DECONSTRUCTING THE CMS PROGRAM AUDIT

APRIL 2016
WHO IS GORMAN HEALTH GROUP?

_Gorman Health Group_ is the leading solutions and consulting firm for government-sponsored health programs.

**Government Programs**
Leading enterprise of national consulting services and software solutions for payers and providers.

**Our Mission**
Our mission, as the industry’s most active professional services consultancy and provider of technology-based solutions, is to empower health plans and providers to deliver higher quality care to beneficiaries at lower costs, while serving as valued, trusted partners to government health agencies.

**Washington, DC**
Headquartered in Washington, DC, with more than 200 staff and contractors nationwide with over 2,000 combined years of Government Programs experience.

**Leadership**
Deep payer and provider knowledge coupled with Centers for Medicare & Medicaid Services (CMS) regulatory expertise.

**Privately Owned**
Founded in 1996
Our clients have one-stop access to expert advice, guidance, and support, in every strategic and operational area for government-sponsored programs, across seven verticals.

**CLINICAL**
Changing how you approach Medical Management, Quality and Stars.

**PHARMACY**
Leading experts in Part D, PBM, formulary and pharmacy programs.

**HEALTHCARE ANALYTICS & RISK ADJUSTMENT SOLUTIONS**
Implementing cross-functional risk adjustment programs for medical trend management and quality improvement.

**PROVIDER INNOVATIONS**
Supporting network design and medical cost control implementation.

**COMPLIANCE**
Offering guidance and support in every strategic and operational area to ensure alignment with CMS.

**OPERATIONS**
Bringing excellence to every aspect of your implementation from enrollment to claims payment.

**STRATEGY & GROWTH**
Driving profitable growth and member retention through strategic marketing, sales, and product development.
LEARNING OBJECTIVES

• Review 2016 CMS Program Compliance Audit Protocols
  o Universe accuracy and completeness
  o Pre-Audit Issue Summary
  o Benefit Impact Analysis
  o Self-assessment questionnaire
  o Aggravating circumstances

• Discuss CMS Audit Hot Spots for the 2016 Program Compliance Audits
  o Common findings from 2015
  o Formulary and Benefit Administration (FA)
  o Coverage Determination, Appeal and Grievance (CDAG) areas

• Discuss Importance of Audit Readiness
• CMS published 2015/2016 program audit updates in an October 20, 2015, HPMS memo
• An Addendum to the 2015/2016 program audit protocols was released on January 19, 2016
• Audit notices will be sent 6 weeks in advance
• Continue to take place over 2-week period
• Additional time to provide requested universe
  o Upload within 15 days of receiving engagement letter
2016 CMS PROGRAM AUDIT

Audit Protocol

• Pilots
  o Medication Therapy Management (MTM)
  o Provider Network Accuracy (PNA)
  o Will not count against sponsor and do not factor into overall audit score
  o Results will be displayed in draft audit report only – not final report
2016 CMS PROGRAM AUDIT

Change Can Bring Risk – Audit Universes

- Changes to format and layout to number and composition from early 2015 protocol
- Sponsors can submit record layouts as text (.txt) or Excel (.xls) files
  - Template changes increase susceptibility to universe errors if not prepared
  - Increase time to provide quality check universe process
  - New data elements may require data merges or multiple system queries
2016 CMS PROGRAM AUDIT

Change Can Bring Risk – Audit Universes

• FA
  o Universe requests – Prescription Drug Event (PDE) increased from 2 months to 3 months
  o Sample review – Removed Pharmacy & Therapeutics (P&T) Committee assessment

• CDAG
  o Universe requests more specific – 15 distinct requests, universes
  o Validation for timeliness assessment – all areas
  o Increased samples sizes
    • Timeliness from 10 to 75
    • Clinical Decision-Making from 30 to 40
2016 CMS PROGRAM AUDIT
Change Can Bring Risk – Audit Universes (cont.)

