deemed first tier entities' employees received timely FWA training.
• Evidence that you provided FWA training or training materials to the non-deemed first tier entity for its employees' timely FWA training or otherwise ensured that the first tier entity completed the CMS FWA training module through the Medicare Learning Network (MLN) (Required)
• Evidence that you require the sampled first tier entities to maintain records for ten years of the training of their employees, including the following details: time, attendance, topic, certificate of completion, if applicable and test scores, if any.
• Evidence that sampled first tier entities' employees were timely checked against the OIG/GSA exclusion lists.

We request that CMS clarify the language in the first bullet point of this element. To maintain continuity with Medicare Managed Care Manual Ch. 21 and Prescription Drug Benefit Manual Ch. 9 Sect 50.3.1 we suggest changing the first bullet to read "Evidence that general compliance information was timely communicated to your FDRs."

CMS RESPONSE:
We concur with the Sponsor’s recommendation. The word “training” should be changed to “information” in order to be consistent with the current manual guidance (Chapters 9 and 21).

ATTACHMENT VI – SELF DISCLOSURE

PUBLIC COMMENT:
Instructions state: For each Universe provided, indicate how any previously identified and self-disclosed issues impact the universe.

We suggest that columns should be added to the template for identifiers (HICN, SSN) otherwise it will not be possible to identify issues at the case level as requested.

CMS RESPONSE:
The sponsor should provide CMS with a listing of all previously self-disclosed and self-identified items that impact the universe. The attachment should not include beneficiary level information such as a HICN/SSN.

ATTACHMENT VII PART C ODAG – TASK 2

PUBLIC COMMENT:
Select 30 Cases: CMS will select a targeted sample of 30 cases from the universe categories as follows:
• 10 favorable organization determination cases:
• 10 favorable reconsiderations cases: and
• 10 cases overturned by the IRE, ALJ or MAC.
If there are not enough reconsideration, IRE, ALJ or MAC cases, CMS will increase the number of organization determinations cases to obtain a total sample size of 30.

Payment and pre-service organization determinations are often supported through the use of first-tier, downstream and related entities (FDRs). In order to ensure a timely response to the CMS universe and sample request, we suggests a list of FDRs performing this work is provided prior to the universe pull, and CMS select a sample of FDRs for which the plan would obtain data and include in the universe pull. This would ensure all FDRs remain audit-ready, but allow plans adequate time to obtain and merge the universes for CMS sample selection and coordinate sample walk through discussions with the various FDRs.

CMS RESPONSE:
Based on feedback CMS has received from the industry and its assessment of the program audits completed last year, CMS believes the requirements for the ODAG universe to be reasonable. Protocols are made available to sponsors prior to CMS conducting the audits. Our expectation is that sponsors will use these tools to conduct internal monitoring to ensure that their FDRs remain audit ready. Please refer to the HPMS memo released on September 10, 2012: entitled, "Best Practices and Common Findings from 2012 Program Audits."

ATTACHMENT VIII – AUDIT PROCESS

PUBLIC COMMENT:
2013 Program Audit Process Center for Medicare Program Compliance & Oversight Group Division of Compliance Policy and Operations.

We suggest that CMS' Calculation of Total Audit Hours & Approximate Cost estimates be re-examined since they do not appear to be reasonable, given that the audit time period for 2013 has increased from one week to two weeks and our historical data indicates that for 2011 CMS Program Audit, conducted on our organization, it took approximately 9,800 hours including more than 65 people working a 40 hour week for more than 3 weeks. For the 2010 CMS Compliance Audit, the hours extended were approximately 3,600 hours and included more than 30 people working an average of a 40 hour week for approximately 3 weeks. Also, this change significantly increases staffing commitment for plan sponsors, especially for compliance teams where participation is required during both weeks.

Week 1 Includes operational areas via webinar
Week 2 includes on-site compliance review

CMS RESPONSE:
CMS understands this to be a resource intensive process, but based on industry feedback we also believe it to be a valuable experience. In arriving at these estimations, CMS took into consideration the improvements we have made to the audit process since 2011. Specifically, we streamlined this process by providing our protocols in advance of the audits, utilizing the SFTP site to facilitate documentation transfer instead of requiring hard copy documentation and CDs, and utilizing webinar technology to facilitate the first week reviews which decreased the onsite team membership by 80%. Additionally, in the past CMS has required the sponsor to upload all cases to the SFTP for review which proved to be a time consuming effort. Going forward, CMS will only require the sponsor to upload failed cases for review. However, CMS will reassess this issue if CMS obtains an increase in feedback related to the total audit hours.

ATTACHMENT X – OEV

PUBLIC COMMENT:
Note: All requested universes in Attachment X should be submitted through the CMS Enterprise File Transfer (EFT) in one zip file.

Required Universe (2):
1. Enrollments Effectuated by Agents/Brokers: For audits conducted between January 1 and June 30, 2013, provide all enrollments effectuated by all agents/brokers with enrollment effective dates of October 1, 2011 through March 1, 2012. For audits conducted between July 1 and December 31, 2012, provide all enrollments effectuated by all agents/brokers with enrollment effective dates of January 1 through June 01, 2012. If a beneficiary in the universe disenrolled from the plan, include the disenrollment date. Sponsors should identify those disenrollments that qualify as a rapid disenrollment (disenrollment within 90 days of enrollment date).
Submit Universe 1 using Attachment X-A-AB Enrollments in Excel format (files may be submitted in CSV or text format if the file is too large for Excel).

2. Agents/Brokers who Sold Sponsor's Contract Year 2012 and 2013 MA and/or Part D Products: Indicate whether the agents/brokers were captive, employed, or independent and whether they sold on behalf of the sponsor for 2012, 2013, or both. Submit Universe 2 using

Attachment X-A-AB Directory in Excel format (files may be submitted in CSV or text format if the file is too large for Excel).

We suggest that CMS limit the universe to agents/brokers who effectuated the enrollments during the timeframe requested and not the entire plan year (as requested in the first bullet), since the description related to the universe appears to have been expanded beyond the requirements of the element being reviewed.

CMS RESPONSE:
CMS is requesting agent/brokers who effectuated enrollments during a five month period: either Oct -March or Jan - Jun depending on the start date of the audit. Please see the Outbound Enrollment Verification (OEV) protocol released in the HPMS Memo on Jan 25, 2013, entitled, "2013 Program Audit Process and Protocols".

COMMENTS ON THE SUPPORTING STATEMENT PART A:

GENERAL COMMENTS

PUBLIC COMMENT:
Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 C.F.R. Parts 422 and 423 Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. In 2010 the explosive growth of these sponsoring organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and risk-based audit approach. We focused on high-risk areas that have the greatest potential for beneficiary harm.

To accomplish this we have combined all Part C and Part D audit elements into one universal guide which will also promote consistency, effectiveness and reduce financial and time burdens for both CMS and Medicare-contracting entities. The Medicare Part C &D Universal combined audit guide received OMB approval in 2010 (Appendix A). It is also available in the Health Plan Management System (HPMS). HPMS is the current conduit by which organizations submit many sources of audit materials such as bids and other ongoing updates to CMS. Please note the guide is very comprehensive in that it describes all areas that could be audited. Due to limited resources, CMS is unable to audit all areas for any particular sponsor. Some areas could be monitored by the Account Manager, etc. Other areas could be the audited in the program audits.

To maximize resources, CMS will focus on assisting the industry to improve their operations to ensure beneficiaries receive access to care. One way to accomplish this is CMS will develop an annual audit strategy which describes how sponsors will be selected for audit and the areas that will be audited. The audit strategy will be shared with the industry via the CMS website, HPMS memo, the Part C & D user call, and other conferences. Once the audit areas are defined, CMS will design audit protocols describing in detail the focus of the audit, the data required for the audit, etc. The engagement letter (Appendix B) and protocols (Appendix C) will be sent to all sponsors selected for audit 4 weeks prior to starting the audit. In addition, the protocols will be released to the industry at the beginning of each calendar year via the same manner as the audit

strategy. To assist in improving the audit process, CMS sends the plan sponsors a survey (Appendix D) at the end of each audit to complete in order to obtain the sponsors feedback. The sponsor is not required to complete the survey.

The Universal Audit Guide in many sections only provides high level or general requirements. In order for plans to effectively operationalize CMS guidance, it would be helpful if additional specificity and detail could be provided too many sections. This clarity and specificity would reduce ambiguity for plans and CMS contracted auditors/staff, and would help promote proactive plan compliance and consistent interpretation of CMS guidance.

