White Paper:

The Case for Auditing Your Pharmacy Benefit Manager

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THE PROBLEM

Pharmacy costs can range from 10% to 20% of total health care expenditures depending on your beneficiaries' demographics. For busy benefit plan administrators, the decision to not allocate your limited budget to audit your pharmaceutical benefit is likely influenced by the relative cost of your medical benefit. However, a small error in implementing pharmacy claim pricing can quickly amount to substantial overcharges. Unlike medical claims, an error with pharmacy claim pricing can affect every claim until the fault is found and corrected.

Even if you have a pass-through pricing arrangement where your Pharmacy Benefit Manager (PBM) should not take any spread on your pharmacy claims, an honest mistake on the PBM's part in implementing your pricing can still occur and inflate your costs. Although pricing errors often result in the most significant overcharges, mistakes routinely occur within the benefit implementation, formulary administration and even within standard claim edits and controls. A review of these elements should not be disregarded.

If you are a Medicare plan sponsor, then you know the onus is on you to self-audit according to Medicare requirements. You do not want a CMS audit to reveal any weaknesses in the implementation or thoroughness of your self-audit procedures. You want to confirm your claims are adjudicating correctly and avoid having to address a CMS issues Corrective Action Plan.

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THE EFFECT

There are many elements to the adjudication of a pharmacy claim, any of which can have errors. To illustrate how one small error can compound quickly, consider an example where an average wholesale price (AWP) discount is averaging 1% below the negotiated rate for brands and 3% for generics. This scenario is for a medium size employer of 2,000 who is self-funding their pharmacy benefit.

Employees	2,000
Covered Lives (2.56 persons per household)[iii]	5,120
Annual Prescriptions (12.0 Rxs per life per year)[iv]	61,440
Annual Pharmacy Spend ($911.33 per life per year)[v]	$4,666,010

Brand Rxs (34.9% of total Rxs)[vi]	21,443
Brand Ingredient Cost per Rx[vii]	$148.40
Total Brand Average Wholesale Price	$3,743,619
Actual Brand Ingredient Cost (15% Discount)	$3,182,076
Contracted Brand Ingredient Cost (16% Discount)[viii]	$3,144,640
Brand Ingredient Cost Discrepancy	**$37,436**

Generic Rxs (65.1% of total Rxs)[vi]	39,997
Generic Ingredient Cost per Rx[vii]	$37.10
Total Generic Average Wholesale Price	$3,905,013
Actual Generic Ingredient Cost (62% Discount)	$1,483,905
Contracted Generic Ingredient Cost (65% Discount)[viii]	$1,366,755
Generic Ingredient Cost Discrepancy	**$117,150**

Total Pricing Discrepancy	**$154,587**

This example is linear; therefore it can be applied to different size plans. A group with 6,000 lives would see a $450,000 discrepancy for the same error.

For Medicare plan sponsors, CMS discovering an error in your pricing that spans past calendar years results in a reporting nightmare. Every claim, Prescription Drug Event (PDE) record and all reports to CMS on cost of operations will have to be restated and resubmitted. Tracking down and reimbursing members may also have to occur.

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BACKGROUND

PRICING

"What else can go wrong?"

Negotiating a PBM contract with precise language and progressive pricing takes time and experience. Although you have a signed contract, there is no assurance all aspects have been implemented. The more your contract terms differ from the PBM's standard operating procedures, the more likely that those terms have not been implemented. The following highlights areas where oversights are commonly made.

LOWEST OF PRICING

The majority of pharmacy claims are priced as a discount off of AWP published by a national pricing source or, for generic products, as a set maximum allowable cost (MAC) created by the PBM. However, PBMs can also take into account two claim costs submitted by the pharmacy; "usual and customary" (U&C) which is their retail price and "pharmacy submitted cost" which is the amount the pharmacy is requesting for payment. The PBM compares all costs applicable to a claim and chooses the lowest. This is an element in pricing that often goes ignored by plan sponsors after their PBM contract is signed. Although PBMs often produce reports on your average pricing, those reports do not reveal if you are receiving the lowest cost available on every claim. A lowest of pricing provision can reduce your average AWP discount by up to 1%. In the example above, 1% of AWP is $61,142.

GENERIC PRICING GUARANTEES

Prescription drugs with generic versions made by more than one generic manufacturer typically are priced according to a MAC list. These lists are created and maintained by the PBM who solely dictates which products are included and at what price. Close monitoring by the PBM is necessary to maintain the correct overall discount as your anticipated mix and volume of generic drugs may change.

PBMs maintain more than one MAC list and apply different lists to different customers and different pharmacies. **It is not uncommon for the PBM to modify these lists on a daily basis to ensure not only that they are meeting their pricing guarantees, but that they are not exceeding their pricing guarantees.** Spread on generic pricing is a large revenue source for PBMs. As such, it is imperative that any overall AWP discount guarantees you have for your generic claims are verified.

