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Hurdles for Medicare Plans Posed by 2014 Audit Requirements

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ABSTRACT

Background: One of the audit areas causing the most difficulty for Medicare Part D plans is coverage determinations and appeals. The recent changes, including the addition of a new "timeliness test," will continue to pose challenges for Medicare Part D plans.

Objectives: To outline the potential areas of risk for Medicare Part D plans as a result of the 2014 Coverage Determination and Appeals (CDA) audit changes, in addition to defining the resultant implications to plans and describing the cascading effect of a poor CDA audit.

Description: Medicare Part D plan managers will need to be aware of the new changes to the CDA audit protocols and prepare accordingly to handle the challenges with data collection, data integrity, case timeliness, and appropriate clinical decision making. Failure of an audit could result in numerous short- and long-term implications for a plan including, but not limited to, corrective and other oversight actions, civil monetary penalties, and increased remediation costs.

Conclusions: Medicare Part D plans need to be prepared for the new hurdles and raised stakes that the 2014 CDA audit protocols pose. Failure to do so could result in a much larger, cascading impact than audit failure alone.

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The Centers for Medicare & Medicaid Services (CMS) conducts performance audits on a significant proportion of its Medicare Part C and Part D plans routinely, and each year releases its Audit Process and Protocols for the calendar year. The methodology for the current year was released on March 5, 2014.[1] Of particular interest to prescription drug plans (PDPs), Medicare Advantage plans offering prescription drug benefits (MAPDs), and prescription benefit management companies (PBMs) providing Part D services are the changes in the coverage determination and appeals area, which are consistently audited each year.[2]

According to Part D claims data from 2011, approximately 92% of Medicare enrollees filled at least 1 prescription that year, with an average of 4.3 prescriptions filled per month.[3] In an effort to manage an ever-increasing drug spend, plan sponsors are judicious in the selection of drugs for formulary inclusion, and are increasing the use of utilization management (UM) tools such as step therapy, prior authorization, and quantity limits. In 2014, 6 of the 9 largest stand-alone PDPs employ UM on more than one-third of drugs listed on their formularies, with about 20% requiring prior authorization.[3] As the volume and significance of decisions requiring prior approval—which CMS calls coverage determinations—and related appeals continue to grow, it is critical for plans to be ready for this year's performance audits. Although the changes to the audit methodology are few, the impact is substantial, including the addition of a "timeliness test."

Coverage Determinations and Appeals Background

A coverage determination is the formal decision issued by a Part D plan in response to a request from a Medicare enrollee, an enrollee's representative, or enrollee's prescriber to obtain Part D benefits.[4] Most often, such determinations involve coverage of a non-formulary drug, or a formulary drug with UM restrictions. These decisions are made by PDPs, MAPDs, and

PRACTICAL IMPLICATIONS

The Process and Protocols for the 2014 CMS Coverage Determination and Appeals audit have changed from those of previous years. The key changes are the additions of new data elements to the CMS universe template, a "timeliness test" that is applied to the entire universe, "pass/fail" timeliness test thresholds for determining audit findings and corrective actions, and civil monetary penalties for failures of data integrity. These changes significantly increase the extent of risk and failure for Part D plans, and may pose significant challenges for plans in the collection, coordination, and integrity of data to be analyzed by CMS. It is imperative that plans prepare for these changes, because a poor audit performance could result in audit failure, mandatory corrective actions, civil monetary penalties, a negative impact on future Star measures, and a negative impact on past performance measurements.

PBMs to manage prescription drug costs, control over- and underutilization of formulary drugs, and meet other Medicare Part D requirements. For example, to ensure that Medicare beneficiaries have access to non-formulary drugs when medically necessary, plans must process formulary exception requests, which are a type of coverage determination. Also of note, any claim submitted by an enrollee for reimbursement when a prescription was paid for out of pocket at the pharmacy is classified as a coverage determination.[4]

Types of Coverage Determinations[4]:
- Prior authorizations
- Step therapy
- Quantity limits
- Formulary exceptions
- Tiering exceptions
- Member reimbursements

Appeals are a critical protection to ensure that beneficiaries have access to the medically necessary drugs to which they are entitled. The beneficiary appeal process starts with a redetermination by the Part D plan and, if the plan upholds its initial denial, an appeal may move to higher levels outside the plan, such as a reconsideration by CMS' Independent Review Entity (IRE).[4]

Part D plans are required to review CDA requests, make a determination, provide notification, and when applicable, effectuate (provide payment or provision of a benefit) within CMS-defined time frames.[4] When a plan intends to deny a coverage determination involving medical necessity, the review must be conducted by a physician or other appropriate healthcare professional with sufficient medical and other expertise (a pharmacist is generally considered appropriate), including knowledge of Medicare coverage criteria. For redeterminations, the Part D plan must designate someone other than the person involved in making the initial coverage determination. If the original denial was based on a lack of medical necessity, the redetermination must be performed by a physician with expertise in the field of medicine that is appropriate for the drug benefits at issue.[4]

