

Deep Dive on DIR

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

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Introductions



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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



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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



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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!



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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)



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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



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