

# ***Independent Validation Audits***

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# Agenda



- Authority for Requiring Independent Validation Audit (IVA)
- Audit Validation and Close Out Process Overview
- Stakeholders' Experience
- Listening Session
- CY 2019 Call Letter
- Summary of Effective Dates
- Questions

- 42 CFR §§422.503(d) (2) (iv) and 423.504(d) (2) (iv)
  - Authorizes CMS to require sponsoring organizations to hire an independent auditor to validate whether audit deficiencies have been corrected
- HPMS Memo: November 12, 2015
  - Outlines steps in validation process
  - Describes roles/responsibilities of involved parties



# *Audit Validation and Close Out Process Overview*



- Audit Validation and Close Out for CMS Program Audits
  - Audit Firm Selection
  - Development and Submission of IVA Work Plan
  - Conducting the IVA
  - Submitting the IVA Report
  - Audit Close Out



# *Stakeholders' Experience*



- Feedback on the validation process
  - Threshold for requiring independent auditor
  - Burden on sponsoring organizations
  - Selection of independent auditing firm
  - Scope and timing of IVA
  - IVA work plan
  - IVA report submission



# *Listening Session*



- 2017 CMS Program Audit Validation/Close-Out Process Listening Session
- Requested improvements in validation audit process



# *CY 2019 Draft Call Letter*



- CMS solicited comment on five validation related enhancements specific to:
  - Threshold for requiring an IVA
  - Conflict of interest limitations on IVA firms
  - IVA work plan template
  - Timeframe for IVA completion
  - Submitting IVA Reports to CMS



# *CY 2019 Call Letter (continued)*



- Commenters represented:
  - Sponsoring Organizations
  - Health Insurance Plans
  - Pharmacy Healthcare Providers
  - Consumer Advocacy Groups
  - Independent Auditing Firms
- The final changes can be viewed in the 2019 Final Call Letter dated April 2, 2018 available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>



# *Threshold for Requiring an IVA*

- Modified threshold to determine when a sponsoring organization must hire an independent auditing firm:
  - if >5 non-Compliance Program Effectiveness (CPE) conditions cited in final audit report, must hire independent auditing firm
  - CPE conditions are not excluded from validation
  - Where the sponsoring organization lands in relation to threshold determines whether CMS or an IVA will conduct validation



# *Conflict of Interest (COI) Limitations on Independent Auditing Firms*



- Clarified that Sponsoring organizations are not precluded from using same firm for annual external CPE audit and IVA as long as:
  - Firm has not previously provided consulting or assistance with correction of audit findings
- Further clarification regarding:
  - Terminology
  - Other CMS COI standards
  - Timing for completing a COI assessment of the prospective auditing firm

# *Conflict of Interest (COI) Limitations on Independent Auditing Firms (continued)*

- COI Examples:
  - COI:
    - Consultants who assist with audit-related operations, and/or the correction of audit conditions
  - No COI:
    - Consultants who have conducted “mock audits” or prior independent audits but have not provided consult or assistance with correction of audit findings
    - Consultants who have conducted data validation audits



# ***IVA Work Plan Template (1 of 3)***



- CMS has included IVA work plan template in Paperwork Reduction Act (PRA) Package
- Comment period closes June 1, 2018
- Essential elements of template
  - Summary of prior Medicare work with organization being audited
  - Audit team staffing and credentials
    - Two auditors per program area



# *IVA Work Plan Template (2 of 3)*



- Audit team staffing and credentials. Sufficient clinical expertise in evaluating program area
  - FA/CDAG: formulary administration, transition, processing coverage request requirements (e.g., pharmacist)
  - CDAG/ODAG/MMP-SARAG: processing coverage request requirements (e.g., physician)
  - MMP-SARAG: evaluating level of care and social supports necessary for provision of long term services and supports for dual-eligible population (e.g., social worker)
  - SNP-CCQIPE/MMP-CCQIPE: care coordination and quality improvement program effectiveness requirements, model of care processes, health risk assessments, interdisciplinary care teams, care coordination and care planning (e.g., nurse)



# *IVA Work Plan Template (3 of 3)*



- Essential elements of template
  - Timeframe of universe periods
  - Case sampling methodology
  - Attach audit report template



# *IVA Work Plan Approval Process*



- Sponsoring organization submits work plan
- CMS review
- Sponsoring organization, auditing firm, and CMS meet to discuss work plan
- Updates as needed
- CMS approval
- CMS anticipates shorter turnaround in approving work plans submitted on a standardized template





# *Timeframe for IVA Completion*



- Extended timeframe to complete IVA and submit report
  - Increased from 150 to 180 days
  - Extensions beyond 180 days to be considered on case-by-case basis
- Extension applies for organizations undergoing program audits in 2018 (and beyond)





# *Conducting the IVA*



- After approval of the IVA work plan, the estimated timing to conduct the audit and submit the report is 3 to 4 months
- Steps:
  - Sponsoring organization provides auditing firm with documentation
  - Auditing firm conducts audit
  - Auditing firm drafts report
  - Sponsoring organization submits report to CMS by day 180



# ***IVA Report Submission***



- Clarified that sponsoring organizations should submit the IVA report, unaltered, to CMS and copy the IVA upon submission
- Required in audit year 2019 but permitted in 2018



# *CMS Review of IVA Report*



- CMS reviews material
- If needed, sponsoring organization, auditing firm and CMS meet to discuss report
- Following clarifications, CMS makes determination whether to close the audit



# *Audit Close Out*



- CMS will formally close the audit once we determine that all conditions identified in the final CMS program audit report have been sufficiently corrected
  - Letter to CEO
  - Close audit in HPMS
- CMS will not close the audit if material deficiencies remain
  - Revalidation notice sent to CEO

# *Summary of Effective Dates*

- Effective for 2018 program audits and beyond
  - Conflict of Interest Clarification
  - Timeframe for IVA completion
- Effective for 2019 program audits and beyond
  - Threshold for requiring IVA
  - IVA Report Submission (optional in 2018)
  - IVA Work Plan Template (subject to PRA process)



# Questions?



- Please direct validation audit questions to:  
[IVA@cms.hhs.gov](mailto:IVA@cms.hhs.gov)