DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

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To: All Medicare Advantage Organizations and Prescription Drug Plan Sponsors

From: Gerard Mulcahy, Acting Director
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Subject: 2011 Program Audit Findings and Best Practices

In 2011, the Centers for Medicare & Medicaid Services (CMS) conducted eleven program audits to ensure sponsors were in compliance with the Medicare Advantage and Prescription Drug Plan requirements relating to the following areas: Part D Formulary Administration, Part D Coverage Determinations and Appeals, Part D Grievances, Part C and D Agent & Broker Oversight, and Part C and D Compliance Program Effectiveness. CMS identified a number of sponsors who were not in compliance with CMS' requirements. The purpose of this memorandum is to communicate systemic audit findings and provide best practices to assist all sponsors in improving their operations and ensuring compliance with CMS requirements.

Part D Formulary Administration

Sponsors must ensure that beneficiaries receive the Part D drugs they are entitled to consistent with CMS guidance. Several sponsors lacked an understanding of the formulary and transition requirements. While most sponsors delegated the implementation of key formulary functions to their Pharmacy Benefit Managers (PBM), they did not ensure the functions were in compliance with CMS requirements. The findings observed include the following:

1. New and continuing enrollees were denied transition fills for non-formulary drugs, protected class drugs, and drugs subject to utilization management restrictions during their transition period. This was due to applying incorrect transition logic in the claims adjudication system, and often included the lack of adequate testing of the logic and appropriate oversight of the PBM. The following examples are transition errors observed during the audits:
    a. Application of dose-optimization edits for transition fills for new enrollees;
    b. Application of step therapy and prior authorization edits during the transition period;
    c. Failure to recognize new enrollees as being eligible for transition fills due to a prior enrollment in a non-Part D plan under the organization;
    d. Failure to recognize new enrollees as being eligible for transition fills due to a break in coverage within the plan; and
    e. Failure to identify continuing beneficiaries eligible for transition fills based upon established regimens.

2. Sponsors had systemic errors in their claims adjudication systems. Specifically, sponsors did not have appropriate point-of-sale claims adjudication for protected class

medications. Also, the adjudication system did not properly effectuate the ending of the transition fill window and was abruptly terminated. The following error was observed during the audits:

a. Sponsors did not provide continuing coverage for protected class medications when a prior authorization or step therapy was added to a medication from one plan year to another.

3. Sponsors had unapproved or inappropriate point-of-sale edits in place, including:
   a. Gender and age edits that were neither supported in the FDA-approved labeling nor contained within the CMS-approved formulary;
   b. Dose optimization and day supply limitations that were not safety-related edits based upon FDA-approved labeling; and
   c. Inappropriate maximum cost edits that were not based upon usual and customary pricing for standard dosing regimens and restricted beneficiary access to prescribed medications.

4. Sponsors had various formulary setup errors in their adjudication system, including:
   a. Rejection of formulary products as non-formulary;
   b. Improper formulary product tier placement; and
   c. Incorrect classification of brand and generic products, resulting in claim rejections or incorrect copayment amounts.

These types of findings have the potential to cause beneficiary harm due to delayed or denied access to Part D drugs.

Best Practices

1. Sponsors should perform regular and adequate oversight of their PBMs and other delegated entities to ensure that they are complying with all CMS requirements.

2. CMS encourages sponsors to routinely review rejected claims to identify discrepancies between the benefit that has been approved by CMS and what is being adjudicated at the point-of-sale. The comparison should be performed using the applicable versions of CMS-approved Health Plan Management System (HPMS) data. Sponsors should be able to detect formulary drugs that are rejecting as non-covered due to the use of unapproved prior authorization or step therapy requirements and inappropriate rejections for quantities that are within the submitted quantity limit restrictions. Sponsors should also focus on rejections for protected class drugs in order to quickly detect any adjudication discrepancies that may inhibit drug access at the point-of-sale. In addition, sponsors should consider other relevant data sources such as the FDA's NDC Directory to ensure that adjudication systems are current and consistent with CMS guidance.

3. Sponsors must ensure compliance with Part D transition requirements. For new members, sponsors should analyze both rejected and paid claims to ensure that appropriate transition supplies are being provided. For continuing members, sponsors should ensure that claims are not being inappropriately rejected for those members affected by a cross-calendar year formulary change.

Part D Coverage Determinations, Appeals, and Grievances

Several sponsors lacked adequate systems and processes for identifying and tracking the receipt of coverage determinations and notifying enrollees of the plans' decision. The findings observed include the following:

1. Coverage determinations were misclassified and processed as grievances which led to providing the beneficiary with incorrect information regarding appeal rights and delays in access to care.

2. Sponsors did not adequately log, track, and document cases; which led to untimely processing and effectuation of coverage determination and redetermination requests. Sponsors failed to forward the untimely cases to the IRE. For example, some sponsors did not date/time stamp requests in a tracking system.

