Crosswalk of Changes from 2012 to 2013 Medicare Part C and D Oversight and Enforcement Group Audit Protocols

Compliance Program Effectiveness (CPE)

Area (Document)	Change
Attachment III – Compliance Program Data and Documentation Requests	• Changed formatting • Added references to Element Numbers to each data request – corresponds in the order of the Compliance Program Guidelines for easy use by the Sponsor • Questions 31, changed reference from 14 above to 15 above.
Attachment III-A – Sample Case File Documentation Requested	• Added 2nd paragraph note to Sponsors: "With the exception of the documents requested for Element I (Written Policies, Procedures and Standards of Conduct), the documentation listed under each sample request is provided as examples of what your organization may provide as evidence of compliance for the respective element." • Cross-identified related compliance elements to the sample requested; streamlined the documentation request

Attachment III- B – Key Contacts for Compliance Program Operations	• Newly created for purposes of identifying key people involved with Compliance Program Operations and able to assist with explaining the sample documentation. This list can also be used to identify the appropriate personnel for interviews.
Attachment IV – Organizational Structure and Governance PPT Template	• Updated to reflect new reporting requirements and information needed for due diligence and reviewing documentation.
Interview Guides for CEO/Senior Management, Board Member, and Employee	• Revised to provide suggestions on how to start a conversation with the subject and inclusion of important questions to weave in. • Deleted Interview Questions for Compliance Officer. The SAQ will be used as a checklist for ensuring all related evidence is collected for each element and will serve as guide for the Compliance Officer interview.
Attachment V - Self-Assessment Questionnaire	• Cross Reference Tool used for Compliance Officer Interview • Expanded to accommodate changes in sub-regulatory guidance • Reorganized questions and provided descriptions that correlate with exact verbiage of “musts” and “should” of the Compliance Program Guidelines • Questions refer to development of the program, implementation of the requirements, and effectiveness measures • In 2012 = 133 questions • In 2013 = 80 questions • 7 elements + FDR oversight (applicable elements)
Communication Strategy	• Enhances communication between compliance program team lead and operational area team leads during the audit.

Effectiveness Measures - Tracer Methodology and Sample Results Grid	• Process to look at how the Sponsor's compliance program works as a system • New Tracer Methodology with 7 sections: (a) Regulatory Requirements and Policy Guidance, (b) What does an Effective Compliance Program Look Like, (c) How to Evaluate Compliance Program Effectiveness, (d) Selecting Samples (e) Evaluating the Evidence (d) Completing the Sample Grid, (f) Sample Case Examples
Methods of Evaluation (MOE)	• Revised to incorporate new sub-regulatory requirements and measures to confirm implementation and effectiveness • 7 elements + FDR oversight
*Sample Case Worksheets *Auditors Manual *Auditors Tool Kit	• Will need to be updated once the MOE and overall strategy is approved by DAO and MOEG FO. It should only take approx. 2 weeks to complete revisions.

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

Area (Document)	Change
Overall Changes	• Format was revised to incorporate multilevel list and bullets for ease in referencing • Footer: contains proposed naming convention and included date the

	protocol was last updated
	• Removed references to overall pass/fail threshold. Added language to explain that an individual sample case failure results in documentation of a condition:
	  • 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.
	• Removed reference to Part C Access to Care
	  • Audit TL and contractors stated not finding a lot of access to care issue when testing in this area
	  • In this element it was found that of the cases found they were mis-classified grievances
	  • These cases are removed from the sample's element, but reviewed in the grievance sample
	  • Essentially sponsor is penalized twice
	  • Review of CTMs rarely found access to care issues
	  • CTM are monitored on a daily basis by RO
	  • Reviewing during an audit, TL feel is double work

Purpose	• removed reference to Part C Access to Care

Review Period	• no longer based on size of plan
	  • Requiring all plans to submit 3 months of data
	  • Takes into account systematic issues that may arise in a specific month that may cause a plan to fail.
	  • Provides audit team with a better assessment of how the sponsor operate

