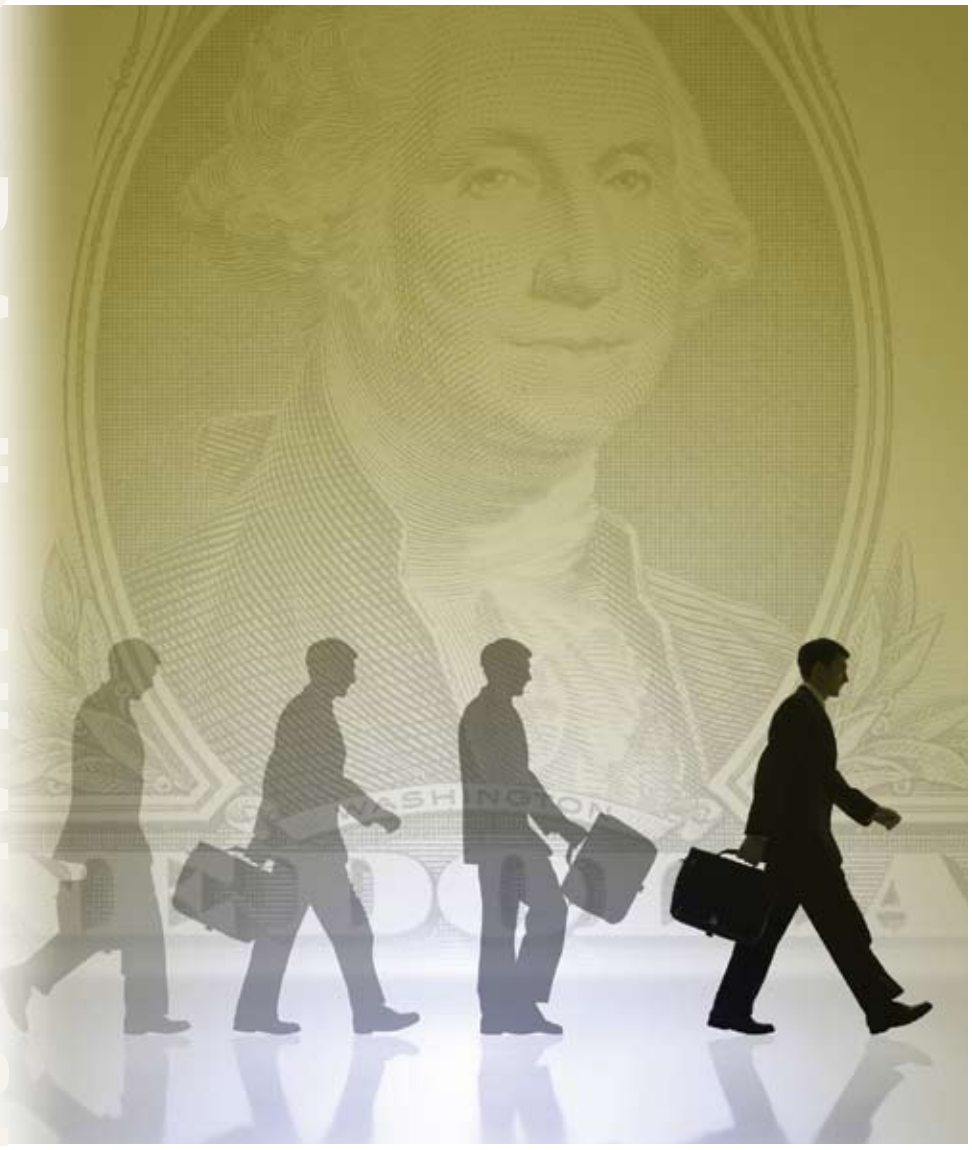
The Centers for Medicare and Medicaid Services regularly conducts compliance and financial audits of pharmacy claims in Medicare Part D plans. It's crucial for plan sponsors to be thoroughly prepared for those audits and to conduct ongoing reviews. This article tells plan sponsors what to expect and what the audits will emphasize, and recommends some important do's and don'ts.

What Are MMA Part D Audits All About?

The Take-Home Message Is—Compliance and Dollars Rule

by Craig S. Stern



Medicare advantage plans (MA-PDs) and prescription drug plans (PDPs) must be cognizant of their responsibilities under Medicare Part D. The Centers for Medicare and Medicaid Services (CMS) holds these plan sponsors accountable and validates their compliance with Part D through regular audits. In time, employers that chose the subsidy option or even the benefit wrap will be accountable for correct payments, compliance with access, formulary, coordination of benefits with Part D, etc. It is imperative that all plan sponsors become aware of the Part D audit process and what is included. Preparation and knowledge early will reduce the likelihood of future surprises.

