Part D Data Techniques
to Prevent Compliance
Findings
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Pharmacy
(Medicare Part D)

Part D - By the Numbers
> Congressional budget office estimates Part D will be
  worth 14% of total Medicare spending in 2015
  > 76 Billion dollars
> 37 Million participants
  > 62% of those in PDPs
  > Estimated growth of 6% per year
> 3 sponsors account for over 50% of Part D enrollees
  in 2015
  > Over 1000 PDP’s available
  > Over 1600 MA-PD’s available

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Part D – The Attention Seeker

Average Number of Sanction Violations by Program Area
- Program Audit Year 2013
- Program Audit Year 2014


CMS Compliance and Audit Findings Related to Part D Data

Average Overall Audit Score by Program Area
2013/2014 Comparison

Test Your Knowledge

What service area/department(s) of a Medicare Plan has the most violations in the last 3 years?

A. CDAG
B. PDE
C. BOFR
D. FA
E. Are these all real acronyms...?
Pharmacy is Data Driven

- Claim Payment rules
  - Part D – under 4 seconds
  - Part C – 30-60 days

- Pharmacy claims contain enormous amounts of data
  - Financial
  - Clinical
  - Service provided
  - Providers

Pharmacy is Data Driven

I dispense more data than pills!!

Data CMS Reviews

- Medicare Part D Over Utilization Monitoring System (OMS)
- Provider Enrollment and Disenrollment
- Retail, Home Infusion, and Long-Term Care (LTC)
- Medication Therapy Management Programs
- Grievances
- Coverage Determinations and Redeterminations
- LTC Utilization
- Employer/Union-Sponsored Group Health Plan Sponsors
- Plan Oversight of Agents
- Data Validation Audits
- Outlier reviews

Program Audits – Universes

- Transition Audits
- Medicare Part D Over Utilization Monitoring System (OMS)
- Opioids
- APAP
- CAPs
- Self-Identified or through audit findings
- Beneficiary remediation

Data Plans Review

- STARs
- Latest CMS fire drill
So, what does CMS want from us?!

CMS Operational Expectations of Part D Plans and Their Vendors

- Oversight and monitoring
- Coordination of functional responsibilities
- Understanding their membership
- Awareness and interpretation of all CMS regulations and guidance
- Operationalizing regulatory guidance in a timely manner

Expectations Ahead!

Plan and Vendor Barriers

- Insufficient Resourcing
  - Staff and Budgets
- Insufficient Monitoring
  - Lack of knowledge, planning and resources
- Poor FDR Oversight
  - Contractual issues
  - Insufficient vendor knowledge and resources
We can't afford all that!!

**CMS 2013-2015 Enforcement Actions UPDATE**

<table>
<thead>
<tr>
<th>Action</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enforcement</td>
<td>21</td>
<td>19</td>
<td>25</td>
</tr>
<tr>
<td>CMPs</td>
<td>21</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>CMPs total</td>
<td>$3.88 million</td>
<td>$3.75 million</td>
<td>$10.97 million</td>
</tr>
<tr>
<td>Intermediate Sanctions</td>
<td>2</td>
<td>3</td>
<td>6</td>
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Part C and D Enforcement Actions, cms.hhs.gov, March 31, 2016

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**CMP Methodology**

CMS has the authority to impose a CMP:

- Up to $25,000 per determination
- Up to $25,000 per enrollee adversely affected (or with the substantial likelihood of being adversely affected)
- Up to $10,000 for each week that a deficiency remains uncorrected after the week in which CMS issues a CMP

*Kaiser Family Foundation statistics 2015*
Standard Penalty

Varies depending on the type of violation and potential for adverse beneficiary impact.