In addition, the proposed Universal Audit Guide has many sections that appear to include out dated guidance, or have not been updated to reflect revised, statutes, regulations or new CMS requirements. To help improve the content and usefulness of the Audit Guide, we would propose that CMS ensure the Audit Guides are consistent with applicable guidance, and that all applicable guidance is cited and linked to the manuals. This will also ensure that any future regulatory or statutory changes can be promptly tracked and incorporated into the Audit Guides.

CMS RESPONSE:
The Universal Audit Guide serves as a tool to identify CMS requirements that could potentially fall within the audit scope while our Audit Protocols discuss in detail which CMS requirements will be audited for a specific audit year. Should the audit scope change in the future, CMS will ensure that the protocols include the applicable guidance. Additionally, CMS updated the Universal Audit Guide to reflect the correct manual chapters.

For 2013 protocols, please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

USE OF INFORMATION TECHNOLOGY

PUBLIC COMMENT:
Sponsoring organizations are able to produce approximately 70% of requested information from their internal systems. Approximately 90% of plan produced information is provided electronically via Secure File Transfer Protocol (SFTP). The SFTP allows sponsors to securely upload information requested by CMS. The remaining 10% is provided while CMS is onsite at the sponsoring organizations location during the audit. CMS is able to obtain the remaining 30% via our internal systems and there is no level of effort required on the part of the sponsoring organizations.

CMS and its subcontractors, in turn, communicate to sponsoring organizations regarding this information. HPMS therefore is already a familiar tool for organizations to navigate through the auditing requirements. Additionally, as access to HPMS must be granted to each user, and is protected by individual login and password, electronic signatures are unnecessary.
The Compliance Program Effectiveness requests include 153 Tasks, none of which all require the plan to draft a narrative to explain how they are compliant (i.e., they are not system

generated): based upon our experience, we believe the 70% estimate is not consistent with actual experience and is overstated. Listed below are a few additional examples of tasks that are not system generated and conflict with the estimates noted in the draft guidance:
• Attachment III Compliance Program Effectiveness includes 34 tasks
• Attachment IV Organizational Structure PowerPoint includes a minimum of 15 slides.
• Attachment V – Questionnaire includes 104 questions.

We suggest that CMS provide data to support the information technology estimates and reassess the calculation of the percentage of requested information provided from internal systems, to be more reasonable, as this appears to be understated.

CMS RESPONSE:
Based on the feedback received from the industry survey, CMS believes these estimations to be accurate. In arriving at these estimations, CMS took into consideration the improvements we have made to the audit process since 2011. Specifically, we streamlined this process by providing our protocols in advance of the audits, utilizing the SFTP site to facilitate documentation transfer instead of requiring hard copy documentation and CDs, and utilizing webinar technology to facilitate the first week reviews which decreased the onsite team membership by 80%. Additionally, in the past CMS has required the sponsor to upload all cases to the SFTP for review which proved to be a time consuming effort. Going forward, CMS will only require the sponsor to upload failed cases for review. CMS understands this to be a resource intensive process, but based on industry feedback we also believe it to be a valuable experience. CMS is cognizant of the variations in sponsor organization plan sizes and will make every effort to be flexible in our consideration of how that relates to the volume of requested information. CMS will reassess the estimate if CMS obtains an increase in feedback related to this issue.

DUPLICATION OF EFFORTS

PUBLIC COMMENT:
This information collection does not duplicate any other effort and the information cannot be obtained from any other source.
The following CMS monitoring efforts seem to duplicate efforts with the CMS Program Audits:
- OEV Monitoring/Pilot Project issued in March 2013 mirrors the CMS Program Audit
Attachment X - Transition Monitoring mirrors the CMS Program Audit Attachment I.

We suggest that CMS eliminate duplicative data collection efforts.

CMS RESPONSE:
CMS concurs. CMS is currently working internally to develop a global audit schedule. Going forward, we will work closely with our colleagues to ensure we are requesting similar data only once.

BURDEN ESTIMATES (HOURS & WAGES)

PUBLIC COMMENT:
Anticipated staff needed for collecting data and their estimated hourly rate follow: program director $66 compliance officer 82 lead analyst 50 quality assurance specialist 33 information technology specialist 39 2 clerical/administrative assistants 5 ea Lead claims analyst 37 Total $357 Taking the average of the above rates, we estimate an average hourly rate of $44.62.

Sponsor estimates that the impact of a CMS audit is 2,400 hours, based on direct experience during a One-Third Financial audit and industry experience for program audits. We believe that the estimate of 124 hours as published in the Federal Register (Volume 78, Number 14) underestimates the time investment by a plan undergoing a CMS audit.

CMS RESPONSE:
CMS disagrees. The One-Third Financial audit is a distinctly different process than the program audits. In arriving at these estimations for the program audits, CMS took into consideration the improvements we have made to the audit process since 2011. Specifically, we streamlined this process by providing our protocols in advance of the audits, utilizing the SFTP site to facilitate documentation transfer instead of requiring hard copy documentation and CDs, and utilizing webinar technology to facilitate the first week reviews which decreased the onsite team membership by 80%. Additionally, in the past CMS has required the sponsor to upload all cases to the SFTP for review which proved to be a time consuming effort. Going forward, CMS will only require the sponsor to upload failed cases for review. CMS understands this to be a resource intensive process, but based on industry feedback we also believe it to be a valuable experience. However, CMS will reassess the estimates if CMS obtain an increase in feedback related to extending the preparation timeframes for the audits.

PUBLIC COMMENT:

ROUTINE AUDITS
Based on our audit strategy, routine audits are defined as the audits scheduled throughout the year. CMS describes the audit selection methodology in the audit strategy. For each sponsoring organization we estimate an average of 80 hours for administrative and systemic work to assemble the requested information, 39.5 hours to review the information for completeness, 30 minutes to submit the information to CMS and 30 mins to complete the post audit survey. This is a total of approximately 121 hours for each sponsoring organization. The average number of parent organizations that will receive a routine audit annually is 75. This number includes 40 Medicare Part C and D sponsoring organizations, plus 35 PACE organizations.

ADHOC AUDITS:
Based on our audit strategy, adhoc audits are audits not scheduled like a routine audit. Ad hoc audits are an oversight tool that allows PCOG to promptly act when there is reason to believe that a sponsor is non-compliant with CMS policy. For each sponsoring organization we estimate an average of 40 hours for administrative and systemic work to assemble the requested information, 19.5 hours to review the information for completeness and 30 minutes to submit the information to CMS. This is a total of approximately 60 hours for each sponsoring organization

but this estimate may be less based on the elements selected for audit. The average number of parent organizations subject to an adhoc audit annually is 120. Although some parent organizations may be subject to multiple focused audits. So for purposes of the burden estimate, we estimate that approximately 250 focused audits will be performed on 120 parent organizations.

CALCULATION OF TOTAL AUDIT HOURS & APPROXIMATE COST:
Some of the parent organizations mentioned above may receive both a routine and ad adhoc audit, however, we have simply added the 101 parent organizations mentioned under the routine audits and the 120 parent organizations mentioned under the adhoc audits to come up with a total of 221 parent organizations subject to audit annually. The average number of hours per parent organization is roughly 121. Total audit hours (221 x 121) =26,741 Average hourly wage=$44.62 per hour Total Cost of Collection Effort=$ 1,193,183.40

This estimate is not reasonable given the amount of documentation requested for 8 separate attachments which include at a minimum 22 data universe requests and 153 compliance requests. This estimate also does not include time for compiling of the data Universes. These audits require full engagement of the Compliance Team. Our historical data indicates that for the 2011 CMS Program Audit conducted on our organization it took 9,800 hours, including more than 65 people working for more than 3 weeks. The 2010 CMS Compliance Audit took 3,600 hours and included more than 30 people working for approximately 3 weeks.

We suggest that CMS provide data to support the time-burden estimates and reassess the Calculation of Total Audit Hours & Approximate Cost, to be more reasonable, as these appear to be grossly understated.

CMS RESPONSE:
In arriving at these estimations, CMS took into consideration the improvements we have made to the audit process since 2011. Specifically, we streamlined this process by providing our protocols in advance of the audits, utilizing the SFTP site to facilitate documentation transfer instead of requiring hard copy documentation and CDs, and utilizing webinar technology to facilitate the first week reviews which decreased the onsite team membership by 80%. Additionally, in the past CMS has required the sponsor to upload all cases to the SFTP for review which proved to be a time consuming effort. Going forward, CMS will only require the sponsor to upload failed cases for review. CMS understands this to be a resource intensive process, but based on industry feedback we also believe it to be a valuable experience. However, CMS will reassess the estimates if CMS obtains an increase in feedback related to this issue.