3. Sponsors did not resolve coverage determinations, redeterminations, or grievances appropriately. For example, there were cases of inappropriate, untimely, or premature denials of coverage determinations. Sponsors did not make reasonable efforts to obtain additional documentation from prescribers or enrollees before denying coverage determinations or redeterminations. In addition, the reasons for denials within the notification letters were broad, and did not provide enough information for the beneficiary to understand what they needed to do to appeal the decision.

These types of findings have the potential to cause beneficiary harm due to delayed or denied access to Part D drugs.

Best Practices

1. Sponsors should ensure that customer service representatives are properly trained and able to distinguish between a grievance and a coverage determination or redetermination request, and correctly and promptly triage requests to the appropriate department(s) for processing.

2. Sponsors should undertake routine internal auditing and monitoring of the coverage determination, redeterminations, and grievance units to ensure compliance with CMS regulations and requirements. Also, sponsors should monitor the process for auto-forwarding requests to the IRE when the applicable timeframes for a decision have not been met.

3. Sponsors should improve the content of the denial letters, which should include the specific reason for the denial and clear explanation of additional information needed to obtain coverage.

Agent/Broker Oversight

Most sponsors were compliant with the requirements for compensation, recoupment, training/testing and licensure/appointment. However, many sponsors failed the requirements for outbound enrollment verification (OEV) calls and the complaints process. The findings observed include the following:

1. Sponsors lacked internal monitoring of OEV calls, including monitoring of vendors conducting the calls on the sponsor's behalf.

2. Sponsors did not successfully complete the OEV process, including making three attempts to contact the member and issuing the OEV letter after the first unsuccessful call attempt.

3. Sponsors failed to recognize and execute cancellation requests that occurred during the OEV calls.

4. Sponsors lacked adequate tracking of and failed to appropriately address beneficiary questions and complaints against agents and brokers. This included answering questions or directing them to the appropriate area, or directing complaints to the appropriate area.

Best Practices

1. Sponsors should record OEV calls and monitor/listen to a sample of OEV calls. This will assist in ensuring compliance with the scripts, as well as ensuring customer service representative answer questions and route complaints appropriately.

2. Sponsors should follow up with the appropriate area to ensure complaints identified through the OEV process are thoroughly investigated and documented. This includes routinely reviewing complaint logs to ensure issues are appropriately addressed and resolved with respect to both the individual beneficiary and agent/broker, as well as on a systematic level.

3. Sponsors should conduct internal audits to ensure that all three OEV call attempts were made and that the OEV letters were mailed following the first unsuccessful call attempt.

Compliance Program Effectiveness

CMS identified areas of concern with sponsor's compliance programs. The findings observed include the following:

1. Sponsors lacked sufficient senior leadership level/board level involvement, awareness, oversight and support of compliance functions.

2. Sponsors did not perform formal organizational risk assessments to identify and address potential compliance and fraud, waste, and abuse (FWA) risks associated with the Medicare Parts C and D program.

3. Sponsors did not perform effective monitoring, auditing, and oversight of First Tier, Downstream, and Related Entities (FDRs) delegated to perform critical Medicare operational functions, especially over PBMs.

4. Sponsors failed to implement policies and procedures to screen employees, board members, and FDRs against the DHHS OIG List of Excluded Individuals/Entities (LEIE) and GSA Excluded Parties List, including documenting the organization's monitoring efforts.

5. Sponsors did not implement effective systems to consistently track, respond to, and report detected non-compliance and FWA issues and corrective actions in a timely and appropriate manner.

Best Practices

1. Sponsor's board agenda should include the Medicare program's compliance performance as a standing agenda item. Documentation related to Medicare product operation and compliance should be adequate to demonstrate level of board awareness and commitment to compliance and resolution of compliance issues.

2. Sponsors should implement a program for oversight and evaluation of FDR performance, including an escalation process to senior management to report non-compliance or projected areas of non-compliance.

3. Sponsors should meet regularly with leaders of their FDRs and hold them accountable for the functions they are contracted to perform.

4. Business function leaders should be held accountable for compliance results (e.g. this should impact performance evaluations and incentives).

5. Sponsors should promptly identify the root cause of non-compliance and FWA issues and respond appropriately to prevent reoccurrence.

6. Sponsors should develop enterprise-wide metric reports and measurement tools (e.g., dashboards, scorecards, self-assessments, etc) to evaluate operational compliance and compliance program effectiveness.

7. Sponsors should ensure remedial efforts to correct non-compliance and FWA issues are well-documented.

CMS expects all sponsors to carefully and routinely review their operations and processes to ensure compliance with CMS requirements. To assist sponsors in improving their operations and processes, we will participate on the Part C and D User Call on Wednesday, February 1, 2012 to discuss the 2012 audit process. If you have any questions regarding the audit findings or best practices, please submit your inquiry to part_c_part_d_audit_pcog@cms.hhs.gov.