- Standard Penalty
- + Aggravating Factors
- - Mitigating Factors
- CMP Amount

Enforcement Actions – Other Costs

- Remediation costs
- CAP production and implementation
- Validation audits
- Star Rating reduction
- Automatic 2.5 for sanction
- Marketing/Enrollment Impact
- Staff distraction from daily duties
- Vendor Costs

CMS Compliance and Audit Findings Related to Part D Data
Common Finding from CMS Audits:
Sponsor misclassified a coverage determination or redetermination request as a grievance and/or customer service inquiry.
- Failed to classify reimbursement requests as coverage determinations, leading to a failure to issue payments

Best Practices:
- Fully-trained staff who understands the difference between:
  - Inquiry
  - Grievance
  - Coverage Determination
  - Redetermination
  - Reconsideration
- Daily monitoring processes to ensure compliance

Common Finding from CMS Audits:
Sponsor failed to effectuate exception approvals through the end of the plan year.
- Sponsor made inappropriate effectuations.
  - Allowed one strength of the medication (e.g., NDC level)
  - Commonly found during Formulary Administration audits
- Effectuation date and timeframe did not match written notification.

Best Practices:
- Quality checks and review processes to ensure approved requests are properly entered into the claims processing system
- Effectuations should be approved/entered for 12 months, versus the end of the plan year
- Effectuations should allow for payment of any strength of the approved medication to prevent multiple requests
- Run test claims after effectuation entry

Common Finding from CMS Audits:
Sponsor failed to properly administer its CMS-approved formulary by applying unapproved quantity limits.
- Sponsor failed to properly administer its CMS-approved formulary by applying unapproved utilization management practices.

Best Practices:
- Product dosing guidelines/indications should be consistent with approved compendia

Helpful Hint:
Perform quality checks by routinely comparing the formulary file submitted to CMS and the adjudication system file to ensure that there are not inconsistencies that could create discrepancies and inappropriate rejections (e.g., unapproved Utilization Management (UM), drug deletion, etc.)
### CMS Compliance and Audit Findings Related to Part D Data

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<th>Common Finding from CMS Audits</th>
<th>Best Practices</th>
<th>Helpful Hint</th>
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<tr>
<td>Sponsor failed to properly administer the CMS transition policy.</td>
<td>Maintaining the same transition process for new and existing members was found to ease administration, as all beneficiaries are treated as newly enrolled for the purposes of meeting CMS transition requirements.</td>
<td>Test transition logic prior to the start of the new plan year to ensure that claims for new beneficiaries will not reject for transition supplies. Complete a review of 100% of rejected claims to identify and correct any vacancies and transition errors and then periodically review rejected claims to ensure no new errors develop.</td>
</tr>
<tr>
<td>Sponsor improperly effectuated a prior authorization (PA) or exception request.</td>
<td>The updating process of PAs on file is conducted in such a way that the PA can be extended into the next plan year without disruption to the beneficiary.</td>
<td>Effective communication with your claims processor/Pharmacy Benefit Manager (PBM) is key. An issue log should be maintained and updated accordingly.</td>
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### Part D Data Streams CMS Expects Plans to Review and Monitor
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- **Rejected Claims**
  - Transition Files – new and existing members
  - B vs. D
  - Protected Class
  - NPI rejections

- **Overutilization Monitoring Systems Reports – opioids**

- **Drug Utilization Review (DUR) Programs**

- **Prescription Drug Event (PDE)**
  - Accurate, timely, edits, financials
  - Direct and Indirect Remuneration (DIR) Payment Reconciliation

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Part D Data Streams CMS Expects Plans to Review and Monitor

- **Coverage Determination, Appeals and Grievance Data**
  - Standard Coverage Determinations and Exceptions
  - Direct Member Reimbursement and Redeterminations
  - Expedited Coverage Determinations and Exceptions
  - Standard and Expedited Redeterminations
  - Independent Review Entity (IRE) Cases
  - Standard and Expedited Grievances

- **Audit Data**
  - Claims
  - Recovery Audit Contractor (RAC)
  - Overpayments and Underpayments (esp. LICS beneficiaries)

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Part D Data Streams CMS Expects Plans to Review and Monitor

- **2016 Part D Reporting (Data Validation Audits)**
  - Enrollment and Disenrollment
  - Retail, Home Infusion, and Long-Term Care (LTC) Pharmacy Access
  - Medication Therapy Management Programs
  - Grievances
  - Coverage Determinations and Redeterminations
  - Employer/Union-Sponsored Group Health Plan Sponsors
  - Plan Oversight of Agents

- **2016 Medication Therapy Management (MTM) Pilot Audit**
  - Enrollment
  - Comprehensive Medication Reviews (CMR)
  - Targeted Medication Reviews (TMR)
Part D Data Streams CMS Expects Plans to Review and Monitor