GENERAL COMMENTS ON THE AUDIT PROCESS

PUBLIC COMMENT:
The Federal Register entry states, "Due to limited resources, CMS is unable to audit all areas for any particular sponsor. Some areas could be monitored by the account manager, etc. Other areas could be audited in the audit universal guide, to define which areas are more likely to be subject to monitoring rather program audits." It is requested, when possible, in the Part C and Part D

audit universal guide, to define which areas are more likely to be subject to monitoring rather than a formal audit.

CMS RESPONSE:
Any area that is not identified for audit in the 2013 audit protocols may be subject to monitoring by the Regional Office Account manager.

PUBLIC COMMENT:
Please continue to release the audit templates and universes at the beginning of the calendar year for the program audits. These tools have proven valuable for planning purposes and for internal auditing and monitoring. Advanced release of templates and universes for other types of audits would also be appreciated.

It would be appreciated if consideration is given to the number and timing of audits, especially when a sponsor is selected for multiple audits. Process streamlined by electronic process, information provided prior to start of audit season, templates.

CMS RESPONSE:
CMS is currently working internally to develop a global audit schedule to ensure sponsors are not burdened by multiple CMS audits conducted simultaneously. However, in the event that there are conflicting CMS audits, please notify your program Audit Lead so that they can intervene and coordinate with the other CMS audit contacts.

COMMENTS ABOUT CMS' AUDIT SURVEY

PUBLIC COMMENT:
Upon completion of the audit fieldwork, CMS sends an email to the sponsors containing a link to the web-based survey that highlights the pre-audit, audit, and post-audit processes. The survey consists of 14 questions related to various aspects of the audit. Sponsors are asked to score each process with a rating of either good, fair or poor and to provide additional comments regarding the specific audit area. Once the feedback is collected from the sponsors, CMS develops a summary of the survey results, survey trends and detailed results of each survey question. From the collective information, CMS is then able to propose a list of primary recommendations capable of improving the efficiency and effectiveness of the audit process.

2011 CMS Program Audit Survey was received 5 months post-audit. With such a long lag time, some constructive feedback may have been lost with employees leaving the department/company. We recommend CMS conduct more timely surveys in the future and ensure that plans have feedback on their performance and potential findings so plans can provide effective and meaningful comment on the process.

CMS RESPONSE:
CMS agrees. CMS is currently sending the survey with the draft report which is issued 60 days post audit and is making every effort to send out final reports in a more timely fashion.

COMMENTS ON THE UNIVERSAL AUDIT GUIDE

CHAPTER 1 – ENROLLMENT AND DISENROLLMENT:

AUDIT GUIDE ELEMENT ER01

PUBLIC COMMENT:
Correct Enrollment Election Elections must be completed by the beneficiary or representative, authorized under laws of the state.

42 C.F.R. § 422.60(c)(1): Medicare Managed Care Manual Ch. 2 – Section 40.2.1 42 CFR §423.32(b)(i): Prescription Drug Benefit Manual Ch. 3 – Section 30.2.1

General Comment: References to Prescription Drug Manual Chapter 3 Sections are incorrect throughout. They Appear to be off by 10 (ex. Section 30.2.1 for ER01 is actually Section 40.2.1).

We request that CMS address the incorrect manual references in the element description.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

AUDIT GUIDE ELEMENT ER10

PUBLIC COMMENT:
Retroactive Enrollment Requests.
The Sponsoring Organization requests retroactive enrollments, when appropriate, and adheres to CMS requirements in requesting retroactive enrollments from the Regional Office or Program Safeguard Contractor.

42 C.F.R. § 422.60: Medicare Managed Care Manual Ch. 2 – Sections 40.4.2 & 60.4, Medicare Managed Care Manual Ch. 19, pp. 32-33 42 CFR § 423.32: Prescription Drug Benefit Manual Ch. 3 – Section 50.3

We request that CMS expound on its description and indicate that this element does not apply to EGWPs.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols clearly address all CMS requirements.

AUDIT GUIDE ELEMENT ER16

PUBLIC COMMENT:
Group Enrollment into Employer/Union Sponsored Plans
The entity must use either a group enrollment process that meets specific CMS group enrollment requirements or individual enrollment forms. The group enrollment procedures must include provision of a specific notice to beneficiaries not less than 21 calendar days prior to the effective date of enrollment. The information must include how to opt out, the consequences of doing so, the summary of benefits, how to get more information on the plan and Medicare, and all required authorization and release language.

42 CFR § 422.60(c): Medicare Managed Care Manual Ch. 2 – Section 40.1.7: Medicare Managed Care Manual Ch. 9 – Section 20.1.6 42 C.F.R. § 423.32(b): Prescription Drug Benefit Manual Ch. 3 – Section 30.1.6: Prescription Drug Benefit Manual Ch. 12 – Section 20.1.4

Reference to Chapter 2 is incorrect. The correct reference is 40.1.6. The reference to Chapter 9 is incorrect. The correct reference is 30.6.

We request that CMS address the incorrect references in this element and reflect Chapter 2 - 40.1.6 and Chapter 9- 30.6. respectively.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

AUDIT GUIDE ELEMENT ER18

PUBLIC COMMENT:
Enrollment Forms
The Sponsoring Organization must have and accept a paper enrollment form, and may use any other enrollment mechanism that has been approved by CMS.

42 CFR § 422.60(c)(1): Medicare Managed Care Manual Ch. 2 – Section 40.1 42 CFR § 423.32(b): Prescription Drug Benefit Manual Ch. 3 – Section 30.1. This element references a very broad requirement.

We request that CMS narrow the requirement and reference each subsection (i.e. type of enrollment mechanism) separately.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols clearly address all CMS requirements.

AUDIT GUIDE ELEMENT ER20

PUBLIC COMMENT:
Auto- and Facilitated-Enrollment of Full Benefit Dual-Eligible Beneficiaries and Other Low Income Subsidy Eligible Beneficiaries.
The Sponsoring Organization must accept auto- and facilitated-enrollments and distribute plan materials in accordance with CMS procedures for full benefit dual eligible and other low income subsidy eligible beneficiaries who have failed to enroll in a Part D plan.

42 CFR § 423.34(d): Prescription Drug Benefit Manual Ch. 3 – Section 30.1.4: Medicare Managed Care Manual Ch. 2 – Section 40.1.6

We request that CMS elaborate on its description and indicate that this element doesn't apply to EGWPs.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols clearly address all CMS requirements.

AUDIT GUIDE ELEMENT ER22

PUBLIC COMMENT:
Confirmation of Enrollment for Members of Employer/Union Group Receiving Employer Subsidy
The Sponsoring Organization must meet CMS requirements for obtaining a confirmation of the intent to enroll from any individual who attempts to enroll in the Part D plan, but whose enrollment is conditionally rejected by CMS due to a detected match indicating that the beneficiary may have existing employer or union drug coverage. Prescription Drug Benefit Manual Ch. 3 – Section 10.4 PDP. This reference is not appropriate for EGWPs.

We request that CMS add the following corresponding reference which applies to EGWPs Chapter 12: 20.1.6

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references.

AUDIT GUIDE ELEMENT DN05

PUBLIC COMMENT:
Involuntary Disenrollment for Non-Payment of Premium (Optional)
The Sponsoring Organization may involuntarily disenroll Medicare members who fail to pay monthly basic or supplementary premiums only after demonstrating to CMS that the Sponsoring Organization has made reasonable efforts to collect the unpaid premium amount, including

notifying the individual that the premiums are delinquent, providing the individual with a grace period to pay past premiums due, and advising the individual that failure to pay will result in termination. An Sponsoring Organization may not disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the member has requested that premiums be withheld from his/her Social Security benefit check, or any individual considered to be in premium withhold status by CMS, as outlined in Section 50.3.1 of Manual Chapter 2. The Sponsoring Organization may only disenroll the Medicare member when the Sponsoring Organization has not received payment within a grace period of a minimum of 1 calendar month that begins on the first day of the month for which the premium was not paid. The effective date of disenrollment is the first day of the month after the grace period ends.

42 C.F.R. § 422.74(d)(1): Medicare Managed Care Manual Ch. 2 – Section 50.3.1 42 C.F.R. § 423.44(b)(1)(i): § 423.44(c): § 423.44(d)(1): Prescription Drug Benefit Manual Ch. 3 – Section 40.3.1

DN05 states "The Sponsoring Organization may only disenroll the Medicare member when the Sponsoring Organization has not received payment within a grace period of a minimum of 1 calendar month that begins on the first day of the month for which the premium was not paid." However, MMCM and the PDBM section 50.3.1 Failure to Pay Premiums both reference that if a plan sponsor chooses to disenroll for failure to pay premiums, the sponsor must apply a consistent grace period of no less than two (2) months..The description in the element appears to be at variance with the Managed Care Manual and the Prescription Drug Benefit Manual.

