Addendum to the CY 2016 Program Audit Protocols:

This document should be used in conjunction with the CY 2016 audit protocols. The items below are meant to provide clarification on commonly asked questions or areas that have caused confusion among sponsors. Please let your Auditor- in- Charge (AIC) know if you have any additional questions.

All Protocols:

The following clarifications will impact all program audit protocols.

Attachments: ALL	Current Language	Clarification or Change	Instructions for Sponsors
Audit Purpose and General Guidelines: Sponsor Disclosed and Self-Identified Issues	Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from January 1, 2015 through the date of the audit start notice, which CMS may find in your data universes. **For 2016**: the period will be from January 1, 2016 through the date of the audit start notice.	The time period for previously disclosed and self-identified issues of non-compliance that should be provided to CMS should align with the starting date of the universe period for each program area of the audit. The list should not be limited to only those issues identified on or after January 1, 2016.	The instructions should read: Sponsors will be asked to provide a list of all previously disclosed and self-identified issues of non-compliance, from January 1, 2015 through the date of the audit start notice, which CMS may find in your data universes. **For 2016**: the period will be from the starting date of each universe period, through the date of the audit start notice.

Attachments: ALL	Current Language	Clarification or Change	Instructions for Sponsors
Universe Preparation and Submission: Responding to Universe Requests	**For 2016:** If multiple attempts are made and the sponsor fails to provide accurate and timely universe submissions after the first 2 attempts, CMS will document this as an observation in the sponsor's program audit report. After the 3rd failed attempt or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.	This field needs clarification. If the sponsor fails to provide accurate and timely submissions for both the first and second attempt (i.e., two failed attempts), an observation will be cited in the sponsor's program audit report.	The instructions should read: **For 2016:** If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third failed attempt, or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

Part C and Part D Compliance Program Effectiveness (CPE):

The following clarifications have been provided for the CPE protocol and record layouts.

Attachment I, I-A	Current Language	Clarification or Change	Instructions for Sponsors
CPE Self-Assessment Questionnaire (Attachment I-A): Monitoring and Auditing Line 44	… Note: The CMS program audit of a sponsor's compliance program audit does satisfy this audit requirement.	This sentence should include the word "not".	Sponsors should use the following corrected note: The CMS program audit of a sponsor's compliance program audit does NOT satisfy this audit requirement.

Attachment I, I-A	Current Language	Clarification or Change	Instructions for Sponsors
Page 14: Sponsor Accountability and Oversight of FDRs: Review Tracer Case Documentation	Evidence ensuring the sponsor's FDRs (including the FDR's employees) have satisfied the general compliance and FWA training requirement by completing the CMS training modules on the Medicare Learning Network (MLN) (i.e., MLN-generated certificate of completion, attestation, training logs, spreadsheets, etc.).	Per the recent HPMS memo released December 28, 2015, CMS will not request documentation related to this bullet during the 2016 CPE audits.	Sponsors will not be asked to provide any documentation relating to FDRs satisfying general compliance and FWA training.
Record Layout 5: Column ID E: Date FWA Activity Completed	Provide the date that the monitoring or investigation ended. Submit in CCYY/MM/DD format (e.g., 2015/01/01).	Sponsors are supposed to include both completed and ongoing monitoring efforts in this universe.	For any ongoing monitoring efforts for which no completion date is available, sponsors should enter TBD in this field.

Part D Formulary and Benefit Administration (FA):

The following clarifications have been provided for the FA protocol and record layouts.

Attachment II	Current Language	Clarification or Change	Instructions for Sponsors
Page 3: Review Period Section-PDE description	All final action prescription drug event data with dates of service in October, November and December 2015 accepted by CMS for those members in the Rejected Claims Transition Universe. For 2016: all final action PDEs with dates of service September-December 2016.	These dates for the requested data should be pushed back one year.	The instructions should read: All final action prescription drug event data with dates of service in October, November and December 2014 accepted by CMS for those members in the Rejected Claims Transition Universe. For 2016: all final action PDEs with dates of service September-December 2015.

Attachment II	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 3: Instructions for pulling universes	Include all final action PDEs accepted by CMS with dates of service in October – December of 2015. **For 2016:** September - December of 2016.	These dates for the requested data should be pushed back one year.	The instructions should read: Include all final action PDEs accepted by CMS with dates of service in October – December of 2014. **For 2016:** September - December of 2015.

