



# BNA's Medicare Report

Reproduced with permission from BNA's Medicare Report, BNA's Medicare Report, 07/15/2011. Copyright © 2011 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## 2011 Medicare Advantage and Part D Program Audits: Are You Ready to Answer If CMS Knocks?



BY ANNE W. HANCE

In the summer of 2010, the Centers for Medicare & Medicaid Services (CMS) audited 33 Part D Plan Sponsors, focusing on various “beneficiary access” issues as well as the “effectiveness” of their compliance programs. The audits were viewed by many as a “game changer” because they evaluated performance against unanticipated, heightened standards.

*Hance is a partner in the law firm of McDermott Will & Emery LLP and is based in the Washington office. She focuses her practice on advising health plans, health care providers, and manufacturers of pharmaceuticals and medical devices on federal and state regulatory matters. She may be contacted at [AHance@mwe.com](mailto:AHance@mwe.com).*

Its now the summer of 2011, and CMS is ready to roll out its next round of audits.

Medicare Advantage Organizations and Part D Plan Sponsors (Plan Sponsors) that receive a CMS audit letter will find themselves with a limited amount of time—likely just *five business days*—to pull, validate, and submit a significant amount of data and information that CMS will use to evaluate performance. Some advance planning and critical analysis of current operations may enable Plan Sponsors to better position themselves for responding to CMS's inquiry and any resulting findings.

Plan Sponsors who do not receive an audit report this year still can benefit from this preparation, which may enhance current operations (and potentially improve results under future audits).

### Learning From the Past: Key Lessons From the 2010 Audits

Similar to the 2010 audits, CMS anticipates conducting 2011 audits on a rolling basis beginning in mid-July. Plan Sponsors with a greater risk profile (size, growth, known performance deficiencies) are more likely audit subjects. CMS will not release publicly the list of Plan Sponsors subject to review, and it is not known whether entities subject to evaluation in 2010 will be included in this year's review.

In other words, every Plan Sponsor should be prepared to act in the event a CMS letter arrives.

A significant portion of CMS's audit will be data driven, making the accuracy and completeness of the data and information a Plan Sponsor furnishes to CMS auditors critical to the Plan Sponsor's success. Plan Sponsors should not expect an opportunity to remedy during the on-site visit any issues associated with any

inaccurate data pulls, incomplete documentation, or other defects in the data and information submitted in advance of the site visit. Thus, Plan Sponsors need to be prepared to make the pre-audit data submission count.

Another consideration for a Plan Sponsor is the ability to demonstrate that it is a proactive organization with engaged leadership that undertakes appropriate responses to performance deficiencies. Plan Sponsors that are able to demonstrate active monitoring of key performance areas, such as through “dashboards” and other metrics, and to furnish to auditors corrective action plans that address non-compliance issues might positively influence CMS’s potential reaction to audit findings, which, past experience demonstrates, could include intermediate sanctions.

## **Actions Steps for Plan Sponsors Before An Audit Occurs**

Implement a “SWAT Team”

- This work group should be comprised of key individuals who are trained and prepared to react to an audit (or any other CMS) letter and facilitate the organization’s quick, effective and comprehensive response
- Members should be subject matter experts with appropriate management capability to orchestrate the response for a specific area subject, including pulling together necessary personnel and other resources
- Legal and compliance departments should participate in order to coordinate with existing legal and compliance initiatives and to protect the company’s legal rights, such as attorney-client privilege with regard to specific issues, as appropriate
- Representatives from one or more first-tier, downstream, or related (FDR) entities that provide core functions to or on behalf of the Plan Sponsor, such as pharmacy benefit managers, may be appropriate participants

Educate the SWAT Team on the 2010 audits to create baseline knowledge

- Particular focus should be paid to the scope, form and format of information requests/submission requirements
- Review CMS summaries and other documents, including HPMS memoranda, issued after the 2010 audits regarding CMS’s policies and expectations and confirm implementation in the appropriate areas

Develop a process for data validation

- Area-specific and overall data validation processes should include every step as well as timing for validating completeness and accuracy of data submissions, understanding the time limitations CMS imposes
- SWAT Team members should analyze and coordinate data validation processes for their area(s) of responsibility
- The SWAT Team collectively should coordinate overall data validation process for the Plan Sponsor based on the requirements and timing of each sector

Undertake a performance self-assessment

- Priority areas for review, based on the 2010 audits:
  - Formulary administration, including transitions fills and member notices, unrestricted access to