We ask that CMS address the variance in language between the description in the element and the Managed Care and Prescription Drug Benefit Manuals. We also request that CMS indicate if the grace period reference in the description should be 1 month or 2 months.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment or Late Enrollment Penalty. Should the scope of the audit change, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT DN06

PUBLIC COMMENT:
Involuntary Disenrollment for Move Out of Service Area
The Sponsoring Organization must disenroll Medicare members who permanently leave the approved plan service area, or who reside outside the approved plan service area for more than six (6) months, unless they move into an approved plan continuation area and the member has elected the continuation of enrollment option, or the plan offers a visitor/traveler program. Member notice is required prior to transmission of the disenrollment to CMS.

42 C.F.R. § 422.74(d)(4): Medicare Managed Care Manual Ch. 2 – Section 50.2.1 42 C.F.R. § 423.44(b)(2)(i): § 423.44(c): § 423.44(d)(5): Prescription Drug Benefit Manual Ch. 3 – Section 40.2.1

Reference to 6 months refers strictly to the MAPD guidance (Chapter 1), however PDBM Chapter 3 is listed as a regulatory citation. PDBM timeframe differs (12 months instead of 6 months for MAPD). This reference could lead to confusion of the actual timeframe for OOA Disenrollment.

We request that CMS address the variance between the requirements in the Manual and the description for this element.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment or Late Enrollment Penalty. Should the scope of the audit change, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT DN07

PUBLIC COMMENT:
Involuntary Disenrollment for Move Out of Service Area
The Sponsoring Organization must disenroll Medicare members who permanently leave the approved plan service area, or who reside outside the approved plan service area for more than six (6) months, unless they move into an approved plan continuation area and the member has elected the continuation of enrollment option, or the plan offers a visitor/traveler program. Member notice is required prior to transmission of the disenrollment to CMS.

42 C.F.R. § 422.74(d)(4): Medicare Managed Care Manual Ch. 2 – Section 50.2.1 42 C.F.R. § 423.44(b)(2)(i): § 423.44(c): § 423.44(d)(5): Prescription Drug Benefit Manual Ch. 3 – Section 40.2.1

Reference to 6 months refers strictly to the MAPD guidance (Chapter 1), however PDBM Chapter 3 is listed as a regulatory citation. PDBM timeframe differs (12 months instead of 6 months for MAPD). This reference could lead to confusion of the actual timeframe for OOA Disenrollment.

We request that CMS address the variance between the requirements in the Manual and the description for this element.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols clearly address all CMS requirements.

AUDIT GUIDE ELEMENT DN16, DN17

PUBLIC COMMENT:
Transmission of Disenrollments to CMS
For all voluntary disenrollment requests that the Sponsoring Organization does not deny, the Sponsoring Organization must submit the disenrollment transaction to CMS within 7 calendar days of receipt of a complete disenrollment request from an enrollee.

42 CFR § 422.66(b)(2)(i): Medicare Managed Care Manual Ch. 2 – Section 50.4.1 42 CFR § 423.36(b)(1) Prescription Drug Benefit Manual Ch. 3 – Section 40.4.1

DN16 and DN17 appear to be the same.

We request that CMS delete either DN16 or DN17, since DN17 appears to be a duplication of DN16.

CMS RESPONSE:
DN16 and DN17 are not duplicative. DN16 addresses voluntary disenrollments while DN17 addresses involuntary disenrollments due to a member losing their SNP eligibility. The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

CHAPTER 2 – LATE ENROLLMENT PENALTY:

AUDIT GUIDE ELEMENT LP02

PUBLIC COMMENT:
Creditable Coverage Attestation Process.
The Sponsoring Organization shall adhere to CMS requirements in sending and processing creditable coverage attestation forms. Prescription Drug Benefit Manual, Ch. 4 — Section 10.2.1: Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008). The reference in Chapter 4 is incorrect. The correct reference is 20.1.

We request that CMS change the reference for this element from Chapter 4- section 10.2.1 to Chapter 4- Section 20.1

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual Chapters.

AUDIT GUIDE ELEMENT LP03

PUBLIC COMMENT:
Changes Due to LIS Eligibility and Subsequent IEPs
In cases where an enrollee who is paying a late enrollment penalty becomes LIS eligible, the penalty is removed effective with the start of LIS eligibility. In cases where the enrollee is eligible for Medicare prior to turning age 65, the Sponsoring Organization shall have processes in place to identify those enrollees who will have a new Initial Enrollment Period (IEP) upon turning age 65 and will notify CMS and the enrollee according to CMS requirements. Prescription Drug Benefit Manual, Ch. 4 –Section 10.1.1: Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty HPMS Memo (April 11, 2008) The reference in Chapter 4 is incorrect, since it appears to be a reference from an older version of the Managed Care Manual.

We request that CMS reflect the most current reference in this element description.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

AUDIT GUIDE ELEMENT LP04

PUBLIC COMMENT:
Notification of Late Enrollment Penalty.
The Sponsoring Organization shall provide timely notification to the beneficiary of the imposition of, or adjustment to, the Late Enrollment Penalty.

42 CFR § 423.46: Prescription Drug Benefit Manual, Ch. 4 –Section 30: Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)

The reference in Chapter 4 is incorrect. The correct reference is 50.

We request that CMS correct the reference for this element from Chapter 4-Section 30 to Chapter 4- Section 50.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

AUDIT GUIDE ELEMENT LP05

PUBLIC COMMENT:
Late Enrollment Penalty Billing Requirements.
The Sponsoring Organization shall bill the beneficiary for the Late Enrollment Penalty in accordance with CMS requirements.

42 CFR § 423.286(d)(3), 423.780(e): Prescription Drug Benefit Manual, Ch. 4 –Section 40: Updated Guidance on Creditable Coverage Period Determinations and Late Enrollment Penalty Memo (April 11, 2008)

The reference in Chapter 4 is incorrect. The correct reference is 60.

We suggest that CMS correct the reference in the element from Chapter 4- Section 40 to Chapter 4-Section 60.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Enrollment, Disenrollment, or Late Enrollment Penalties. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

CHAPTER 4 – MARKETING

GENERAL COMMENTS

PUBLIC COMMENT:
While CMS previously audited Agent/Broker compensation, the draft of the audit guide does not include an element for Agent/Broker compensation. If this is an area CMS will audit in the future, we request CMS to include the specific requirements which will be audited and a reference to the appropriate regulatory source, as this will help ensure plans can internally monitor and audit in line with CMS' expectations.

CMS RESPONSE:
The 2013 audit scope does not include a review of Agent Broker Compensation. Should the audit scope change in the future, CMS will ensure that the protocols include the correct requirements and references.

AUDIT GUIDE ELEMENT MR01

PUBLIC COMMENT:
Appropriate Submission and Distribution of Marketing Materials
The Sponsoring Organization follows the requirements contained in the regulations and Medicare Marketing Guidelines for submission and distribution of marketing materials, including appropriate timelines and content of model, non-model, and File & Use materials.

42 C.F.R. § 422.2262(a)(1) and 422.2264, Section 103 of MIPPA: 42 C.F.R. § 423.2262(a)(1): Medicare Managed Care Manual Ch.3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

We recommend that CMS clarify that the scope of this item excludes all materials eligible for File & Use submission. (See related item MR11.)

CMS RESPONSE:
The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the scope of the audit is clear.

AUDIT GUIDE ELEMENT MR02

PUBLIC COMMENT:
Reference to Medicare Managed Care Manual Ch. 4 – Section 160.2. The current version of Chapter 4, Rev. 107, 06-22-12, does not include a section 160.2.

Please confirm the referenced section.

CMS RESPONSE:
The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the scope of the audit is clear. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

AUDIT GUIDE ELEMENTS MR02, MR03, MR26, CN06 & CN07

PUBLIC COMMENT:
Reference in the title to Deemable and Non-Deemable information to beneficiaries.

Clarify what is meant by "deemable" in this context.

CMS RESPONSE:
The 2013 audit protocols no longer include the reference to deemable and non-deemable information.

AUDIT ELEMENT MR03

PUBLIC COMMENT:
Disclosure of Required Non-Deemable Information to Beneficiaries
At the time of enrollment and annually thereafter, the Sponsoring Organization must disclose to each beneficiary electing an MA plan, in a clear, accurate, and consistent form, the information required by CMS.

42 C.F.R. § 422.111(a) and (b): § 422. 2264(a): Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

In contrast to MR16, is CMS referring to pre-enrollment materials here? If that is the case, we recommend CMS clarify what materials it will audit. Based on our understanding of the Medicare Marketing Guidelines (MMG), there are no pre-enrollment materials that members must receive each year (MMG 30.8). (See related item MR16.)

CMS RESPONSE:
The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly identify the enrollment materials under review.