- 2016 Patient Safety Reports
  - High Risk Medication (HRM) measure
  - Diabetes Treatment (DT) measure
  - Medication Adherence (ADH) for Cholesterol (Statins)
  - Medication Adherence (ADH) for Hypertension (RAS Antagonists)
  - Medication Adherence (ADH) for Diabetes Medications
  - Drug-Drug Interaction (DDI) measure
  - Diabetes Medication Dosage (DMD) measure
  - Medication Adherence for HIV/AIDS (Antiretrovirals)

Plan and Vendor Toolbox

Plan & Vendor Toolbox

Compliance
  - Active compliance program
  - Operational and compliance team collaboration
  - Communication with regional office
  - Pull Universes
Plan & Vendor Toolbox

CMS Regulations and Memos
- Common findings/best practices
- HPMS memos
- PDE memos (CSSC-PDE contractor)
- Complete testing
- Universes

Plan & Vendor Toolbox

Monitoring
- Targeted
  - Trend
  - Outliers
- Depending on area and item how much and how often
- Look for high risk
  - Beneficiary access
  - Timeliness
- Use Universes

Plan & Vendor Toolbox

Mock Audits
- Internal or external
- Use CMS protocols at minimum
- Go further than CMS
- Practice universe pull and review
**Plan & Vendor Toolbox**

**FDR Oversight**
- Number one issue for plans and the FDRs
- CMS not tolerant of vendor ‘black box’
- Look for partnership
- Vendor experience with many plans
- Have internal experts that can talk the vendor language
- Universes
- COMMUNICATE

**Plan & Vendor Toolbox**

**Training**
- Continuous
- On the spot
- Formal
- Coordinated with FDR's

**Test Your Knowledge**

Which one of these is a tool in your audit toolbox?
A. Boxing gloves
B. A sledgehammer
C. Bad words
D. Practice Universes
D. All of the above
Where do I START?!?

Must slow down and plan
Look for cost savings through automation
Consolidate data
Remove silos
Internal and with vendors
Remediate with care
Don’t create additional issues

CMS’ Expectations for Internal and Downstream Vendor Monitoring
Sponsors must monitor and audit their operational areas and those of their first tier entities to test and confirm compliance and protect against noncompliance and Fraud, Waste and Abuse (FWA).

Sponsors must develop a monitoring and auditing work plan for the calendar year.

- Monitoring activities: regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.
- Audit: formal review of compliance with a particular set of standards used as base measures.

CMS' Expectations for Internal and Downstream Vendor Monitoring

Monitoring and Auditing Work Plan “Musts”:

- Must be based on risk assessment results
- Must be coordinated, overseen and/or executed by the compliance officer
- Must include a process for responding to all monitoring and auditing results and for conducting follow-up reviews
- Must include a schedule that lists all of the monitoring and auditing activities for the calendar year

CMS' Expectations for Internal and Downstream Vendor Monitoring

Monitoring and Oversight:

- Sponsors must have a system in place to monitor their First Tier, Downstream and Related Entities (FDRs).
- Sponsors must demonstrate to CMS that their method of monitoring is effective.
CMS' Expectations for Internal and Downstream Vendor Monitoring
Internal Monitoring and Oversight Program

New emphasis on FDRs in 2015/2016 Audit Protocols:

- "Sponsor Accountability and Oversight of FDRs" replaces "Well-Publicized Disciplinary Standards" to become one of the seven Compliance Program Effectiveness (CPE) audit elements.
- Of the 6 tracer samples for the CPE audit, 2 will be used to test the sponsor's oversight and accountability of FDRs.

Accountability

- Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions relating to the sponsor's Medicare Parts C and D contracts.
- The sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS and for meeting the Medicare program requirements.
- Therefore, CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements.
- FDR contracting language should include compliance with Medicare Program requirements.