ODAG

• Universe requests
  o Universe requests more specific – 13 distinct requests, universes
  o Timeliness assessment – Separate universe templates will allow CMS to more accurately assess timeliness
  o Increased samples sizes
  o Timeliness from 10 to 75
  o Clinical Decision-Making from 30 to 40

CPE

• Protocol redesigned to be less burdensome and outcome-focused
  o No longer required to submit such a large volume of documents
  o 7 elements tested through a total of 6 tracer samples
2016 CMS PROGRAM AUDIT

Universe Accuracy and Completeness

- **Emphasis on data accuracy and consequences for failures**
  - “3 strikes” policy
    - Sponsors will have a maximum of 3 attempts to provide each universe requested
    - 2 failed attempts = observation in the sponsor’s program audit report
    - 3 failed attempts = sponsor cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested grouped by the type of case
  - If CMS is unable to evaluate an element due to inaccurate or incomplete universe:
    - Sponsor may be cited every applicable condition for the affected element that cannot be tested
    - Sponsor may be referred for possible enforcement action
2016 CMS PROGRAM AUDIT PROTOCOL

Pre-Audit Issue Summary

- CMS focus on the ability for sponsor’s to identify their own issues
- The Pre-Audit Issue Summary (PAIS)
  - Requires sponsor’s to report the disclosed issues submitted to CMS on an ongoing basis
  - Requires sponsor to report self-identified issues
    - If there is evidence of appropriate and adequate remediation in the sponsor’s systems and for its beneficiaries
    - either prior to or during the audit review period
    - but before the receipt of the audit start notice
  - Issues reported as uncorrected will automatically be cited as conditions
Impact Analysis (IA) replaces Beneficiary Impact Analysis (BIA)
IA no longer required for the disclosed and self-identified issues communicated in the PAIS template
Impact Analyses specific to issues found during audit having potential beneficiary impact and may be cited as a condition of non-compliance
2016 CMS PROGRAM AUDIT PROTOCOL

Questionnaires

- CMS has introduced 17 supplemental questions for CDAG that must be submitted before the start of the audit webinars
- Questions cover various facets of operations ranging from staffing to mailroom practices
- Answers help CMS test webinar responses against actual operations and performance and gain insight into plan compliance
CMS has released 4 memoranda summarizing the common compliance issues found during its program audits and has stated the agency continues to find many of the same “Common Conditions or Findings” during its yearly program audits.

CMS will escalate the consequence of finding a condition from one or more of these memos, and substantial failures may result in additional enforcement actions due to these “aggravating circumstances”.

For example, an observation might be elevated to a Corrective Action Required (CAR), or a CAR might be elevated to an Immediate Corrective Action Required (ICAR) if the condition cited had been addressed in a prior Best Practice memo.
AUDIT HOT SPOTS

Coverage Determinations, Organization Determinations, and Grievances

• General
  o Inappropriate grievance handling
  o Misclassification of cases
  o Untimely resolution of Part A/B vs. Part D cases
  o Scrutiny of protected class drug

• Appeals
  o Failure to forward coverage determination and redetermination requests to the IRE within the required time frame
  o Failure to provide enough information about an appeal within a beneficiary notification
AUDIT HOT SPOTS

Coverage Determinations, Organization Determinations, and Grievances

• Denials
  o Clinical decision-making
    • Continuity of care
    • Level of effort made to obtain information
  o Beneficiary follow-up
    • Untimely effectuation
    • Untimely notification
    • Denial notice language is not tailored to specific case and written in appropriate language
    • Exception tolling not well defined
AUDIT HOT SPOTS

Formulary and Benefit Administration

• Accurate Administration of CMS-Approved Formulary
  o Unapproved Utilization Management (UM) Edits
    • Max daily dose (MDD) limits applied that were more restrictive than the CMS-approved and/or Food and Drug Administration (FDA) labelling
    • Non-safety-related UM applied to non-formulary medications
    • Applied unapproved edits not supported by FDA labeling (e.g., age, gender)
  o Benefit-Related Edits
    • Claims rejected for drugs dispensed in the smallest available package size when days’ supply prescribed exceeded the plan’s day supply benefit
AUDIT HOT SPOTS