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What is considered a generic drug is subject to interpretation and debate. A multi-source brand product claim submitted with a Dispensed As Written (DAW) code of 5 should price as a generic despite the brand product being dispensed. Generics with a trademarked name can also price as a brand or a generic. Products with patent litigation issues, production issues, or within the 180-day period of exclusive marketing for being the first generic maker are commonly excluded from any pricing guarantees. But, products can be excluded from the aggregate pricing calculations longer than appropriate. An audit can reveal if all generic product claims have been included in the PBM's reporting of your overall generic or MAC rates.

ADMINISTRATIVE FEES

Determining if the per-claim administrative fee is accurate goes beyond just verifying the rate charged. These fees can be charged for each claim transaction or for final paid claims only. If your contract states these fees are charged per transaction, then you are likely getting charged for every reversal and rejection as well. Even if your contract clearly states that you are to get charged for paid claims only, you may be surprised by how paid claims are being defined. In a situation where a pharmacist has to correct a claim, three transactions are produced; the original paid, the reversal, and the resubmitted paid claim. You may be paying for an extra two of these transactions rather than the final paid claim.

SPECIALTY PHARMACEUTICALS

Specialty Pharmaceuticals have become a big player in overall pharmacy benefit costs in recent years. The cost and use of these products are increasing at a significant rate. In 2009, specialty drug costs **increased 19.5%** PMPY from 2008[v]. All of the large PBMs own their own specialty pharmacies and dictate AWP discounts to their customers, typically on a drug- by-drug basis. Often these rates should be applied to retail networks, but are either never implemented or not updated when the rates change at the specialty pharmacies. Almost all specialty products are expensive, often by definition[i]. Many cost in excess of $1,000 per month, increasing the magnitude of a seemingly small AWP discount error.

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REBATES

You may feel you have ensured you are getting all of the rebate revenue due to you if you have negotiated a 100% pass through of rebates. But, is your true-up happening before all funds have been received for the year? Even waiting 180 days after year end may still leave large sums of money outstanding if the PBM is in dispute over payment from one of the top-paying manufacturers. Having a set date for final settlement can actually result in lost revenue.

An onsite audit at the PBM is necessary to verify the accuracy of the rebate invoicing. Especially if you are using a custom formulary, it is not uncommon for communication to the PBM's rebate department to be lacking. If your formulary favors products not on the PBM's formulary, and this is not conveyed to the rebate department, your claims will be left out of their rebate invoicing and your earned rebates left unclaimed. This commonly occurs when routine updates to your formulary affect rebate-earning drugs.

There was a time when any clinical edits were considered disadvantaging activity and manufacturers would not pay rebates for products with edits like a quantity limit, prior authorization (PA) or step therapy. With the increased use of step therapy and other edits, rebate contracts have become more complex in detailing which edits are allowed. This is another area where mistakes can occur in leaving out rebate-eligible claims.

For Medicare plan sponsors, all manufacturer revenue must be reported to CMS in the Direct and Indirect Remuneration (DIR) report. CMS is recommending that plan sponsors perform audits of their rebates to ensure all DIR has been reported. CMS's description of DIR includes all discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, and other price concessions or similar benefits from manufacturers, pharmacies or similar entities. Many of these types of funding and revenue were not traditionally reported back to clients by PBMs so it is prudent to verify they have updated their procedures to capture all remuneration as defined by CMS.

BENEFIT DESIGN AND FORMULARY

PATIENT PAY

Overcharges on member copays and coinsurance are often caught by the patients themselves and reported to the call center. However, undercharges go largely unreported by patients. Some examples of factors causing erroneous patient pays include incorrect tier assignments, day supply multipliers, DAW codes, and inaccurate accumulators such as deductibles and max-out-of-pocket. Reversing

transactions disorder accumulators, often allowing members to avoid deductibles or reach their out of pocket maximums too early.

Even coinsurance, where the member pays a flat percentage of the total claim cost, can be implemented incorrectly. The total cost of the claim is normally made up of three parts; ingredient cost, dispensing fee and sales tax. Copay differentials, pharmacy incentives and other charges may also apply. Rebates can also be deducted at point of sale, lowering the final claim cost. It is easy to see how a PBM could miss including all of these fields from the coinsurance calculation.

You may have negotiated "lowest of" pricing, but are your members paying the lowest possible price? A zero balance claim refers to when the member's copay covers the cost of the claim and there is no balance left to bill to the insurer. Typically the copay logic applied is the lesser of U&C or the member's copay. That might seem like a good deal for the patient, however, most often these low-cost claims are for generic products on the MAC list. Some of these products cost just pennies per unit. In almost all cases, the MAC price or even the negotiated AWP discount is less than U&C and the flat copay. The higher your generic copay, the more likely this scenario is occurring. Even if you have instructed your PBM to allow your members to benefit from paying the lowest cost for the claim, it is not uncommon to find that was not implemented.

EXCLUDED PRODUCTS

If you are using the PBM's definition of your exclusion categories, you may be surprised by what drugs and devices are being covered. Although PBMs often tout their cost-saving abilities, the fact is they make money by adjudicating claims. As such, their interests do not lie in restricting claims from being paid. One area where this can be seen is in their clinical definitions of what is a cosmetic drug.