Note	• added to stress the importance of submitting universes in accordance with the instructions and to submit universes on time.
I. Effectuation Timeliness - 1. Select Universe and submit to CMS	• Clarifying language about what should be included in the universe • inserted additional element for review- DAP provided feedback that IRE,ALJ, MAC overturns are included in this review • on 2/12/13-deleted first sentence "The plan expected to provide accurate and timely universe submissions," as this is stated in previous note
I. Effectuation Timeliness – Note	• 2/12/13- corrected note to state "favorable" rather than "unfavorable" determinations
I. Effectuation Timeliness – 4.1 Apply Compliance Standard	• Deleted appropriate as there is no clear guidance about what should be included in an approval letter. Guidance is only clearly provided

	for denial letters and the appropriateness of the notification letter is reviewed in ODAG CDM.
II. Appropriateness of Clinical Decision Making - 1. Select universe and submit to CMS	• Included clarifying language to ensure ALJ/MAC decisions are included in the sample • Inserted Reconsiderations overturned by the IRE, ALJ, or MAC. Per SME feedback, this parallels ET review above and CDAG review
Note	• Clarifying language
II. Appropriateness of Clinical Decision Making – 2. Select 30 cases	• Change sample selection to include IRE/ALJ/MAC cases
II. Appropriateness of Clinical Decision Making – 3 Obtain Evidence	• added language to clarify what is being reviewed for compliance • 1st bullet: Clarified original request is needed to assess how the sponsor processed reconsideration from initial request
II. Appropriateness of Clinical Decision Making – 4.1.6 – Initial Organization Determination	• added additional compliance standard "If the plan made as adverse decision or did not meet the decision making timeframe, did the plan auto-forward to the IRE properly and within required timeframe." Insert, reflects compliance standards for reconsiderations and further clarifies the purpose for testing this element
II. Appropriateness of Clinical Decision Making – 4.2.4 Reconsideration	• deleted and notification requirements as notification is reviewed in ET, not CDM
II. Appropriateness of Clinical Decision Making – 4.2.6 added	• made an adverse decision or" as this clarifies type of decision
III. Grievances, 1. Select Universe and submit to CMS	• added a note under select universe and submit to CMS

III. Grievances - 3. Obtain Evidence, 3.1	• Inserted additional clarification for what is needed in review of quality of care cases
III. Grievances – 4. Apply Compliance Standard, 4.1	• language added to clarify that this area is to determine if plan is properly categorizing and process grievances. If misclassified as a grievance did the plan route it to the proper unit untimely?
IV. Dismissals – 1. Select Universe and submit to CMS	• added language to clarify what is needed in the universe • inserted (non-contracted providers only) after WOL to clarify which provider type
IV. Dismissals - 2. Select 20 Cases	• Reduced sample size as sponsors' universes typically yields low amount of dismissals
IV. Dismissals - 4, Apply Compliance Standard	• removed last bullet under 4.1.2 as it is redundant removed last bullet under 4.2.2 as it is redundant • Formatted compliance standards to ensure sponsor is aware of what is required for each type of dismissal

Part D Coverage Determinations, Appeals and Grievances (CDAG)

Area (Document)	Change
Attachment II - Audit Process of Universe Request	• Removed references to overall pass/fail threshold. Added language to explain that an individual sample case failure results in documentation of a condition: • 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.
Purpose	• Updated review period to reflect "Three (3) month period preceding the date of the audit engagement letter (Month, Day, Year) CMS reserves the right to expand the review period to ensure a sufficient universe size." • Added the following note about the proper use of naming conventions • "**Note:** The sponsor is expected to present their supporting documentation during the audit and upload it to the secure site using the designated naming convention within the timeframe specified by the reviewers. If the sponsor fails to submit the supporting documentation using the designated naming convention and within the timeframe specified by the reviewers, CMS will document this as an observation in the sponsor's program audit report."
I. Effectuation Timeliness Coverage Determinations and Appeals (CDA)	• Added language to emphasis overturns by the IRE, ALJ and MAC during the review period must be included in the universe • Removed reference to review periods dependent of the size of the Plan Sponsor • Removed reference to finding threshold
II. Appropriateness of Clinical Decision-Making & Compliance with	• Removed reference to finding threshold

