Independent Validation Audit Work Plan

Sponsoring Organization Information

Name of Sponsoring Organization

Enter Sponsoring organization name

Contract Numbers

Enter contract number(s)

Total Enrollment

Enter total current enrollment number for all corresponding contracts listed above

OMB Approval 0938-1395 (Expires MM/DD/CCYY)

Independent Validation Auditor Information

Independent Auditor

Enter independent validation auditor name

Summary of Previous Work for Sponsoring Organization

Enter a summary of previous work performed for the Sponsoring organization's Medicare line of business. Enter NA if not applicable.

Validation Audit Team

List of all auditors (i.e., at least two per program area) with sufficient subject matter expertise, including those with clinical expertise as necessary:

- *FA and/or CDAG clinical auditor (e.g., pharmacist) with expertise in the requirements for formulary administration, transition, and processing of coverage requests.*
- *CDAG and/or ODAG clinical auditor (e.g., physician) with expertise in requirements for processing of coverage requests.*
- *SNPCC clinical auditor (e.g., nurse) with expertise in the requirements for care coordination requirements, including model of care processes, health risk assessments, interdisciplinary care teams, care coordination, and care planning.*

☐ **Checked box indicates individual resumes are attached to work plan.**

Name	**Program Area(s)**	**Auditor Type**
Enter name. Example: John Doe, RPh	Enter program area(s). Auditors with appropriate expertise may be assigned to more than one program area. Example: FA and CDAG	Enter auditor type (e.g., Physician, Nurse, Pharmacist, or Non-clinician). Example: Pharmacist

Independent Validation Audit

Scope

List of all conditions of noncompliance (or remaining conditions for revalidation) found during the initial program audit. Additionally, identify all universe record layouts that will be collected during the validation audit, and the scope of universe requests.

Note: Universe scope and actual data requests may be modified from the original requests in the program audit protocol in order to allow for appropriate testing of correction.

Condition Number	**Universe Record Layout**	**Scope of Universe Request**	**Additional Documentation or Data Needed**
Enter condition number (as listed in final report).	Enter universe record layout. Example: Table 1: Rejected Claims Formulary Administration (RCFA)	Select scope of universe request (both start date and end date). In general, this "clean period" must start on or after the projected completion date provided in the accepted corrective action plan (CAP), and will generally be consistent with the initial audit of the specific program area. For SNPCC, the scope may vary based on the audit approach to testing the condition.	Identify any additional data or documentation needed in order to test correction (e.g., formulary files, negative formulary changes, approved Models of Care (MOC))

Methodology

Description of the approach to determine remediation for each condition.

Program Area: Enter program area. Example: Part D Formulary and Benefit Administration (FA)

Element: Enter program area element. Example: Formulary

Administration Condition: Enter condition number and condition (as stated in final report). Cause: Enter cause (as stated in final report).

Method of Evaluation:

Describe how the independent auditor will test the condition (identified above) to determine if full remediation has been achieved. The method of evaluation must address the original root cause and consider all impact analyses submitted during the program audit. Additionally the method of evaluation must address at least the following[1]:

- Universe integrity testing sampling that aligns with the respective program area protocol to ensure the accuracy and completeness of universe(s), as applicable. The threshold criteria used to assess each applicable universe for accuracy and completeness must also be included.
- Number of samples to be selected for review from specific universe record layout/s, which must be appropriate to test the noncompliance. For timeliness and IRE auto-forward conditions, evaluation must be conducted at the universe level (i.e. sample cases are not selected for evaluation but the entire universe is evaluated). For all other conditions, a minimum of 10 cases must be targeted for selection.
- Sampling criteria to target and identify applicable cases in the universe(s). Specify all parameters and preparatory steps taken prior to sample selection (e.g., call types, drug types, number of days' supply, formulary comparison to identify negative cross-year changes and use of prior year PDE data for continuing enrollee transition issues, all possible rejections associated with the issue not limited to those in the impact analyses).

  For FA, sampling criteria must include:
  - Types of rejections that will be targeted based on the root cause (focusing on those from the impact analysis but also targeting other that may be associated with the root cause)
  - Types of medications that will be targeted based on the root cause

[1] At a minimum, the method of evaluation must address subjects identified by CMS. The independent auditor may expand the method of evaluation to include additional subjects as warranted.

- Additional factors that may be applicable such as days' supply

Continuing enrollee transition issues:

- IVA must create a negative formulary changes file based on the CMS approved formularies obtained from Sponsor
- IVA to request historical PDE data to appropriately target for continuing enrollee transition issues (based on Sponsor's lookback timeframe)
- Transition issues should be tested in January and/or February.

- Alternative evaluation approach if 10-sample minimum is not achieved to assess remediation of a condition (e.g., expanded scope of universe request, use of test claims, CAP review, policies and procedures review). (Note: For FA, use of test claims must always be considered as an alternative approach.)
- Process for requesting and evaluating impact analyses if noncompliance is identified to understand the root cause and extent of the issue.

Timeline

Schedule of validation audit activities and other key milestones.

Activity	**Start Date**	**End Date**
Enter activity, including necessary details. Examples: Kick-off	Select activity start date.	Select activity end date. If milestone, use start date.
Work Plan – *allow two to three weeks for CMS review and approval of final work plan*	Select activity start date.	Select activity end date. If milestone, use start date.
Data Request	Select activity start date.	Select activity end date. If milestone, use start date.
Universe Submission	Select activity start date.	Select activity end date. If milestone, use start date.
Universe Integrity Testing	Select activity start date.	Select activity end date. If milestone, use start date.
Sample Selection	Select activity start date.	Select activity end date. If milestone, use start date.
Validation Audit/Fieldwork	Select activity start date.	Select activity end date. If milestone, use start date.
Report Submission	Select activity start date.	Select activity end date. If milestone, use start date.

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