Audits of Medicare Prescription Drug, Improvement, and Modernization Act (MMA) Part D plans require two primary elements—compliance audits and financial audits of pharmacy claims. Why should we care? Because CMS conducts regularly scheduled desk and on-site program audits to assess plan sponsors' compliance with Part D regulations. The bases for CMS audits are included in federal regulations. Refer to 42 Code of Federal Regulations (CFR) 422 and 423, the CMS Audit Guides and Chapter 9 of the *Prescription Drug Benefit Manual* for specifics.

Financial audits are performed on the prescription drug events (PDE) data and the pharmacy claims detail supporting

claim adjudication. While financial and compliance audits have different emphases, the need for preparation and ongoing review is crucial for both.

For fiscal year 2008, the Office of the Inspector General (OIG) work plans include an evaluation of CMS' oversight of marketing and sales of Medicare Advantage plans, including the adequacy of sanctions against noncompliant plans. The expectation is that CMS will be auditing plans even more stringently.

What Should We Expect Will Be Audited? Or, What Are the Audit Areas of Special Emphasis?

The following table provides specific areas included in the federal regulations. Any of these areas may be topics of audit now and in the future. Plan sponsors are well-advised to acquaint themselves with these regulations and to establish policies and procedures for each area.

Even for areas that the current Audit Guides do not cover extensively, it is important to establish policies now with the expectation that audits are dynamic and that new issues will be added to future audits. Where do you find the basic references for CMS Part D regulations? Refer to the following chapters in the federal regulations for background on each element of Part D.

What Should Be Emphasized in Financial Audits of PBMs

The emphasis of financial audits is directed primarily to patient payables and how they apply to out-of-pocket maximums, formulary compliance, coordination of benefits (COB) and patients for whom medication therapy management (MTM) is applicable.

Typical issues that should be addressed include, but are not limited to:

- Eligibility tests
- Benefit compliance
- Formulary compliance, generic substitution, in/out-network access, prior authorization and redetermination analysis
- Analysis of true out of pocket (TrOOP) by patients, including those approaching the "donut hole" and the catastrophic limit
- Analysis of all elements of claim payments, including average wholesale price (AWP) discounts, maximum allowable costs (MAC) for generics, usual and customary (U&C), state tax, etc.
- Comparison of prescription data elements (PDE) with raw claims to analyze claims adjudication rules and correct patient, plan and Medicare payments
- Efficiency of drug utilization review (DUR) edits
- Efficiency of medication therapy Management
- Coordination of benefits for Part B vs. D drugs
- Rebates.

What Are Compliance Audits?

Compliance audits are conducted to determine the pre-CMS audit readiness. They are governed by the CMS Audit Guides and Fraud-Waste-Abuse (FWA) guidelines in Chapter 9 of the *Pharmacy Benefits Manual.*

Common elements reviewed in compliance audits and preaudit readiness testing are listed below, but all elements listed in the Audit Guides are fair game. Data analysis and problem identification may require expanding the list to include additional areas requiring further readiness.

Particular emphasis should be placed on coverage determination, marketing materials, grievances, redeterminations of denials, formulary change notifications and the communication of Pharmacy & Therapeutics (P&T) Committee minutes.

Other common elements are:

- Audit maps/road maps including evidence of internal monitoring
- Analysis of universes identified for testing
- Corrective action plans (CAPs).

How Do We Prepare for Part D Audits, or What Is Included in Preaudit Preparation?

CMS Part D audit preparation is similar to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) audits in hospitals. In fact, the same principles apply to any audit, namely:

- A successful audit begins before you receive the confirmation letter.
- Communicate expectations, deliverables and timeframes with all functional departments and contractors managing delegated functions.
- Audit and monitor your PBM.
- Don't assume compliance of the plan or of its contractors! The plan is ultimately responsible.
- The audit is of the entire plan, so all departments must be included in audit preparation.

Keys to year-round audit readiness are:

- Develop good relationships with the applicable CMS regional offices.
- Create a road map for audit planning and organization of materials.
- Audit and monitor internally.
- Review materials regularly.

The Mapping Process Is Crucial

The compliance department is responsible for creating maps from the Audit Guides. All functional departments must be apprised of their responsibilities, which should include documentation of compliance, all reports, routine monitoring results, committee minutes, and policies and procedures. Next, the compliance department should regularly monitor (at least quarterly for noncompliant areas) the functional departments using the Audit Guides and the maps. An annual meeting of the compliance department with each functional department should include updates, reviews of documentation and miniaudits for readiness.

Policies and Procedures Are Crucial

Policies and procedures, compliance documents, and FWA plans are important documents to maintain and review annually. All functional areas should report to the compliance department when significant process changes occur. All documents should be reviewed and approved by the compliance department and all applicable committees at least annually. Particular emphasis should be on materials that go to members. The compliance department should approve these materials before distribution.

