CMS Oversight

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ABSTRACT

BACKGROUND: Medicare Part D plans are subject to strict oversight by the Centers for Medicare & Medicaid Services (CMS) to ensure that they are meeting all the statutory and regulatory requirements of Medicare Part D programs. Oversight includes CMS auditing and reconciliation procedures.

OBJECTIVE: To provide a brief overview of the auditing and reconciliation procedures required from Medicare Part D plans by CMS.

SUMMARY: Because Medicare Part D plans are required to meet all of statutory, regulatory, and program requirements that govern the Medicare Advantage program, CMS oversees the operation of both Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDPs). This oversight requires effective record keeping and reporting procedures by plans so that they can provide CMS with the necessary accounting of cost, utilization, and availability/accessibility of their services. Plans that are unprepared for adequate accounting face stiff penalties, including civil monetary penalties. In the event of noncompliance, CMS may also issue a request for a corrective action plan that will address concerns within 2 to 6 months. CMS reconciliation involves the submission of data to CMS in order for a plan to receive the drug benefit payment to cover the costs of drugs provided to beneficiaries. Reconciliation occurs with CMS itself, or with another Part D contractor that may have paid for drugs for a beneficiary covered under the plan. Reconciliation is a critical component in how plans are reimbursed for the services they provide to beneficiaries.

CONCLUSIONS: Although compliance with the auditing and reconciliation procedures required by CMS represents a substantial burden for plan sponsors, it is necessary for continued participation in Part D. In addition, much of the data that are needed to meet CMS auditing and reconciliation requirements are also important to the plans themselves as they evaluate the management of their programs and assess the quality and profitability of their benefit offerings.

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Introduction

Medicare Part D plans are subject to strict oversight by the Centers for Medicare & Medicaid Services (CMS) to ensure that they are meeting all statutory and regulatory requirements. From the perspective of the plans themselves, CMS oversight can represent substantial administrative and financial burdens. However, successfully meeting the CMS requirements of auditing and reconciliation provides the platform for continued participation in Part D. As such, it is a necessary component of the administration of all Part D plans.

CMS Auditing

Medicare Part D plans are required to meet all statutory, regulatory, and program requirements that govern the Medicare Advantage program. As a result, CMS oversees the operations of Part D plans—both Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDPs)—to assess if plans are in compliance with all federal requirements. This is done through the monitoring of day-to-day activities, periodic performance audits, and ad-hoc compliance events. CMS uses a risk assessment approach to determine which organizations it audits; not all MA-PDs and PDPs are audited each year.

According to the Medicare Prescription Drug, Improvement and Modernization Act (MMA), each part D sponsor is required to maintain effective record keeping and reporting procedures to enable it to provide statistics indicating:[1]

1. the cost of its operations;
2. the patterns of utilization of its services;
3. the availability, accessibility, and acceptability of its services;
4. information that demonstrates it has a fiscally sound operation; and
5. other matters as required by CMS.

The data provided are used by CMS to monitor the prescription drug benefit being provided to Medicare beneficiaries. In addition, each Part D sponsor is required to provide the "necessary data to CMS to support payment, program integrity, program management, and quality improvement activities," as well as supplementary reporting requirements as indicated in additional guidance documents throughout the year.[1]

CMS Audit Process

Approximately 9 weeks before a scheduled audit, CMS will contact the part D sponsor to schedule an acceptable date for the audit and review audit logistics.[2] Within 3 weeks of that initial contact, CMS will provide a written notification that will identify the chapter(s) that will be covered in the audit and initiate a request for documentation. According to CMS, Part D audits are likely to be conducted as desk audits (outside the sponsor's site) and will take no more than 1 month to complete (from the entrance conference to the exit conference).[2] Audits held onsite generally last no more than 1 week, during which time, the spon-

sor is expected to make available key staff responsible for compliance in the selected areas.[2]

A critical component of the audit process is the ability of the plan's sponsor to provide the CMS audit team with sufficient documentation to demonstrate compliance with CMS requirements.[2] To be prepared for the potential CMS audit and to keep in compliance, plans usually have an internal auditor and compliance officer for Part D.

Plans that are not prepared face stiff penalties, including civil monetary penalties of as much as $25,000 per error.[3] CMS may also issue a request for a corrective action plan, then return in 2 to 6 months to determine if the errors have been corrected.[3]

When CMS determines that a plan is not complying with Medicare program requirements, it issues a corrective action requirement (CAR) letter from CMS. Corrective action requirement letters are posted on the CMS Web site and updated monthly. If the errors identified in the corrective action plan are not addressed within 2 to 6 months, it is likely that CMS will suspend the plan's enrollment.[3]

Common problems reported during audits include a lack of testing, out-of-date policies and procedures that do not reflect current guidelines, and incomplete training.[3] Plans can best be prepared for CMS audits by developing effective internal and external monitoring procedures well before the audit is requested.[3] Components that are critical to monitor include enrollment, coverage determinations, exceptions to coverage determinations, direct and indirect remuneration, prescription drug event (PDE) transaction data, CMS's complaint tracking module, grievances, and pharmacy benefit manager (PBM) data.