AUDIT GUIDE ELEMENT MR04

PUBLIC COMMENT:
Information Provided to Beneficiaries Upon Request.
A Sponsoring Organization must provide the information required by CMS upon the request of a beneficiary.

42 C.F.R. § 422.111(c) and (f): § 422.210: 42 CFR § 423.120(b)(7): § 423.128(c): § 423.128(d)(3): § 423.505(f)(3): § 423.514(a)(3): Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

We suggest that CMS be more specific about which materials it will audit. While we provide materials upon request, the MMG does not clearly state which materials must be available on request.

CMS RESPONSE:
The 2013 audit scope does not include reviews of Marketing. Should the audit scope change in the future, CMS will ensure we clearly indicate the required materials.

AUDIT GUIDE ELEMENT MR07

PUBLIC COMMENT:
Allocation of Marketing Resources to Disabled.
The Sponsoring Organization demonstrates that marketing resources are allocated to the disabled Medicare population as well as beneficiaries ages 65 and over. Please note: “Disabled” is used in this element per the definition in the Americans with Disabilities Act.

42 C.F.R. § 422. 2272(a): 42 C.F.R. § 423.2272(a): Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

We suggest that CMS clarify whether, by "allocation of marketing resources," it is referring to the requirement to provide materials in alternate formats to beneficiaries as requested (MMG 40.1.1, 90.2.1).

CMS RESPONSE:
The 2013 audit scope does not include reviews of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR08

PUBLIC COMMENT:
No Engagement in Activities Which Mislead, Confuse, or Misrepresent the Sponsoring Organization
The Sponsoring Organization does not engage in activities which materially mislead, confuse, or misrepresent the Sponsoring Organization.
The Sponsoring Organization may not:

- Claim recommendation or endorsement by CMS or Medicare or the Department of Health and Human Services, or that CMS, Medicare, or the Department of Health and Human Services recommend that beneficiaries enroll in the plan Make erroneous written or oral statements including any statement, claim, or promise that conflicts with, materially alters, or erroneously expands upon the information contained in CMS-approved materials
- Use providers or provider groups to distribute printed information comparing benefits of different health plans, unless the materials have the concurrence of all Sponsoring Organizations involved and the materials have received prior approval from CMS:
- Use providers to accept enrollment applications or offer inducement to persuade beneficiaries to join plans
- Use providers to offer anything of value to induce plan enrollees to select them as a provider
- Accept plan applications in provider offices or other places where health care is delivered except in the case where such activities are conducted in common areas in the health care setting
- Conduct sales presentations or distribute and accept plan applications at educational events Provide meals regardless of value at sales events
- Use names or logos of cobranded network providers on plan membership and marketing materials
- Market non-health related products to prospective enrollees during any MA or Part D sales activity or presentation
- No Engagement in Activities Which Mislead, Confuse, or Misrepresent the Sponsoring Organization
- The Sponsoring Organization does not engage in activities which materially mislead, confuse, or misrepresent the Sponsoring Organization.

The Sponsoring Organization may not:

- Claim recommendation or endorsement by CMS or Medicare or the Department of Health and Human Services, or that CMS, Medicare, or the Department of Health and Human Services recommend that beneficiaries enroll in the plan

- Make erroneous written or oral statements including any statement, claim, or promise that conflicts with, materially alters, or erroneously expands upon the information contained in CMS-approved materials
- Use providers or provider groups to distribute printed information comparing benefits of different health plans, unless the materials have the concurrence of all Sponsoring Organizations involved and the materials have received prior approval from CMS:
- Use providers to accept enrollment applications or offer inducement to persuade beneficiaries to join plans.
- Use providers to offer anything of value to induce plan enrollees to select them as a provider
- Accept plan applications in provider offices or other places where health care is delivered except in the case where such activities are conducted in common areas in the health care setting
- Conduct sales presentations or distribute and accept plan applications at educational events
- Provide meals regardless of value at sales events
- Use names or logos of cobranded network providers on plan membership and marketing materials
- Market non-health related products to prospective enrollees during any MA or Part D sales activity or presentation

We recommend that CMS cite all references from statutes, regulations and manuals that pertain to this audit element.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references.

AUDIT GUIDE ELEMENT MR10

PUBLIC COMMENT:
Materials Provided for Significant Non-English Speaking Population
For markets with a significant non-English speaking population, the Sponsoring Organization provides materials in the language of these individuals.

42 C.F.R. § 422. 2264(4)(e): 42 C.F.R. § 423(3)(e): Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

MR10 talks about significant non-English speaking population and the requirement to provide materials in the language of these individuals. We request that CMS explain if this is specifically referring to the 5% rule cited in the MMG (Section 30.7). If it is, there are only certain materials that are required to be translated. The phrasing of this particular element seems to be broader than the 5% rule.

We suggest that CMS address the ambiguity in the element description. We request that CMS elaborate on the description for the element to explain that this element does not apply to EGWPs .

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR11

PUBLIC COMMENT:
File and Use Marketing Materials
The Sponsoring Organization must certify that qualified materials for File and Use Certification comply with CMS requirements, and must wait 5 days to distribute these materials. The Sponsoring Organization must submit at least 90% of materials that qualify for File and Use Certification under this process. If a Sponsoring Organization has File and Use Eligible status, it must submit qualified materials to CMS 5 days prior to use.

42 CFR § 423.2262(b)(1)(2): Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

We request that CMS elaborate on the description for the element to explain that this element does not apply to EGWPs.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR13

PUBLIC COMMENT:
Public Notification of Enrollment Period.
The Sponsoring Organization must notify the general public of its enrollment period in an appropriate manner throughout its service area.

42 CFR § 423.2264(3)(b)

We request that CMS elaborate on the description for the element to explain that this element does not apply to EGWPs.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR14

PUBLIC COMMENT:
Plan Responsibility for Persons Employed or Contracted to Perform Marketing.
The Sponsoring Organization must meet CMS requirements for any person directly employed or contracted to market the plan to ensure that beneficiaries receive truthful and accurate information.

42 CFR § 423.2272(c)(d), § 423.2274, § 423.2268: Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

We agree with CMS' prior approach of auditing agent/broker files for licensure, appointment, and training/testing and would encourage CMS to continue to exclude Employer Group agents/brokers, as well as internal agents.

CMS RESPONSE:
CMS agrees. However, CMS reserves the right to audit Agent/Broker which could include EGWP and Internal Agents.

AUDIT GUIDE ELEMENT MR16

PUBLIC COMMENT:
Requirements for Annual Post-Enrollment Materials
The Sponsoring Organization must distribute annual post-enrollment materials as required by CMS, to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter. This information must be provided in writing, if requested. In addition, the Sponsoring Organization must provide written information about its grievance and appeals procedures and the process for quality of care complaints available to the enrollee through the Quality Improvement Organization (QIO) process.

42 CFR § 423.120(b)(7): § 423.128(a)(3): § 423.128(b): § 423.128(d)(3): § 423.505(f)(3): § 423.562(a)(2): Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans.

We suggest that CMS be more specific about which materials will be audited, since, some post-enrollment materials must be provided to members at the time of enrollment and annually thereafter (MMG 60.5 and 60.7): however, other post-enrollment materials must be provided at the time of enrollment and at least every three years after that (MMG 60.4).

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR17

PUBLIC COMMENT:
Toll-free Customer Call Center
The Sponsoring Organization must have a toll-free customer call center that provides customer telephone service in accordance with CMS requirements. The Sponsoring Organization must provide CMS with information related to the operations of its customer call center according to guidelines specified by CMS.

42 CFR § 423.128(d)(1): § 423.514(a)

We request that CMS add a reference to MMCM Ch 9:50.9 and PDBM Ch 12:20.15 to indicate that EGWPs have a waiver for this standard.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references.

AUDIT GUIDE ELEMENT MR18

PUBLIC COMMENT:
Internet Website
The Sponsoring Organization must have an Internet website that meets CMS marketing guidelines, including providing a current formulary for its Part D plan that is updated at least monthly and providing current and prospective Part D enrollees with at least 60 day's notice regarding the removal or negative change to utilization management or the preferred or tiered cost-sharing status of a drug on the formulary.

42 CFR § 423.120(b)(7): § 423.128(d)(2): Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for

We request that CMS add a reference to MMCM Ch 9:50.9 and PDBM Ch 12:20.15 to indicate that EGWPs have a waiver for this requirement.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR24

PUBLIC COMMENT:
Outbound Education and Verification Calls
All Sponsoring Organizations offering PFFS plans are required to conduct outbound education and verification calls to all applicants to ensure beneficiaries requesting enrollment understand the plan rules, except enrollments into employer or union sponsored PFFS plans or switches from one PFFS plan to another PFFS plan offered by the same MA organization.

