Deep Dive on DIR

CMS' 2017 Focus on Enforcement for One-Third Financial Audits and Your Rebates

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Introductions

Derek Frye, CISA, MBA

Practice Leader, Audit and Compliance

10 years of healthcare audit and compliance experience

Oversees 100+ audits for our firm annually

The Burchfield Group, Inc.

Sonya Henderson, CHC

Senior Vice President, Corporate Compliance and Government Programs

Over 25 years of corporate compliance, government programs and operations experience in the healthcare arena

FirstCare Health Plans

Agenda

- What is a 1/3 financial audit and why are we talking about it?
- One plan's experience in the audit
- CMS areas of scrutiny
- Monitoring recommendations
- Audit recommendations
- Areas for a deeper dive

What is a 1/3 Financial Audit?

- One-third of all Sponsors audited each year
- Focus is on financial process, bid, controls, PDEs, DIR
- NEW: 2017 call letter outlines potential enforcement actions
- We're going to focus on DIR, specifically pharma (drug) rebates

1/3 Financial Review One Plan's Journey

- 1/3 Financial Review in 2016 (2013)
- 2 Observations noted:
  - Part D Costs - Plan to Plan (P2P) payments were not made within 30 days
  - Direct Medical – Part C claims were paid as primary vs. secondary
- Plan Response:
  - Reviewed P2P process with Finance to ensure adequate controls are in place
  - Reviewed COB file process with Enrollment; retraining occurred, annual CMS file will be used for reconciliation

CMS Areas of Scrutiny One Plan's Journey

- DIR to rebate reconciliation
- Explanation of Benefits (EOB) accuracy
- Plan oversight of the PBM's PDE adjudication
- Plan oversight of PBM compliance to Part D claims adjudication rules

CMS Areas of Scrutiny

"Who is responsible for implementing the controls mentioned in (P&Ps)? … How does senior management monitor the controls?"

- Lessons Learned:
  - *Detailed* P&Ps matter
  - Compliance oversight (independent) matters

CMS Areas of Scrutiny

"List of all internal audit reports from time period under review to present (e.g., 2015 to present for a 2017 audit)"

- Lessons Learned:
  - Don't wait until you're notified before you audit
  - Your interpretation of guidance matters

CMS Areas of Scrutiny

"Provide allocation methodology depicting how DIR balances were allocated to the individual plans."

- Lessons Learned:
  - Some auditors expect great things… but, reasonable approaches usually work

CMS Expects You're Monitoring

- Number of levels for monitoring, in order of difficulty
  - DIR reporting validation
  - Detailed review or sample of PDEs to claims
  - Ongoing claim to PDE to "live DIR" comparison
- Strike the right balance between:
  - What you can and should monitor
  - What your PBM allows you to monitor

Monitoring Recommendations DIR to Rebate reconciliation

In partnership with your PBM:

- Clearly understand your contract and how your rebate program will be administered
- Obtain routine detail level rebate reports ideally at member and NDC level reporting with markers for PBP (plan benefit package).
- Request and review a reconciliation report that "bridges" the amount submitted in DIR to the rebate amount received by the plan.
- Develop (and document) a detailed process that includes an annual reconciliation in advance of DIR submission to CMS. Document your execution of this process annually.
- *Note*: Ensure your auditor has latest submitted DIR from HPMS along with the most updated DIR reporting requirements for that plan year!

Monitoring Recommendations PBM Oversight of PDE Adjudication

- Increase the frequency of error review from once per month to every 2 weeks to align with the PBM submission schedule
- Ensure the PBM provides a detailed PDE report that includes the acceptance rate by error code and a break out of PDEs by age
- Implement a monthly PDE call with your PBM
- Monitor aging and escalate within the PBM for PDEs older than 60 days
- Audit and monitor of PDE origin (including proof of pick up and original script)

CMS Expects You're Auditing

- Couple of different levels to audit, in order of difficulty
  - Verify guarantees achieved
  - Independent recalculation of rebates due (onsite audit)
- CMS expects direct copies of reports

Auditing Recommendations Verifying Guarantees

- 100% of eligible rebates *probably* should be passed through
- Challenges:
  - Guarantee calculated on 100% of total claims vs. rebate-eligible claims
  - Reporting (and guarantees) might be per-formulary, and even per-benefit
  - Third-party "aggregators" might prevent you from seeing all the details

Auditing Recommendations Onsite Recalculation of Rebates

- Review of PBM ⇔ Pharma agreements
  - Independent recalculation of rebates due to your plan
  - 60% typical error rate; findings can be in the millions of dollars
- Challenges:
  - How many manufacturers can be reviewed
  - Who can conduct the audit
  - How far back can you review
  - What happens in the case of overpayment to the Sponsor

Areas for a Deeper Dive

There are other areas CMS might (should?) review

- 340B
- Rebate-eligible or rebate-ineligible drugs
- Inconsistent guidance interpretation decisions Sponsors (or PBMs!) make

Areas for a Deeper Dive

340B

- Agreements between manufacturers and the PBM may define 340B-eligible claims (i.e., and not eligible for rebates) at the pharmacy level…
  - Not really how 340B works!
- Those pharmacy-level lists might not be tailored to how pharmacies operate in your service area, even though your pharmacy network arrangements probably are tailored to your service area

Areas for a Deeper Dive

Rebate-eligible vs. ineligible drugs

- Can depend on Part B vs. Part D status, but your PBM's rebate processes might not factor in claim-specific B vs. D determinations
- Alternatively, might depend on how the pharmacy submitted the claim (invalid/old NDC, or maybe pharma contract hasn't been updated to include new NDCs or erroneously omitted valid NDCs, etc.)
- An error on a single claim can be a lot of money…

Areas for a Deeper Dive

Complex DIR allocation rules

- Every PBM, and sometimes every Sponsor, has different interpretation of CMS rules… and no one wants to change a process until CMS directly intervenes
- Example: Suppose arrangement is the PBM passes through 100% of rebates to a Sponsor. Suppose, at the time of DIR reporting, the PBM has received rebates, but has not yet disbursed to the Sponsor. Where should they be reported?
  - DIR Field #1 – "received and not passed through to the Sponsor"?
  - DIR Field #3 – "received and passed through to the Sponsor"?

Areas for a Deeper Dive

- A number of other areas we haven't even begun to touch on…
  - Rebates from medical claims (i.e., "j-code" claims)
  - Contingency rebates
  - Eligibility and how it affects rebates

Key Takeaways

- CMS may penalize Sponsors in 2017 based on 1/3 audit results
- Don't postpone auditing and monitoring
- Common areas you should "shore up" before CMS arrives
  - Financial controls
  - Auditing and monitoring for errors between PDEs/Claims/DIR
- There are some deeper areas CMS could dig into
  - 340B
  - DIR reporting complexities
  - Claim inclusions/exclusions

Questions

Questions? Comments?

Contact Us

Derek Frye, CISA, MBA

Practice Leader, Audit and Compliance

651-389-5673

dfrye@burchfieldgroup.com

The Burchfield Group, Inc.

Sonya Henderson, CHC

Senior Vice President, Corporate Compliance and Government Programs

512-257-6266

SHenderson@firstcare.com

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