Plans that are working with a PBM are strongly encouraged to perform periodic formal audits of their PBMs, as well as updating their contracts with PBMs. Contracts ought to address updated requirements for rebate disclosure, claim reporting statistics, low-income cost-sharing adjustments, and mail-order administrative pricing.[3]

CMS Reconciliation Processes

Reconciliation is the process by which a plan submits data to CMS in order to receive drug benefit payments to cover the costs of drugs provided to beneficiaries. Reconciliation occurs with CMS itself or with another Part D contractor that may have paid for drugs for a beneficiary covered under the plan.

Reconciliation: Prescription Drug Events

PDE is the name given to the fulfillment of a prescription that is covered under Part D. Each time a beneficiary fills such a prescription, the Part D plan must submit a summary record of that event (called the PDE record) to CMS. The PDE record contains the data that make it possible for CMS to provide payment to the plan and administer the Part D benefit. The PDE record includes covered drug costs above and below the out-of-pocket threshold and records payments by Part D plan sponsors, other payers, and beneficiaries. These data, submitted by the plan, fit together to allow the calculation of payment under the following 4 legislated payment mechanisms: direct subsidies; premium and cost-sharing subsidies for qualifying low-income individuals (low-income subsidies); federal reinsurance subsidies; and risk sharing.[4]

In 2007, initial PDE reconciliation turned out to be a huge administrative burden to plans, many of which were not prepared nearly well enough to meet the deadline. Many plans did not have a database to track PDEs and to provide the information needed to reconcile with CMS. As a result, the reconciliation process led to plans having to pay CMS huge sums of money—a total of more than $4 billion among all of the parent organizations that sponsor plans.[5] Of all the parent organizations, 80% owed money to CMS. Twenty-nine percent of the parent organizations were required to pay less than $1 million, while 22% had to pay in excess of $10 million back to CMS.[5]

Some of the key challenges that were identified in this process included a variety of operational issues. Perhaps most important was the issue of plans not having valid membership data. In addition, many plans experienced a high level of PDE rejections.

Part D plans are now recognizing how important it is to understand how enrollment reconciliation is connected with PDE data. A key element of PDE reconciliation is having access to valid membership data so that PDE data can be tied to enrollment data. A critical first step in this process is to build a platform for reconciliation: a system that can track weekly, monthly, and special transaction reports, along with monthly membership reports.[3]

In addition, sponsors must identify membership discrepancies and rejected PDEs. This can be done by categorizing members according to their active status both according to the records of CMS and in the plan's records.[3] Discrepancies also need to be categorized and prioritized by whether members were active in 1 or more plan benefit packages (PBP) in a given year, as well as those members with and without breaks in coverage over the calendar year.[3]

Once the discrepancies are categorized, sponsors should develop clear procedures for reconciling the discrepancies, including start-to-finish research that identifies which entity (the plan or CMS) can fix the discrepancy, the steps necessary to fix it, and confirmation that it has been corrected.[3] At that point, it is time to do the actual reconciling, which can consist of processing transactions to CMS, updating plan systems, and providing necessary correspondence.

Plan-to-Plan Reconciliation

The Plan-to-Plan (P2P) financial reconciliation process provides a means by which the contracted plan of record pays any other Part D contract that reimbursed Part D drugs in good faith when Part D plan enrollment data were not current. P2P reconciliation has 2 primary objectives: it corrects payment discrepancies that occurred during program start-up, and it enables Part D payment reconciliation.

P2P reconciliation has taken place in 2 phases. The first phase emphasized the reconciliation of PDE data for any dates of service between January 1, 2006, and April 30, 2006, which was the initial start-up period for Part D plans. Phase II extended the reconciliation process between Part D plans to those claims that occurred after April 30, 2006. In this period, although plans should have been notified of beneficiary disenrollments before the effective date of enrollment in another plan, there were lag times associated with the enrollment process, which in combination with lags in CMS information system updates, resulted in instances where a plan continued to pay for covered prescription drugs after the effective date of disenrollment. As a result, the plan may have paid drug costs for a beneficiary who was no longer covered under that plan, precluding the possibility of receiving compensation directly from CMS for those costs.

Conclusions

Medicare Part D plans are subject to strict oversight by CMS to ensure that they are meeting all statutory and regulatory requirements. Although this oversight can be a substantial administrative and financial burdens for health plans, the CMS auditing and reconciliation procedure is a necessary component for the plan's continued participation in Part D.

In order to comply with CMS oversight, each part D sponsor is required to maintain "effective" record keeping and reporting procedures to demonstrate the cost of its operations; show utilization patterns for its services; disclose the availability, accessibility, and acceptability of its services; and provide information that demonstrates it has a fiscally sound operation. In addition, each Part D sponsor is required to provide data to support payment, program integrity, program management, and quality improvement activities. Without this information, plan enrollment is subject to suspension. Consequently, plans need to have effective internal and external monitoring procedures in place well before an audit is requested.

Oversight of Medicare Part D providers, although perhaps viewed as burdensome by health plans, is critical to ensure plans meet the standards set by CMS. From a plan's perspective, however, the data required to meet CMS's auditing and reconciliation requirements can be beneficial in evaluating the management of programs and for assessing the quality and profitability of their benefit offerings.

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