42 C.F.R. § 422.80(e)(2)(ii): May 25, 2007 Memo to Medicare Advantage Private Fee-for-Service (PFFS) Plans: Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

This requirement was changed to the following: 70.8 - Outbound Enrollment and Verification Requirements 42 CFR 422.2272(b), 423.2272(b) - All plan sponsors are required to conduct outbound enrollment and verification (OEV) calls for enrollments effectuated by both independent and employed agents/brokers to ensure individuals requesting enrollment understand the plan's rules. It is important for the plan sponsor's sales staff to obtain from the applicant the best phone number to be used for verification and to provide a description of the enrollment verification process to the applicant during the application process. OEV calls must be made to the applicant after the sale has occurred: they cannot be made at the point of sale. The plan sponsor must ensure that the verification calls are not conducted by sales agents and those sales agents are not physically present with the applicant at the time of the verification call. Plan sponsors may not use automated calling technologies to conduct these outbound calls: CMS expects OEV calls to be interactive. The following agent/broker-effectuated enrollments are excluded from the OEV requirement:
- Enrollments into employer or union sponsored plans
- Plan-to-plan switches within a parent organization involving the same plan type or product type (e.g., PFFS to PFFS, D-SNP to D-SNP, PDP to PDP).
- Plan sponsors must make a minimum of three documented attempts to contact the applicant by telephone within fifteen (15) calendar days of receipt of the application: the first two attempts must be made within the first 10 days. If the enrollment application is incomplete, plan sponsors should concurrently conduct the OEV process while obtaining the missing information needed to complete the application.
- Plan sponsors must not delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the OEV process. If the sponsor does not have all the information required to complete the enrollment process at the time of the OEV call, the sponsor should obtain that information during the call. If the sponsor makes a determination to deny an enrollment request prior to completing the OEV process, the sponsor must discontinue the OEV process. If the sponsor receives a TRR from CMS rejecting the enrollment prior to completing the OEV process, the sponsor must suspend the OEV process but must resume if the sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS.
- Plan sponsors that do not successfully reach the beneficiary on the first or second attempt must send the applicant an enrollment verification letter in addition to making the third documented outbound verification call attempt within the 15 day timeframe.

We note inconsistencies between the language in the audit element and CMS' current (6/27/12) OEV policy and request that CMS update the Manuals to reflect the most current requirement and to also ensure that the language in the Audit Guide reflect CMS' most current requirement as stated in the updated Manuals.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR25

PUBLIC COMMENT:
Planned Marketing and Sales Events
Sponsoring Organizations must provide CMS with listings of planned marketing and sales events in a format and within timeframes required by CMS. Medicare Managed Care Manual Ch. 3 and Prescription Drug Benefit Manual Ch. 2 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

Per section 70.10.1 of Chapter 3 of the Medicare Managed Care Manual, plans are required to submit all marketing and sales events via a module in HPMS. To reduce the time-burden on CMS and plans and to support CMS' thrust for greater efficiency, we recommend that CMS utilize data already reported via HPMS when auditing this element. If this is not possible, we suggest that CMS modify the module to include all data elements required in the event of an audit.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will consider this recommendation.

AUDIT GUIDE ELEMENT MR26

PUBLIC COMMENT:
Disclosure of Required Non-Deemable Information to Beneficiaries
At the time of enrollment and annually thereafter, the Sponsoring Organization must disclose to each beneficiary electing an MA plan, in a clear, accurate, and consistent form, the information required by CMS.

42 C.F.R. § 422.111(a), (b) (1) – (11) and (f): § 422.80(c): Medicare Managed Care Manual Chapter 3 – Section 40.3: CMS Guidance to Regional PPOs on Ensuring Enrollee Access to Covered Services Using Methods Other than Written Agreements with Providers, pg. 2-3

We suggest that CMS clarify how this item differs from MR03. Is the difference that this item relates to R-PPO?

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

AUDIT GUIDE ELEMENT MR27

PUBLIC COMMENT:
Targeted Marketing to Special Needs Individuals.
The Sponsoring Organization must ensure that all SNP-related marketing materials adequately address the eligibility criteria of the SNP. The Sponsoring Organization also must ensure that all SNP-related marketing materials are made accessible to all eligible individuals. Interim Guidance Regarding MA Special Needs Plans for Dual Eligible and Institutionalized Individuals:

Medicare Managed Care Manual Ch. 3 - Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

This audit element indicates that "The Sponsoring Organization also must ensure that all SNP-related marketing materials are made accessible to all eligible individuals."

We request that CMS clarify if it is referring to MMG 30.6, Anti-Discrimination, which states, "Only SNPs may limit enrollment to dual-eligibles, institutionalized individuals, or individuals with severe or disabling chronic conditions and/or may target items and services to corresponding categories of beneficiaries. Basic services and information must be made available to individuals with disabilities, upon request," since these two requirements seem to differ.

CMS RESPONSE:
The 2013 audit protocols do not include reviews of Marketing: however, we have forwarded your recommendation for manual chapter changes to the appropriate CMS subject matter experts. Should the audit scope change in the future, CMS will ensure that the protocols clearly address our requirements.

CHAPTER 5 – BENEFITS & BENEFICIARY PROTECTIONS

AUDIT ELEMENT AA01

PUBLIC COMMENT:
Adequate and Appropriate Provider Network
The Sponsoring Organization maintains and monitors a network of appropriate providers that is sufficient to provide adequate access to and availability of covered services. 42 C.F.R. § 422.112(a)(1): Medicare Managed Care Manual Ch. 4 – Section 120.2

Citation refers to Chapter 4 - Section 120.2, -Requirements, Rights, and Beneficiary Protections - the guidance reference does not line up accurately. It appears as though the correct citation should be section 110. Since the reference does not tie to the current MMCM chapter and section, we request that CMS make the corrections to the element description and the program manual. We also request that CMS indicate to plans when they expect to update the program manuals to reflect current guidance. We note that the disparity between the language in several audit elements and the current guidance is a recurring theme throughout the protocols.

We wish CMS to address these disparities prior to the start of any audits to avoid the confusion this may cause.

CMS RESPONSE: The 2013 audit scope does not include a review of Marketing. Should the audit scope change in the future, CMS will ensure that the protocols include the correct references. CMS updated the Universal Audit Guide to reflect the correct manual chapters.

CHAPTER 06: QUALITY IMPROVEMENT & ASSURANCE - QY08

PUBLIC COMMENT:
Appropriate Utilization Management Program for Regional PPO Plans
If the Sponsoring Organization uses written protocols for utilization management, it must employ a utilization management program that meets CMS requirements for each plan.
42 C.F.R. § 422.152(e)(2)(iii): Medicare Managed Care Manual Ch. 5 – Section 20

We could not ascertain why CMS separated the UM program for RPPO, from the LPPO. We recommend combining audit elements QY03 and QY08 and simply indicate "PPO."

CMS RESPONSE:
The 2013 audit protocols do not include reviews of the Quality Improvement & Assurance. Should the scope of the audit change in the future, CMS will be sure that the protocols clearly communicate requirements.

CHAPTER 8 - ORGANIZATIONAL/COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES

GENERAL COMMENTS

PUBLIC COMMENT:
There are no measures for auditing Complaints Tracking Module (CTM) or the non-contracted provider payment dispute resolution process.

Add elements for auditing CTMs and the non-contracted provider payment dispute resolution process.

CMS RESPONSE:
The 2013 audit protocols do not address CTM or the non- contracted provider payment dispute resolution process since we are not auditing these areas.

Please refer to the HPMS memo issued January 25, 2013, entitled, “2013 Program Audit Process and Protocols” located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Part D Coverage Determination, Appeals & Grievances/Part C Organization Determinations, Appeals & Grievances (CDAG/ODAG) protocols.

AUDIT GUIDE ELEMENTS OC03, OC05

PUBLIC COMMENT:
Clearly describe the expectation. Is it to have the payment/notice of denial mailed no later than the 30th/60th day?

Describe how this is measured and what evidence is reviewed to test compliance.

CMS RESPONSE:
CMS agrees that it is the 30th/60th day unless an extension is granted when applicable.

Per **MMCM Chapter 13** section 70.7.1- **Standard Reconsideration of a *Pre-Service* Request,** **"**Upon reconsideration of an adverse organization determination, the Medicare health plan must *issue* its reconsidered determination *(i.e., make and place in the mail)* as expeditiously as the enrollee's health condition requires. This must be no later than 30 calendar days from the date the Medicare health plan receives the request for a standard reconsideration."