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Table

Areas of Federal Regulations That Are Topics of Audit

Part 432 Sections	Issue
30	Eligibility and enrollment
56	Prescription drug coverage—creditable status
104	Qualified prescription drug coverage
120	Access to covered Part D drugs
124	Out-of-network access to covered Part D drugs
132	Public disclosure of pharmaceutical prices
153	MTM
159	Electronic prescription program
162	Quality improvement
286	Premiums—rules regarding
315	General payment provisions
423	General requirements for Part D sponsors
440	State taxes
462	Medicare secondary payer
464	COB
578	Exceptions process

Functions Delegated to PBMs Do not Remove the Plan From Responsibility

An important part of the compliance audit is the compliance of all functions delegated to external entities. Of particular importance is PBM compliance. It should not be assumed that the PBM is handling delegated functions appropriately. All required elements, including PBM policies and procedures and sample cases, must be tested and audited internally at least quarterly. This function should be coordinated with the financial audits of PBM claim adjudication and PDE claims. Part D audits are new for everyone and, ultimately, the plan assumes responsibility for all delegated functions. The PBM should be contractually obligated to provide specific reports and information for functions specified in the Audit Guides. All of these reports should be reviewed and included in the audit documentation. In addition, results of the reports should be used for oversight of plan compliance.

Samples, Samples, Samples

Samples of claims need to be prepared and monitored on a regular and ongoing basis as well as in preparation for the audit. These sample universes should be run regularly to ensure that data is available and adequate, as well as to test the ability of the PBM to generate applicable samples. Particular emphasis should be on formulary changes and the members affected; coverage determinations for payment, including paper claims, and the members who submit receipts for reimbursement; and expedited coverage determinations and redeterminations. Any universe that cannot be supported by samples is a candidate for critical review. If there is a valid reason that samples cannot be generated for a universe, or if one does not legitimately exist, then it must be explained with valid supporting documentation.

Medication Therapy Management (MTM)

Medication therapy management is required, but may be delegated to pharmacists or other health care professionals. The plan must ensure that applicable patients are identified and referred for MTM. MTM delegated providers can identify applicable patients and monitor outcomes, or these services can be performed internally.

An important reference for internal monitoring of MTM providers can be obtained from the American Pharmaceutical Association (APhA). Refer to Medication Therapy Management in Pharmacy Practice, Core Elements of an MTM Service Model at the American Pharmacists Association Web page or www.pharmacist.com/AM/Template.cfm?Section=Pharmacist_Practitioners&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=17031.

Audit Recommendations—Do's and Don'ts

The following recommendations itemize things to consider doing and not doing in the audit process. They were taken from a presentation by the Gorman Group at the 2008 Academy of Managed Care Pharmacy meeting in San Francisco. These recommendations concur with the experience of Pro Pharma and various plans that reported their experiences to Pro Pharma as follows:

Audit Do's

- Always negotiate a date for the audit when all management staff will be present.
- Review how the audit will be conducted with your staff and their particular involvement in the audit process.
- Feel free to call the CMS regional office plan manager as many times as necessary to ask questions you may have about the audits.
- Send requested material to the regional office in a timely fashion. If you cannot send the material on time, ask for an extension well in advance of the due date.
- Pull the universes requested as soon as you can and call your regional office plan manager if you cannot pull a universe or a universe is very small.
- Make sure that the sample cases selected are not misclassified. If you find a misclassified case, call your regional office plan manager and ask to have the sample case substituted.
- Make sure that all the documentation requested is in the file in chronological order.
- Review the file to make sure that you are aware of any deficiencies that CMS will encounter.

- Ask for help when needed.

Audit Don'ts

- Request a change in the audit date because you are not ready
- Assume that a universe is correct if there are no cases found for that universe
- Create documentation that should be in the sample files, but is not
- Give files to CMS that have not been organized properly
- Get caught by surprise; know what deficiencies CMS will find
- Ignore any CMS request (Read the audit confirmation letter thoroughly.)
- Be afraid to let CMS know what deficiencies they will find. They appreciate you not letting them waste their time looking for what is not there.
- Make up any answers you are not sure of during the interviews. CMS will accept "I don't know" or "Let me check on that."
- Answer anything CMS has not asked during the interviews
- Argue.

Conclusion

The audit experience of health plans, hospitals and other entities, both public and private, that have undergone JCAHO, NCQA, URAC and Part D are similar. The fundamental lessons are the same: prepare a plan or road map for the audit; monitor and audit internally on a regular and ongoing basis; prepare early and exhaustively; maintain all appropriate documentation to make it easy for the auditors to find required information; take action on areas of noncompliance; and generate appropriate samples. Audits are not a one-time thing. They are an ongoing responsibility to ensure effective oversight and management. B&C

References

Audit requirements

a. 42 CFR 422 and 423

b. Prescription Drug Benefit Manual

c. Chapter 9 – Part D Program to Control Fraud, Waste and Abuse

<www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp>

Corrective Action Plans (CAPs)

a. CMS Home > Research, Statistics, Data and Systems > Medicare Advantage/Part D Contract and Enrollment Data > Corrective Action Plans

b. <www.cms.hhs.gov/MCRAdvPartDEnrolData/CAP/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=2&sortOrder=ascending&itemID=CMS1203697&intNumPerPage=10>

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