Audit Selection

The CMS Medicare Part C and D Oversight and Enforcement Group (MOEG) is responsible for conducting the performance audits. It states: "It is MOEG's goal to audit every sponsor in the Part C and D programs within a reasonable time period." By the end of 2013, MOEG anticipated that 93% of Part C and Medicare Part D beneficiaries would be enrolled in sponsors audited by CMS.[5] In 2014, sponsors will be selected for a performance audit from the following groups:

- High-risk plans: as defined by MOEG's Proprietary Risk Assessment
- Lower-risk plans: for purposes of testing the level of correlation between audit result and MOEG Risk Assessment
- Plans with low performing icons: contracts with fewer than 3 Stars over 3 years and not recently audited
- Sponsors not audited in the previous 4 years and not in the above 3 categories
- CMS regional office referrals: based upon concerns or trends identified by CMS regional offices
- Ad hoc audits: using an oversight tool to promptly act when there is reason to believe a sponsor is noncompliant.[6]

Coverage Determination and Appeals Audit Process

The audit process begins with offsite analyses by CMS auditors, followed by an interactive audit over a 1-week period via webinar. There are 2 focal points of the Coverage Determination and Appeals (CDA) audit: Effectuation Timeliness (ET) and Clinical Decision Making (CDM). The audit process can be broken down into the 4 key components as shown below.[7]

1. Universe Submission

To begin the process, CMS will request a universe for ET and a separate universe for CDM. The data collected are compiled from coverage determinations and appeals (including member reimbursement claims) for the 3-month period preceding the audit, with CMS reserving the right

to expand the review period to ensure sufficient universe size. Plans will have 10 business days to provide the universes to CMS using the model template provided with the March protocol release. The ET universe includes all decisions that were approved (ie, favorable to the beneficiary) at any level (coverage determination, redetermination, IRE, and higher levels of appeal) during the audit review period. The CDM universe contains all decisions that were denied (ie, unfavorable to the beneficiary) at the coverage determination or redetermination level, including those that were untimely and those that were auto-forwarded to the IRE. In addition, all IRE decisions that reversed the Part D plan's denial during the appropriate time period are included in the CDM universe.[7] While most data elements on CMS' universe templates remain the same from previous years, both universes have increased in size by 30% or more.[8-10]

2. Timeliness Test

The addition of a timeliness test is one of the most significant changes for 2014. Previously, CMS would conduct a brief check of the data and proceed to the selection of samples.[11] Now, after receipt of the universe, and prior to the selection of samples, CMS will conduct a new, more comprehensive analysis to determine whether the regulatory standards for completing within time frames are met. This includes assessing the timeliness of *all* cases within the universe to ensure the plan made a timely determination, notified all appropriate parties of the decision, and provided payment or authorization of the benefit (effectuated) when applicable. In addition, any requests that were untimely and sent to the IRE will be reviewed to ensure that the plan forwarded the case file within applicable time frames. The percentage of cases considered timely for each metric will be recorded and scored against new thresholds set by CMS:

- ***First Threshold:*** Sponsors above this threshold will generally not be cited an audit finding, or "condition."
- ***Second Threshold:*** Sponsors falling below this threshold will receive a "corrective action required," or CAR.
- ***Third Threshold:*** Sponsors falling below this threshold will be cited an "immediate corrective action required," or ICAR.[7]

3. Sample Review

Following the timeliness test, the webinar portion begins with CMS selecting a sample of cases from different case types (eg, processed under standard and expedited timing) from the universes. Using sampling techniques as well as experience from previous audits to target certain cases for review, CMS will select 10 samples for ET, while selecting 30 samples for CDM.[7] When choosing the samples for CDM, CMS will ensure that half of the samples selected are for drugs that are classified as "protected class drugs."[7,12]

Protected Class Drugs—drug classes of clinical concern due to the high risks and complications associated with interruptions of therapy.[12]

- Immunosuppressants (for prophylaxis of organ transplant rejection)
- Antidepressants
- Antipsychotics
- Anticonvulsants
- Antiretrovirals
- Antineoplastics

During the live webinar, plans are expected to show evidence directly from their systems to demonstrate that the data in the universe match the data within the systems of record. In addition to verifying the accuracy of the data, CMS will assess the plan's compliance with CDA rules and regulatory time frames.[7] Any issues of noncompliance will be documented and may result in some form of corrective action.