The Most Efficient Way to Identify, Fix and Ensure Data Issues Do Not Reoccur
The Most Efficient Way to Identify, Fix and Ensure Data Issues Do Not Reoccur

Identify
- Internal monitoring and auditing
- Complaint Tracking Modules (CTMs)
- Non-compliance and FWA hotline calls
- CMS Common Findings/Best Practices memos

Fix
- Corrective Action Plan
- Root cause analysis
- Member impact
- Remediation
- 60-day timeline
- Data validation to close
- Monitor

Prevent
Prevent

> Step in CAP process – what sponsor will do to prevent issue from reoccurring
> Include in annual risk assessment
> Issue should be high priority in risk assessment to assure monitoring and auditing activities.

Fix

The Most Effective Way to Identify, Fix and Ensure Data Issues Do Not Reoccur

The Most Effective Use of Internal Resources to Monitor the Data Mountain

Make Good Use of Data and Internal Resources:

1. Operational area maintains data metrics dashboard
2. Deficiencies are reported to Compliance Department
   • Monitoring and Auditing
   • Hotline Calls
   • CTMs
3. Compliance Department works with operational area to develop and implement CAP.
4. Internal Audit performs data validation audit.
   • Pass – CAP completed
   • Fail – Repeat steps 4 and 5 as needed
On March 16, 2016, CMS announced the release of the MTM pilot audit protocol for the 2016 calendar year. Similar to the process for existing program audit areas, the MTM pilot protocol defines:

- Audit purpose,
- Data universes and sample selection processes,
- Evidence required for review and submission, and
- Compliance standards tested during the audit.

MTM pilot will be conducted via webinar during second week of the program audits.

Purpose: To evaluate the implementation of the sponsor’s CMS approved program.

Review Period/Universes: 2014 & 2015 calendar years

- Three Universes
  - All beneficiaries who were enrolled in the sponsor’s program(s) including all enrollees that were disenrolled
  - CY 2014 MTM Universe (1)
  - CY 2015 MTM Universe (2)
  - 2015 Prescription Drug Event (PDE) Universe (3)
    - Extracted by CMS from the Integrated Data Repository (IDR)
MTM Program Audit Protocol – 2016 Pilot

- MTM pilot audit results
  - Will be provided in the draft audit report
  - Are not factored into the overall audit score
  - Will not appear in the final audit report

Audit Elements

- Enrollment/Disenrollment
  - 20 cases
    - CY 2015 MTM Universe & 2015 PDE Universe
- Comprehensive Medication Review (CMR)
  - 15 Cases
    - CY 2015 MTM Universe
- Targeted Medication Review (TMR)
  - 15 cases
    - CY 2015 MTM Universe that received a TMR

Enrollment/Disenrollment

- Applying the compliance standard to each case:
  - Appropriate identification of beneficiaries who met the targeting criteria of the CMS approved MTM program?
    - Meet the annual cost threshold
    - Multiple chronic diseases, minimum threshold can be set at 2 or 3
    - Take multiple Part D drugs, must be equal to or between 2 and 8
  - Appropriate disenrollment of beneficiaries?
    - Auto-enroll/opt-out only, may decline individual services
**Comprehensive Medication Review (CMR)**

- Applying the compliance standard to each case:
  - CMR offered annually? For newly identified beneficiaries, CMR offered within 60 days of enrollment in MTM program?
  - Was appropriate outreach performed for cognitively impaired members to offer the CMR to the beneficiary’s authorized representative?
  - Did the sponsor perform the annual CMR in accordance with CMS’ professional service definition?

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**Comprehensive Medication Review (CMR) cont.**

- Applying the compliance standard to each case:
  - Written summary provided in the standardized format?
  - Written summary provided within 14 days of the completed CMR?
  - Did the appropriate staff perform the CMR?
  - Were the required CMR services offered and provided consistent with the approved MTM description?

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**Targeted Medication Review (TMR)**

- Applying the compliance standard to each case:
  - Were TMRs provided at least quarterly or according to the timeframe as described in the CMS approved MTM description?
  - Were the TMRs performed consistent with the approved MTM description?
MTM Program Audit Protocol – 2016 Pilot

Data Monitoring
- 2015 Prescription Drug Event (PDE) Universe (3)
  - Extracted by CMS from the Integrated Data Repository (IDR)
- Enrollment and Disenrollment
  - Targeting criteria
    - Opt-out only
- CMR
- TMR

Thank You
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