Formulary and Benefit Administration

• **Claims Response Messaging**
  - Messaging accuracy
  - Instruct next steps at point of sale

• **National Provider Identifier (NPI)**
  - Resolution time exceeded 24 hours

• **NDA / ANDA Classifications**
  - Properly defining brand vs. generic in all benefit phases and low-income situations
AUDIT HOT SPOTS

Formulary and Benefit Administration

- **Transition Policy**
  - Inappropriate prior authorization (PA) applied to protected class drugs (e.g., look-back logic)
  - Long-term care beneficiaries not allowed multiple transition fills as necessary during the entire length of the transition period
  - Drugs with a negative cross-year formulary change not allowed transition
AUDIT HOT SPOTS

Formulary and Benefit Administration

• **Transition Policy**
  - Drugs in unbreakable packages denied when days’ supply exceed transition days’ supply limits
  - Transition Letters
    - Transition notices untimely
    - Transition notices mailing not documented
    - Language unclear/member appropriate
    - Inaccurate description of transition reason
    - Medication noted does not match rejected claim
AUDIT HOT SPOTS

Special Needs Plan Model of Care (SNP MOC)

• Initial Health Risk Assessments (HRAs) administered > 90 days
• Reassessments not being administered within 12 months of initial HRA
• Individualized Care Plans (ICPs) are not implemented
  o Relying on nursing home to develop ICP
  o Sponsors are relying on phone call attempts
  o Little or no follow-up
  o Issues identified in the HRA are not addressed in the ICP
• Sponsors are not following what is outlined in the MOC
AUDIT HOT SPOTS

Compliance Program Effectiveness (CPE)

- Sponsors are not reviewing OIG and GSA exclusion lists
  - New and temporary employees, volunteers, consultants, board members, and FDRs
- CPE annual audits must be done annually with results shared with the governing body
- FWA and Compliance training not distributed to FDRs
- Standards of Conduct and policies and procedures (P&Ps) not distributed to those who support the Medicare line of business
  - Within 90 days of hire
  - When updates are made
  - Annually
AUDIT PREPARATION

Failing to Prepare is Preparing to Fail

• Always be Audit Ready
  o Written P&Ps in place
  o Who’s on first?
    • Assimilate teams and key personnel
    • Leadership and subject matter experts (SMEs)
  o Leverage lessons learned/Best Practice memos
    • Document
    • Continuous monitoring
    • Regulatory update communication
  o Pharmacy Benefit Manager (PBM) Oversight and other FDRs
AUDIT PREPARATION

Failing to Prepare is Preparing to Fail

- **Mock Audit – Practice Makes Perfect**
  - Identify and prepare sample universes regularly
  - Validate universes
    - All field names, character length, field descriptions, etc.
    - No cells blank, unless stated otherwise in CMS audit protocols
    - All dates within the audit review period as requested in Data Request
  - Monitoring and Auditing Plans
    - Conduct risk assessment
    - Start/update issue summary and IA as issues occur
    - Use to track corrective actions plans (CAPs)
  - Build and coordinate communication with first-tier, downstream, and related entities (FDRs) to ensure prompt communication of issues and resolution plan
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GHG offers software to solve problems not addressed by enterprise systems. Our Valencia™ software reconciles membership of more than 10 million members in Medicare, Medicaid and the Health Insurance Marketplace. Over 3,000 compliance professionals use the Online Monitoring Tool™ (OMT), our complete Medicare Advantage and Part D compliance toolkit, while more than 25,000 brokers and sales agents are certified and credentialed using Sales Sentinel™. In addition, hundreds of health care professionals are trained each year using Gorman University™ training courses.

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