protected classes, and utilization management techniques that are CMS-approved

- Coverage determinations, appeals, and grievances, including proper classification, timely processing, effectuation of decisions, and timely and complete beneficiary notices
- Compliance program effectiveness, including the following:
  - Up-to-date policies and procedures that reflect every date of review/amendment and all CMS regulations and related issuances
  - Documentation showing annual and new employee/officer/director compliance education and training was conducted within CMS-required timeframes
  - Methods for reporting potential issues of non-compliance (including anonymous reporting mechanisms)
  - Disciplinary action for employees and FDR entities relating to issues of non-compliance
- FDR entity relationships
  - Screening FDR entities against federal exclusion lists
  - Inclusion of mandatory contract clauses in written agreements
  - Dissemination of the Plan Sponsor’s code of conduct, conflict of interest and other relevant policies (and documentation of the same) to every FDR entity
  - Validation of FDR entities’ annual compliance education and training
- Priority areas for review, based on CMS imposition of intermediate sanctions:
  - Agent/broker licensure and appointment in accordance with applicable state law
  - Agent/broker education and training on Medicare Advantage and Part D Plans as well as the Plan Sponsor’s products
  - Accuracy of agent/broker compensation, based on commission schedules and regulatory requirements regarding advance payment and recoupment
  - Investigation, corrective action and follow up by the Plan Sponsor in response to agent/broker complaints on unsolicited contact (including telephone calls and door-to-door marketing), inaccurate or misleading information, and marketing beyond the (pre-determined) scope of appointment
- Performance metrics, such as “dashboards” and other data-driven systems and processes, that monitor Plan Sponsor performance in key areas. Examples may include:
  - Review of rejected prescription drug claims to validate accuracy of the denial, including potential for transition fill and application of improper prior authorization or step-therapy requirement
  - Review of coverage redeterminations automatically sent to the Independent Review Entity to assess systems for timely processing
  - Identification of trends or patterns in complaint tracking module relating to issues, policies, departments, or individuals
- Areas of past performance deficiencies and issues of non-compliance issues, with a focus on those ar-

eas subject to prior CMS action, such as a warning letter or other notice of non-compliance

- Performance history as measured against CMS's December 2010 HPMS Memorandum, "2012 Application Cycle Past Performance Review Methodology"
- Be wary of self-evaluation tools that do not identify performance issues.
  - These tools are *intended* to enhance performance by identifying potential deficiencies and providing an opportunity to implement corrective action in advance of more serious developments or CMS audit findings
  - Tools that fail to identify performance issues may lack the "effectiveness" that CMS expects of these initiatives

Implement corrective action for identified performance deficiencies

- Develop corrective action plans that include "root cause" identification, step(s) for halting and correcting improper activity, beneficiary outreach (if appropriate), verification of the corrective action, and on-going monitoring for the same or similar issues
- Corrective action should be documented in a form/format that can be reproduced and understood by third parties, such as CMS auditors
- SWAT Team members should be involved in corrective action for their area(s) of responsibility to ensure demonstration of Plan Sponsor's response in any data submissions to CMS

### And for Those Plan Sponsors Who Receive an Audit Letter . . .

Check—and Recheck—Data Prior to Submission to CMS

- SWAT Team members should oversee the initial data pull for areas subject to CMS's audit that fall within their area of responsibility to verify completeness and accuracy of the information
- Conduct a second data review and verification that involves an individual with expertise *outside* of the subject matter area to confirm completeness and ensure data is understandable by an unrelated third party
- Involve legal and compliance departments in data compilation to coordinate response with on-going reviews, investigations and initiatives
- Evaluate clarity and messaging of documentation addressing key relationships, reporting chains, and operational nuances to promote CMS's understanding of the Plan Sponsor's organization

Prepare senior leadership, members of the board of directors, and key personnel for CMS interviews during an on-site visit

- Review the individual's areas of Medicare Advantage/Part D responsibilities and education and training received in connection with the same
- Review issues of non-compliance and corrective action involving the individual and/or the individual's

areas of responsibility to refresh memories on details

Monitor and proactively respond to compliance issues that arise between the initial data submission and the end of the on-site audit

- CMS appears to expect Plan Sponsors to self-report to auditors any performance issues that arise after the initial data submission and/or during the audit
- Develop corrective action plans to be submitted along with any reports of new issues to better position the organization vis-à-vis the auditors and audit findings

### Responding to CMS's Findings

Although proactive measures to identify and correct potential performance deficiencies in advance of an audit are the ideal, CMS inevitably will identify areas of non-compliance requiring action. In connection with the 2010 audits, CMS required, for issues affecting beneficiary access to prescription drugs, implementation of corrective action *before* CMS released its audit report. Undertaking some of these actions in advance of, or in follow up to, CMS's audit potentially can enhance a Plan Sponsor's ability to provide CMS with plans for, and updates regarding, rapid implementation of remedial action.

Plan Sponsors also may be able to head off potential adverse findings relating to its compliance program that can arise out of auditors' confusion regarding the complexity of the Plan Sponsor's corporate structure, operations, and reporting relationships. Advance consideration of the materials describing the Plan Sponsor's organization and operations to be submitted to CMS may assist in reducing the potential for any misunderstanding. Specific followup with CMS post-audit may be necessary, however, to ensure that the auditors understand, and the audit findings reflect, the structure, governance, and operations of the Plan Sponsor.

Finally, note that CMS required Plan Sponsors subject to 2010 audits to submit certifications by which the Plan Sponsor's senior executive attested that the identified deficiencies (1) had been corrected, and (2) were not likely to occur again.

CMS's expectation regarding such certifications potentially creates legal and other implications for Plan Sponsors and their corporate officers that extend beyond the immediate resolution of performance deficiencies and other audit findings requiring remediation.

Moreover, depending on the nature and scope of the deficiency, a Plan Sponsor may need to consider whether it can or should attest to "complete" correction of the deficiency as described by CMS or likelihood of recurrence. Plan Sponsors therefore will need to develop a thoughtful approach and strategy for responding to CMS's findings that gives full consideration to the corrective action undertaken as well as these potential implications and nuances. Legal counsel and compliance personnel will be critical to the strategy for such responses.