CMS will review systems used by sponsor organizations to determine compliance with this requirement. In addition, CMS will review all notices, letters, and communications sent from the sponsor organization to the enrollee (and provider/physician, if applicable) to determine when notification was made. This will include reviewing the sponsoring organization's policies for mail operations as it relates to the incoming and outgoing mail for the beneficiaries.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html. for 2013 ODAG protocols

AUDIT GUIDE ELEMENT OP01

PUBLIC COMMENT:
Clearly describe the expectation. Is it to have the written notice in the enrollees' hands by the end of the 14th calendar day (or an additional 14 days if an extension is justified)? Also, if this is the expectation, please describe how this is measured and what evidence is reviewed to test compliance.

CMS RESPONSE:
CMS is unable to verify when a beneficiary actually receives a notice. The sponsor is required to notify the enrollee no later than 14 calendar days after the sponsor receives the request.

Per MMCM Chapter 13, Section 40.1 – Standard Time Frames for Organization Determinations, "When an enrollee has made a request for a service, the Medicare health plan must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

The Medicare health plan may extend the time frame up to 14 calendar days. This extension is allowed to occur if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from *non-contract* providers may change a Medicare health plan's decision to deny). When the Medicare health plan grants itself an extension to the deadlines, it must notify the enrollee, in writing, of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the Medicare health plans' decision to grant an extension. The Medicare health plan must notify the enrollee, in

writing, of its determination as expeditiously as the enrollee's health condition requires, but no later than the expiration of an extension that occurs, in accordance with this chapter. "

CMS will review systems used by sponsor organizations to determine compliance with this requirement. In addition, CMS will review all notices, letters, and communications sent from the sponsor organization to the enrollee (and provider/physician, if applicable) to determine when notification was made. This will include reviewing the sponsoring organization's policies for mail operations as it relates to the incoming and outgoing mail for the beneficiaries.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 ODAG protocols.

AUDIT GUIDE ELEMENT OP04:

PUBLIC COMMENT:
Clearly describe the expectation. Is it to have the written notice in the enrollees' hands by the 72nd hour or, if notice is first provided orally, in the enrollees' hands by the end of the 3rd calendar day of issuing the oral notice? Also, if this is the expectation, please describe how this is measured and what evidence is reviewed to test compliance.

CMS RESPONSE:
If notice is provided orally within 72 hours, CMS requires sponsor to follow up in writing within 72 hours of the oral notification.

Per MMCM Chapter 13 section 50.4- Action Following Acceptance of Requests for Expedited Determinations**, "**Although the Medicare health plan may notify the enrollee orally or in writing, the enrollee must be notified within the 72 hour time frame. Mailing the determination within 72 hours in and of itself is insufficient. The enrollee must receive the notice in the mail within 72 hours. When the determination is adverse, the Medicare health plan must mail written confirmation of its determination within 3 calendar days after providing oral notification, if applicable."

CMS will review systems used by sponsor organizations to determine compliance with this requirement. In addition, CMS will review all notices, letters, and communications sent from the sponsor organization to the enrollee (and provider/physician, if applicable) to determine when notification was made. This will include reviewing the sponsoring organization's policies for mail operations as it relates to the incoming and outgoing mail for the beneficiaries.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 ODAG protocols.

AUDIT GUIDE ELEMENT OP05

PUBLIC COMMENT:
Adverse Expedited Organization Determinations (Notice Content)
If the Sponsoring Organization makes an adverse expedited organization determination, the written CMS-10003-NDMC (Notice of Denial of Medical Coverage), or an RO-approved modification of the NDMC, must be sent to the member and must clearly state the service denied and the specific denial reason. The notice must also inform the enrollee of his or her right to a standard or expedited reconsideration, including the rights to, and conditions for, obtaining an expedited reconsideration, as well as describe the appeal process.
42 C.F.R. § 422.572(e)

We ask CMS to clarify if the description in this element is specific to pre-service, since payment determinations are not subject to be expedited. We recommend that CMS change the heading to specify pre-service

CMS RESPONSE:
This audit element is specific to expedited pre-service organization determinations. Chapter 13 of the MMCM section 50 states "Expedited organization determinations may not be requested for cases in which the only issue involves a claim for payment for services that the enrollee has already received." However, CMS will consider revising this audit element to clarify that it is specific to pre-service organization determinations.

AUDIT GUIDE ELEMENT- OP09

PUBLIC COMMENT:
Favorable Standard Pre-Service Organization Determinations (Timeliness)
If the Sponsoring Organization makes a favorable standard pre-service organization determination, it must notify the member of its determination as expeditiously as the member's health condition requires, but no later than 14 calendar days after receiving the request (or an additional 14 days if an extension is justified).
42 C.F.R. § 422.568(a)

We recommend that CMS specify/clarify what is meant by the "optional" disclaimer.

CMS RESPONSE:
The "optional" disclaimer "(or an additional 14 days if an extension is justified)" as it relates to standard pre-service organizations refers to guidance provided in Chapter 13 of the MMCM section 40.1. This section states "The Medicare health plan may extend the time frame up to 14 calendar days. This extension is allowed to occur if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from *non-contract* providers may change a Medicare health plan's decision to deny). When the Medicare health plan grants itself an extension to the deadline, it must notify the enrollee, in writing, of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the Medicare health plan's decision to grant an extension. The Medicare health plan must notify the enrollee, in writing, of its determination as expeditiously as the enrollee's health condition requires, but no later than the

expiration of any extension that occurs, in accordance with this chapter." However, CMS will consider revising this audit element to clarify what it is meant in the "optional" disclaimer.

AUDIT GUIDE ELEMENT -OP10
PUBLIC COMMENT:
Detailed Explanation of Non-Coverage (Timeliness)
The Sponsoring Organization, upon notification by the QIO that an enrollee has filed a request for a fast-track appeal, must send the written CMS-10095-B (Detailed Explanation of Non-Coverage) to the enrollee by the close of business on the day the QIO notification is received 42 C.F.R. § 422.626(e)

According to the MMCM Ch. 13, Sec. 90.6 and 90.7, the Medicare health plan (or the provider by delegation) must issue the DENC to the enrollee (with a copy provided to the QIO) whenever an enrollee appeals a termination decision about their SNF, HHA or CORF services.

We recommend that CMS include language that the delivery of the DENC can be delegated to the provider.

CMS RESPONSE:
CMS agrees with this recommendation and will consider revising the language in the future audit protocols.

AUDIT GUIDE ELEMENT - OP12

PUBLIC COMMENT:
Effectuation of QIO Decision Reversals
If a QIO reverses a Sponsoring Organization's determination decision to terminate SNF, HHA, or CORF services, the Sponsoring Organization must provide the enrollee with a new notice consistent with §422.624(b). 42 C.F.R. § 422.626(e)(5)

According to the MMCM Ch. 13, Sec. 90.6, the Medicare health plan (or the provider by delegation) must issue the DENC to the enrollee (with a copy provided to the QIO) whenever an enrollee appeals a termination decision about their SNF, HHA or CORF services.

We recommend that CMS include language that indicates that the delivery of the DENC can be delegated to the provider.

CMS RESPONSE:
CMS agrees with this recommendation and will consider revising the language in the future audit protocols.

AUDIT GUIDE ELEMENT - RC03

PUBLIC COMMENT:
Effectuation of Third-Party Claims Reconsideration Reversals
If the Sponsoring Organization's determination is reversed in whole or in part by the independent

review entity, the Sponsoring Organization must pay for the service no later than 30 calendar days from the date it receives the notice reversing the organization determination. The Sponsoring Organization must also inform the independent review entity that the organization has effectuated the decision. If the Sponsoring Organization's determination is reversed in whole or in part by an ALJ, or at a higher level of appeal, the Sponsoring Organization must authorize or provide the service under dispute as expeditiously as the member's health requires, but no later than 60 days from the date it received notice of the reversal.
42 C.F.R. § 422.618(b)(2) and (c): Medicare Managed Care Manual Ch. 13 – Section 140.2.3

Effectuation of Third-Party Standard Pre-Service Reconsideration Reversals
If the Sponsoring Organization's determination is reversed in whole or in part by the independent review entity, the Sponsoring Organization must authorize the service within 72 hours from the date it receives the notice reversing the determination, or provide the service as quickly as the member's health requires (but no later than 14 calendar days from that date). The Sponsoring Organization must also inform the independent review entity that the organization has effectuated the decision. If the Sponsoring Organization's determination is reversed in whole or in part by an ALJ, or at a higher level of appeal, the Sponsoring Organization must authorize or provide the service under dispute as expeditiously as the member's health requires, but no later than 60 days from the date it received notice of the reversal.
42 C.F.R. § 422.618(b)(1) and (c) : Medicare Managed Care Manual Ch. 13 – Section 140.2.1

For ALJ cases, the element does not reference the Medicare health plan's ability to appeal to the MAC if dissatisfied with the ALJ hearing decision.