Part D Coverage Determinations, Appeals and Grievances (CDAG):

The following clarifications have been provided for the CDAG protocol and record layouts.

Attachment III	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 1: (Column IDs P and Q) Record Layout 2: (Column IDs T and U) Record Layout 4: (Column IDs R and S) Record Layout 5: (Column IDs V and W) Record Layout 6: (Column IDs R and S) Record Layout 8: (Column IDs U and V)	Answer NA if the request was approved.	This field allows for NA only when a request is approved, but not when a request is auto-forwarded, dismissed, or withdrawn.	The instructions should read: Answer NA if the request was not denied for lack of medical necessity or the request was not denied (i.e., approved, auto-forwarded, dismissed, withdrawn).

Attachment III	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 1: (Column IDs T and U) Record Layout 2: (Column IDs X and Y) Record Layout 3: (Column ID P) Record Layout 4: (Column IDs V and W) Record Layout 5: (Column IDs Z and AA) Record Layout 6: (Column ID V) Record Layout 7: (Column ID P) Record Layout 8: (Column IDs Y and Z)	Answer NA for denials or IRE auto-forwards.	This field allows for NA only when the request was denied or was an IRE auto-forward but not for dismissals or withdrawals.	The instructions should read: Answer NA for requests that were not approved (i.e., denials, auto-forwards, dismissals, or withdrawals).

Attachment III	Current Language	Clarification or Change	Instructions for Sponsors
Record Layouts 4, 5, and 6: Column ID G: Patience Residence Code	Note: When the patient residence code is not directly populated on the incoming coverage determination (CD) the plan can obtain the information from the rejected claim prompting the CD, other paid claims occurring within 3 days of the CD, or any medical information the plan may have at the initiation of a coverage request. If the plan still cannot determine the patient residence code, then enter 00- not specified in the universe field.	Since these are redetermination universes, the residence code could be pulled from either the CD or the RD (or a rejected claim associated with that request).	Sponsors should use the following instruction when pulling residence codes for redeterminations: Residence code for the beneficiary. Valid values are: 00 – Not specified, other patient residence not identified below 01 – Home 03 – Nursing Facility 04 – Assisted Living Facility 06 – Group Home 09 – Intermediate Care Facility/Mentally Retarded 11 – Hospice Note: When the patient residence code is not directly populated on the incoming redetermination (RD) the plan can obtain the information from the rejected claim prompting the RD or the initial CD, other paid claims occurring within 3 days of the RD or CD, or any medical information the plan may have at the initiation of a coverage request. If the plan still cannot determine the patient residence code, then enter 00- not specified in the universe field.

Attachment III	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 6: Column ID U: Time of decision	Time of the plan decision (e.g., denied). Submit in HH:MM:SS military time format (e.g., 23:59:59).	The time is not needed to determine timeliness for standard redeterminations.	Sponsors should enter NA in this field.

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

The following clarifications have been provided for the ODAG protocol and record layouts.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Page 5: Pull Universes Section	The sponsor should provide all of its organization determinations (both payment and pre-service, both expedited and standard) and all sponsor reconsiderations (both payment and pre-service, both expedited and standard), regardless of whether the request was favorable, partially favorable, unfavorable, auto-forwarded or withdrawn in the appropriate record layout provided in Appendix A.	Remove "withdrawn" from the types of cases submitted.	Sponsors do not need to submit withdrawn cases in the ODAG universes. If a sponsor has already programmed their system to include withdrawn cases, they may include the cases and notify their AIC.
Page 12: Select Sample Cases	CMS will select a targeted sample of 40 cases total that appear clinically significant from the pre-service and payment requests and IRE reversal record layouts (Appendix A, Tables 1 through 9).	CDM samples may be pulled from record layouts 1-10.	The language should read: CMS will select a targeted sample of 40 cases total that appear clinically significant from the pre-service and payment requests and IRE reversal record layouts (Appendix A, Tables 1 through 10).