CDA Processing Requirements	
III. Grievances	• Removed reference to finding threshold
Attachment II-A Universe Template - Effectuation Timelines Tab	• A field was added in column 12 for the Plan Sponsor to indicate if the prescriber is in-network or out-of-network
Attachment II-A Universe Template - CDM & CDA Comp tab	• A field was added in column 12 for the Plan Sponsor to indicate if the prescriber is in-network or out-of-network

Formulary Benefit Administration (FA)

Area (Document)	Change
Attachment I – Audit Process and Universe Request	• Removed references to overall pass/fail threshold. Added language to explain that an individual sample case failure results in documentation of a condition: ▪ 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. • Reformatted document so that outline is consistent throughout. • Page 1 –

	i. Added statement "The rejected claims universes submitted should not be filtered by the sponsor and no attempts to reprocess claims prior to the audit should occur." In 2012 a few sponsors have done one or both of these. ii. Removed universe reference to # of weeks and left as 30 or 60 days. iii. Clarified rejected claims with "dates of service". Same clarification done in transition. • Modified FA sample to 30 cases (instead of 20) to be consistent with transition. • Website review – i. Moved website attestation ahead of P&T committee since many sponsors do not see this at the end of the document ii. At MDBG's request added review of sponsor posted formulary and PA criteria compared to CMS approved formulary. This review would be completed after the audit engagement letter is sent and prior to start of audit. • P&T Committee i. Propose making P&T element three sections: • membership universe – complete for all sponsors; • membership COI - complete for all sponsors; • minutes universe/UM controls would be completed if:

	• when issues identified during the formulary administration or transition portions of the audit warrant additional P&T audit steps; OR • when concerns are raised during the Compliance team review* of Element IV of the MA/Part D Compliance Program Requirements. Element IV is: Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the organization's employees, managers and governing body, and the organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified. 422.503(b)(4)(vi)(D) and 423.504(b)(4)(vi)(D) *new for 2013 – FA TL will be involved or present during Compliance Committee and/or Auditing/Monitoring of FDRs discussions.
Attachment 1A – Universe Template	• Added tab for Transition Rejected Claims Universe • From FA and Transition tabs deleted two columns related to NCPDP 5.1 transactions (Place of Service; Patient Locations (For 5.1 Claims Only)).

	• Added P&T Committee Membership Tab
Attachment 1B – Description of Documentation Required Sample Case File Minimum Documentation Required	• Added language under purpose to clarify that this is documentation that will be requested during the live sample review during audit. One of the contractors noted that some plans were taking original wording to mean that they should prepare samples ahead of time. • Updated contract years. • Clarified "route" to "route of administration"

Outbound Enrollment Verification (OEV)

Area (Document)	Change
	•
Attachment X - Audit Process and Universe Request	• Apply Compliance Standard To Each Case: Apply the following test to each of the 30 cases. OEV calls will be reviewed to determine the following: i. Verify through the review of supporting documentation that the first two call attempts were made within 10 days of the effective enrollment date. ii. Verify through the review of supporting documentation that all three call attempts were made within 15 days of the effective enrollment date. iii. In instances where the sponsor did not successfully

	reach the beneficiary on the first or second attempt, verify that the sponsor sent a fully compliant enrollment verification letter after the second attempt and completed a third call attempt within 15 days of the effective enrollment date. iv. Verify that the sponsor appropriately handled the beneficiary request (e.g. cancellation).