We recommend that CMS add language describing the plan's ability to request MAC review, in accordance with MMCM Ch. 13, Sec. 110. Pending adjustment daily IRE report in place to track timeliness - letters in place.

CMS RESPONSE:
CMS agrees with this recommendation and will consider revising the language in the future audit protocols

AUDIT GUIDE ELEMENT - RC05

PUBLIC COMMENT:
Requests for Expedited Reconsiderations (Timeliness)
The Sponsoring Organization must promptly decide whether to expedite a reconsideration based on regulatory requirements. If the Sponsoring Organization decides not to expedite a reconsideration, it must automatically transfer the request to the standard timeframe, provide prompt oral notice to the member of the decision not to expedite, and provide written notice within 3 calendar days of the oral notice.

If the Sponsoring Organization decides to expedite the reconsideration, it must make a determination and notify the member as expeditiously as the member's health requires, but no later than 72 hours from the time it receives the request for reconsideration (or an additional 14 calendar days if an extension is justified).

If the Sponsoring Organization makes an expedited reconsideration determination that is fully favorable to the member, it must authorize or provide the service as expeditiously as the member's health requires, but no later than 72 hours from the time it receives the request for reconsideration (or an additional 14 calendar days if an extension is justified). If the Sponsoring Organization first notifies the member of its fully favorable expedited determination orally, it must mail written confirmation to the member within 3 calendar days of the oral notification. If the Sponsoring Organization affirms, in whole or in part, its adverse expedited organization determination, it must forward the case to CMS' independent review entity as expeditiously as the member's health requires, but not later than 24 hours after the decision. If the Sponsoring Organization fails to provide the member with the results of its reconsideration within the timeframes specified above (as expeditiously as the member's health condition requires or within 72 hours), this failure constitutes an adverse reconsideration determination, and the Sponsoring Organization must submit the file to CMS' independent review entity within 24 hours. The Sponsoring Organization must concurrently notify the member in writing that it has forwarded the case file to CMS' independent review entity.

We recommend that CMS separate the de-expedite and expedite processes into two (2) separate audit elements as these are separate requirements.

CMS RESPONSE:
To ensure sponsor organizations understand the requirements for processing expedited request for reconsiderations, CMS will review the current audit element and will consider separating the requirements for acceptance of an expedited request versus the non-acceptance of an expedited request.

CHAPTER 14 – COB/TrOOP:

AUDIT GUIDE ELEMENT – CB01

PUBLIC COMMENT:
Collecting and Updating Enrollees' Other Health Insurance Information
The Sponsoring Organization must have a system which the sponsor uses to collect and update information from enrollees about their other health insurance, including whether such insurance covers outpatient prescription drugs, and must report that information to the Coordination of Benefits (COB) Contractor.
Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits

We request that CMS change the description "must have a system" to "must have a process". Since In reality, there is no system needed as a smaller health plan could obtain the information from members and enter it directly into ECRS without storing it systematically on their end.

CMS RESPONSE:
CMS believes the terms "system" and "process" for this element are synonymous. The word "system" should not be interpreted as an automated requirement for this element.

AUDIT GUIDE ELEMENT – CB02

PUBLIC COMMENT:
Coordination of Benefits with Other Prescription Drug Coverage
The Sponsoring Organization must have a system which is used for exchanging payment information and coordinating benefits with other health insurance. The Sponsoring Organization must permit State Pharmacy Assistance Programs (SPAPs) and entities providing other prescription drug coverage to coordinate benefits with the Part D plan, including payment of premiums and coverage and payment for supplemental prescription drug benefits. The Sponsoring Organization must track the expenditures for covered Part D drugs made by other payers for purposes of determining where a Part D plan enrollee is in the benefit. 42 CFR § 423.464(a): § 423.464(f)(2-3) Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits CMS Instructions: Requirements for Submitting Prescription Drug Event Data

We request that CMS change the description "must have a system" to "must have a process". Since In reality, there is no system needed as a smaller health plan could obtain the information from members and enter it directly into ECRS without storing it systematically on their end.

CMS RESPONSE:
CMS believes the terms "system" and "process" for this element are synonymous. The word "system" should not be interpreted as an automated requirement for this element.

AUDIT GUIDE ELEMENT – CB03

PUBLIC COMMENT:
TrOOP Status at Disenrollment
The entity must provide the beneficiary's gross covered drug spend and true out-of-pocket (TrOOP) balance to the beneficiary as of the effective date of disenrollment, and if the disenrollment is due to a mid-year plan change, provides a report of these beneficiary data to the new plan of record. Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits.

We note that this description is outdated and suggest that CMS update the description to reflect what is currently published in the Prescription Drug Manual, Chapter 14, Section 50.9.1. This is a fully automated process using Financial Information Reporting (FIR).

CMS RESPONSE:
The 2013 audit protocols do not include reviews of COB/TROOP. Should the scope of the audit change in the future, CMS will be sure that the protocols clearly communicate requirements and processes.

CHAPTER 15 – COMPLIANCE PLAN

GENERAL COMMENTS:

PUBLIC COMMENT:
Refers to Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse. Should refer to Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines instead.

CMS RESPONSE:
CMS agrees. CMS updated the Universal Audit Guide to reflect the correct titles. The 2013 audit protocols also include references to the new manual chapters. Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Compliance Program Effectiveness protocols.

AUDIT GUIDE ELEMENTS CP01 – CP07

PUBLIC COMMENT:
The audit element descriptions refer to a compliance plan. The current version of the Compliance Program Guidelines (Chapter 21 - Rev. 110, 01-11-13 and Chapter 9 - Rev. 16, 01-11-13) does not use the term "compliance plan". Recommend changing the term to "compliance program" to be consistent with the current version of the Compliance Program Guidelines.

The audit titles and/or elements do not appear to cover the full width and breadth of the compliance elements as articulated in §50 of the Compliance Program Guidelines. Recommend revising the titles and/or the audit element description to more effectively evaluate compliance program elements 1 through 7.

CMS RESPONSE:
CMS agrees with the recommendation. The term "compliance plan" should be updated to "compliance program" to be consistent with the current version of Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. The audit titles and/or elements should be revised to be consistent with the current version of Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. CMS updated the Universal Audit Guide to reflect the change in terminology.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Compliance Program Effectiveness protocols.

AUDIT GUIDE ELEMENT CP01

PUBLIC COMMENT:
References the CMS Part D User's Manual. Clarify which manual this refers to.

CMS RESPONSE:
The Universal Audit Guide has been updated to cover both Medicare Parts C and D Compliance Program Requirements and Policy Guidance as expressed in the current version of Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Compliance Program Effectiveness protocols.

AUDIT GUIDE ELEMENT CP08

PUBLIC COMMENT:
The audit element description refers to a plan to detect, correct, and prevent fraud, waste, and abuse. The current version of the Compliance Program Guidelines (Chapter 21 - Rev. 110, 01-11-13 and Chapter 9 - Rev. 16, 01-11-13) does not include this as a separate requirement. Instead, fraud, waste, and abuse detection, correction, and prevention are integrated into the seven elements as articulated in §50. Also, there is no indication of a requirement to create a separate written plan beyond the compliance program policies, procedures and standards of conduct.

Clarify whether there is an expectation that plans will have a written compliance plan separate from their compliance program policies, procedures and standards of conduct.

CMS RESPONSE:
CMS concurs with the recommendation. A separate plan for fraud, waste, and abuse (FWA) is no longer required. The most recent Compliance Program Guidelines cover both compliance and FWA. Sponsors are required to have a comprehensive compliance program that detect, correct, and prevent Medicare program FWA. The Universal Audit Guide has been updated to be consistent with the regulatory requirements and best practices expressed in the current version of Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website or the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Compliance Program Effectiveness protocols.

UNIVERSAL AUDIT GUIDE ELEMENT CP09

PUBLIC COMMENT:
The requirements regarding executive management are incorporated within compliance program element 2 as per the current version of the Compliance Program Guidelines (Chapter 21 - Rev. 110, 01-11-13 and Chapter 9 - Rev. 16, 01-11-13).

Recommend incorporating the requirements regarding executive management into audit element CP02.

CMS RESPONSE:
The executive management element was expanded and updated in the 2010 compliance program regulations and should be replaced with Element II - Compliance Officer, Compliance Committee, and High Level Oversight as per the current version of the Compliance Program Guidelines (Chapter 21 - Rev. 110, 01-11-13 and Chapter 9 - Rev. 16, 01-11-13). The Universal Audit Guide is updated to reflect the change.

Please refer to the HPMS memo issued January 25, 2013, entitled, "2013 Program Audit Process and Protocols" located on the CMS website at http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html for 2013 Compliance Program Effectiveness protocols.