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layouts 1, 2, 5, 6, 7, and 13: Column ID G: Person who made the request field	Indicate whether the pre-service request was made by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR). Note, CP and NCP entries should be based on the provider performing the service.	Remove the following: "Note, CP and NCP entries should be based on the provider performing the service."	Sponsors should indicate whether the pre-service request was made by a contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR).
Record Layouts 1 and 5: (Column ID M) Record Layouts 2 and 6: (Column ID N) Request for expedited timeframe	If an expedited timeframe was requested, indicate who requested the expedited timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR). Note, CP and NCP entries should be based on the provider performing the service. Answer NA if no expedited timeframe was requested.	Remove the following: "Note, CP and NCP entries should be based on the provider performing the service."	Sponsors should indicate who requested the expedited timeframe: contract provider (CP), non-contract provider (NCP), beneficiary (B) or beneficiary's representative (BR).
Record Layout 1: (Column ID Q) Record Layout 2: (Column ID R) Record Layout 3: (Column ID M) Request Disposition	Status of the request. Valid values are: approved or denied.	This field does not allow for cases that are still open (no decision issued).	Sponsors should note any requests that are untimely and not yet resolved (still outstanding) as "pending". All pending cases should be treated as denials for the purposes of populating the rest of the record layout fields.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layouts 1 and 5: (Column ID R) Record Layouts 2 and 6: (Column ID S) Date of Sponsor Decision	Date of the sponsor decision. Submit in CCYY/MM/DD format (e.g., 2015/01/01).	There is no instruction on what to enter if a decision was not yet issued.	Sponsors should submit "pending" if the untimely case is still open.
Record Layouts 2 and 6: Column ID T: Time of sponsor decision	Time of the sponsor decision (e.g., approved, denied). Submit in HH:MM:SS military time format (e.g., 23:59:59).	There is no instruction on what to enter if a decision was not yet issued.	Sponsors should submit "pending" if the untimely case is still open.
Record Layout 2: (Column ID Y) Record Layout 5: (Column ID W) Record Layout 6: (Column ID Z) Date written notification provided to enrollee	Date written notification provided to enrollee. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01).	This field is missing an option for instances where written notification was not provided. Adding an option for NA to make it consistent with record layouts 1 and 3.	Sponsors should use the following instruction when populating this field: Date written notification provided to enrollee. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer NA if no written notification was provided.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 2: (Column ID Z) Record Layout 6: (Column ID AA) Time written notification provided to enrollee	Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59).	This field is missing an option for instances where written notification was not provided. Adding an option for NA to make it consistent with record layouts 1 and 3.	Sponsors should use the following instruction when populating this field: Time written notification provided to enrollee. Submit in HH:MM:SS military time format (e.g., 23:59:59). Answer NA if no written notification was provided.
Record Layout 3: Column ID S: Date written notification provided to the provider	Date written notification provided to the provider. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01).	This field is missing an option for instances where written notification was not provided. Adding an option for NA to make it consistent with record layouts 1 and 3 (enrollee notification).	Sponsors should use the following instruction when populating this field: Date written notification provided to provider. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01). Answer NA if no written notification was provided.
Record Layouts 3 and 4: (Column ID N) Record Layout 7: (Column ID M) Date the claim was paid or denied.	Date the claim was paid or denied. Submit in CCYY/MM/DD format (e.g. 2015/01/01).	There is no instruction on what to enter if a decision was not yet issued.	Sponsors should submit "pending" if the untimely case is still open.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layouts 3 and 7: Instructions for Pulling Universes	Submit cases based on the date the sponsor's decision was rendered, or should have been rendered (the date the request was initiated may fall outside of the review period).	In this record layout there is a "date the claim was paid or denied" field instead of a "date of sponsor decision" field.	Sponsors should pull payment organization determinations (claims) by the date the claim was paid or denied, or should have been paid or denied.
Record Layout 4: Instructions on Pulling universes	Include all requests processed as direct member reimbursements, including approvals, denials and partial approvals.	This record layout includes both organization determinations and appeals (reconsiderations).	Sponsors should make sure that their DMR universe includes all DMRs, whether processed as organization determinations or reconsiderations.