4. Applying the Compliance Standard

After reviewing the evidence, CMS will apply the compliance standard to each sample to determine if it "passes" or "fails." To "pass" the ET portion, each sample must indicate that the dates observed during the live audit are consistent with the timeliness fields in the universe submission. If requirements are not met, a case "fails," and a condition (finding) is documented.[7]

For each of the 30 sampled CDM cases, CMS will assess the clinical appropriateness of the decision, including determining if the plan had adequate outreach for needed clinical information, based its decision on available information, and followed CMS coverage and notification requirements.[7] Cases denied for lack of medical necessity will be assessed to ensure that a person with the appropriate level of expertise conducted the review in accordance with CMS guidelines.[3,7] Depending on the type of sample being reviewed, a favorable response for up to 5 compliance standard questions may be required to "pass."[7]

For both universes, CMS guidelines note: "The integrity of the universe will be questioned if the timeliness metrics on 6 or more cases observed during the live audit do not match the metrics provided in the universe. If this occurs, CMS will request a new universe to test timeliness.

Sponsors providing misleading information will be referred to the Division of Compliance and Enforcement for a civil monetary penalty."[7]

Impact of Changes for Part D Plans

As we analyzed the new protocols, the following areas of risk were identified for plan sponsors and their delegated entities:

- ***Coordination of universe data from multiple systems for timely submission.*** As the number of universe data fields continues to increase, plans will be challenged with compiling all the data (oftenfrom multiple systems); unifying the format, including date and time fields; and validating the content within 10 business days. In addition, a particular challenge for Part D plans will be the coordination and integration of data from the systems used for processing claims for member reimbursement. As these reimbursement decisions are usually processed by a Part D claims department, plans must merge the payment data with clinical data to accurately complete the CMS universe templates. After compilation of the universe, a thorough validation will need to be conducted to ensure the accuracy of the data and compliance with CMS instructions. For PBMs delegated to perform CDA services on a plan's behalf, this process will need to be repeated for every client plan audited.
- ***Data integrity is now more essential than ever.*** With CMS expanding its audit scope to the entire universe, data integrity will be validated as part of the audit. This approach presumably allows CMS to significantly and confidently widen the audit scope, without incrementally increasing the demand on the agency's own staff time and resources. While the integrity of data has always been an expectation, civil monetary penalties are now on the table for those with data integrity issues.[7] It can be expected that any degree of data discrepancy will be subject to increased scrutiny, and confidence in the data will quickly erode.
- ***Increased exposure for timeliness.*** One of the largest concerns for plans stemming from the 2014 changes to the audit methodology is the new timeliness test. While CMS has always audited timeliness, the sample size was relatively small (typically 30). Now, the entire universe of coverage determinations and appeals will be assessed for timeliness and scored as a part of the audit.[7] By applying the test to the entire universe, CMS will have greater ability to detect late cases and trends in untimely performance. This increases a plan's exposure to audit findings as well as risks for corrective actions levied by CMS.
- ***CMS has not disclosed the set values of the thresholds.*** The new timeliness test comes with 3 thresholds to determine if plans will be cited with findings; however, CMS has not disclosed the set values of the thresholds.[7] It is unknown if each threshold will be based on a simple percentage or, alternatively, a formula created to incorporate differences in population size among plans.

Implications

The short- and long-term implications for plans are abundant. Short-term implications for PDPs, MAPDs, and PBMs, in addition to any impact on the beneficiary, may include: corrective actions (including ICARs), audit failure, civil monetary penalties, and other oversight actions by CMS.[7] Remediation in the form of modifications of systems, updating policies and procedures, staff training, and intensified oversight mechanisms will be costly to a plan.

The longer-term implications of these methodological changes could include a negative impact on future Star ratings and negative points assigned during a "past performance review" by CMS.[13,14] Historically, there has been a Star measure (Beneficiary Access and Performance Problems) that has incorporated audit results in the calculation of the metric.[13] Due to the methodological changes to the audit protocols, CMS will not include the audit results as part of the 2015 Star measures, but they are generally anticipated to be re-included in future years. By the end of 2014, and continuing into future years, CMS intends to "terminate the contracts of organizations that fail for 3 consecutive years to achieve at least 3 stars on their Part C or D performance."[2] Each year, CMS conducts a comprehensive "past performance review" of plan sponsors and assigns negative performance points in 11 distinct performance categories.[14] The results of a poor audit could lead to the accumulation of negative performance points in up to half of the performance categories. Based upon the results of the past performance methodology, CMS "may deny an organization's application either to offer Medicare benefits under a new contract or in an expanded service area during the subsequent contract year."[14]

Summary

The new coverage determination and appeals audit protocol changes for 2014 will challenge plans, particularly in data collection, data integrity, case timeliness, and appropriate clinical decision making. The latest publicly available data on Medicare Part D audits show that plan sponsors have struggled the most in the area of coverage determinations and appeals.[5] With the recent changes to the protocols and process requirements, plans will likely continue to struggle in this area. The implication is that a poor audit could result in a much larger, cascading impact on the plan than audit failure alone. With the new hurdles, and stakes that are higher than ever, it is imperative for plans to be prepared.

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