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

What Are MMA Part D Audits All About?
The Take-Home Message Is—Compliance and Dollars Rule

by Craig S. Stern
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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 whole-sale 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.

Continued on next page
Is Crucial

The Mapping Process

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.

Areas of Federal Regulations That Are Topics of Audit

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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.

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...
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.

References
Audit requirements
a. 42 CFR 422 and 423
c. Chapter 9 – Part D Program to Control Fraud, Waste and Abuse
<www.cms.hhs.gov/PrescriptionDrugCoverage/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

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