Record Layout 4: Instructions for Pulling Universes	Submit cases based on the date the sponsor's decision was rendered, or should have been rendered (the date the request was initiated may fall outside of the review period).	In this record layout there is a "date reimbursement issued or denied" field instead of a "date of sponsor decision" field.	Sponsors should pull Direct Member Reimbursements (DMR) based on the date the reimbursement was issued or denied, or should have been issued or denied.
Record Layout 4: (Column ID M) Record Layout 5: (Column ID Q) Record Layout 6: (Column ID R) Record Layout 7: (Column ID L) Request Disposition	Status of the request. Valid fields are: approved, denied, denied with IRE auto-forward, or IRE auto-forward due to untimely decision.	There is no instruction on what to enter if a decision was not yet issued.	Sponsors should submit "pending" if the untimely case is still open. All pending cases should be treated as denials for the purposes of populating the rest of the record layout fields.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 5: (Column ID T) Record Layout 6: (Column ID V) If denied for lack of medical necessity, was the review completed by a physician or other appropriate health care professional?	Answer NA if the request was approved.	This does not allow for NA to be used when the request was denied but not for lack of medical necessity.	The instructions should read: Answer NA if the request was not denied for lack of medical necessity or the request was not denied (i.e., approved, auto-forwarded, or dismissed).
Record Layout 8: Instructions for pulling universe	Submit cases based on the date the sponsor's decision was rendered, or should have been rendered (the date the request was initiated may fall outside of the review period).	This universe is for IRE cases, so sponsors should pull cases based on the date the sponsor received the IRE decision.	Sponsors should submit cases in this universe by the date they received the IRE decision.
Record Layout 8 and 10: Missing Row/Field	There is no row/field to differentiate between standard and expedited cases.	These record layouts capture both standard and expedited cases but do not distinguish the cases in the record layouts.	Sponsors have two (2) options for this field. **Option 1:** Sponsors should enter a time for all expedited cases and should put NA for any standard cases. If a sponsor is missing the time for an expedited case, they must list NR (no record). **Option 2:** Sponsors may add an additional column at the end of the record layout that distinguishes standard and expedited cases by listing either standard or expedited.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 9: Instructions for pulling universe	Include all requests processed as pre-service non-contract provider payment or member reimbursement cases overturned by the IRE (i.e., a favorable decision was rendered).	These instructions include a reference to pre-service requests, but the universe being collected is for IRE payment cases requiring effectuation.	Instructions should read: Include all requests processed as non-contract provider payment or member reimbursement cases overturned by the IRE (i.e., a favorable decision was rendered).
Record Layout 10: Column ID O: Date written notification provided to IRE	Date written notification of sponsor's effectuation sent to ALJ or MAC. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01).	This field makes reference to the ALJ and MAC instead of the IRE.	Sponsors should use the following instruction when populating this field: Date written notification of sponsor's effectuation sent to the IRE. The term "provided" means when the letter left the sponsor's establishment by US Mail, fax, or electronic communication. Do not enter the date a letter is generated or printed within the sponsor's organization. Submit in CCYY/MM/DD format (e.g., 2015/01/01).
Record Layout 13: Column ID H: Type of Request	Was the original request for a determination on payment or a pre-service request about coverage? Valid fields are: pre-service OD, Pre-service Recon., Non-contract provider claim, direct member reimbursement, non-contract provider payment reconsideration, or DMR reconsideration.	The words "original request" are causing confusion. Sponsors should identify what type of request was dismissed. Additionally, grievances were not identified as a type of request that could be dismissed.	Sponsor should identify what type of request was dismissed (what was the request at the time it was dismissed): pre-service OD, pre-service Recon, payment OD, etc. Sponsors should also include the option of "grievance" into the type of request as a possible option.

Attachment IV	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 13: Column ID O: Time the request was dismissed	Time the grievance/complaint was received from the beneficiary or their authorized representative.	The field description does not match the field name.	Sponsors should enter the time the request was dismissed.

Part C Special Needs Plan- Model of Care (SNP-MOC):

The following clarifications have been provided for the SNP-MOC protocol and record layouts.

Location in Protocol (Attachment V)	Current Language	Clarification or Change	Instructions for Sponsors
Record Layout 1: Column ID Q: Cumulative # of Parts C and D Claims Paid Column ID R: Cumulative # of Parts C and D Claims Denied	Enter the number of all [denied/paid] claims with dates of service during the audit review period (e.g., 2,000). Claims should be counted based on the service level. This field is not to be populated with a dollar amount.	We are removing the sentence that claims should be counted on the service level.	Sponsors should use the following instruction when populating this field: Enter the number of [denied/paid] claims with dates of service during the audit review period (e.g., 2,000). This field should not be populated with a dollar amount.