Hydroquinone is a skin bleacher typically used cosmetically to reduce age spots, acne scars, freckles and to lighten skin in Asian and African populations for cosmetic reasons. However, because it can be used to treat vitiligo, a disease causing depigmentation of the skin, some PBMs do not routinely consider this a cosmetic product and do not include it with their cosmetic exclusions. Another example is testosterone gel which is a legitimate treatment for men with abnormally low testosterone levels and to

treat AIDS wasting in men with HIV. However, this product is often abused by body builders and athletes looking to artificially augment their muscle growth. The brand versions of this gel can cost about $300 a month. These are just two examples of products with good potential for misuse that may not be excluded by your PBM.

CLINICAL EDITS

A prior authorization not being implemented may be easy to spot, but the intricacies of other edits are not as easy to detect. Many PBM's default parameters for a refill-too-soon (RTS) edit require the previous claim to have the same prescription number and/or the same national drug code (NDC). This means when a patient brings in a replacement for an expired prescription, or the pharmacy stocks a new brand or package size of a medication, the RTS edit does not hit. A step therapy (ST) can be circumvented by processing a claim for the previous therapy on the same day. The pharmacist may even reverse the claim for the previous therapy once the target drug claim gets approved.

Quantity limits are a popular utilization management tool, but can be tricky to code. Billing unit is not consistent from product to product. For example, a Pulmicort inhaler has a billing unit of one (1) for each inhaler but an Albuterol inhaler has a billing unit of 17 which represents the number of grams of product in each inhaler. This can make coding quantity limits tricky if the PBM staff is not experienced. Imitrex is a product which commonly has a quantity limit. The billing unit for one vial of Imitrex is 0.5, however it is not uncommon for a PBM to implement the limit as 1 which allows two vials to go through every fill.

There may also be unintended consequences of an edit incorrectly coded. If you have products that require both a PA and have a quantity limit, processing the PA may nullify the quantity limit edit. Sometimes a PA can cause the copay to drop down a tier. Another alarming situation is when inputting a compound code allows any drug to be filled. And, do you know if a pharmacist can overwrite your edits by inputting a certain code for any claim? That situation occurs regularly.

EVERYTHING ELSE

These are examples of the more common findings, but there are many other aspects to your PBM contract and your benefit that need oversight. Performance guarantees, retail pharmacy auditing, fraud, waste and abuse oversight and member eligibility are all additional areas of vulnerability. Medicare plans also need to verify the PBM is meeting the Medicare requirements for the functions they have delegated to the PBM.

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Mistakes may not be PBM's fault. Bad or outdated information may have been passed to the PBM during the initial implementation of the benefit. The implications of the various choices available for claim edit parameters are often misunderstood by plans until the consequences are reviewed by an audit firm. The adjudication of pharmacy claims is intricate which allows for much vulnerability.

MISGUIDED COMPLACENCY

MY PBM HAS A SAS 70

One may site the fact that their PBM has a SAS 70 performed each year as a reason not to audit. These audits do not ensure your particular benefit or pricing was implemented correctly. Having good policies and procedures in place is not a guarantee that PBM employees have followed them properly or used them to test your claims.

"But I do not need to audit because…"

MY HEALTH INSURER IS AUDITING THE PBM

If your pharmacy is bundled with your health benefits, you cannot assume the health plan is conducting thorough audits. If you are a smaller plan then chances are none of your claims were part of the sample reviewed. If your health plan is not at risk for your pharmacy costs, they are not motivated to allocate funds to a comprehensive audit of the PBM. Plus, many health plans make money off of the pharmacy claims by adding an additional percentage to each claim.

I HAVE HAD AN AUDIT PERFORMED IN THE PAST

Even if you have performed an audit within the last few years, any changes to your pricing or benefit need to be verified. Everyone experienced changes in their AWP discounts in 2009 in response to the AWP rollback[ii]. To make the most of your audit budget, target the audit scope to only areas with changes.

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SOLUTION

An audit of 100% of your pharmacy claims is the best way to ensure your claims are adjudicating properly. Plans that schedule annual audits find that the number of issues reduce significantly each year and are often eliminated completely. A proactive approach like this ensures your CMS reporting will not have to be restated.

If your budget is limited, you can work with a firm to develop a comprehensive multi-year strategy that reviews different contract areas each year.

HOW DO I SELECT A QUALITY AUDIT FIRM?

EXPERIENCE

A quality compliance audit of a PBM can only be performed by a firm with a seasoned staff experienced in pharmacy claim adjudication. A thorough knowledge of the PBM industry and its history is needed to understand the implications of the claims being reviewed. Conversely, normal PBM operations may look suspicious to someone outside the industry who will waste time chasing unsupportable findings. The cost of the audit increases if time spent by you and the PBM is needlessly lengthened by auditors that are not knowledgeable, efficient and prepared.

The pharmacy and PBM industry is constantly changing and firms not dedicated to PBM auditing are unlikely to keep up with the latest issues and trends. Pricing models vary greatly from one client to another and between PBMs, so even a firm having completed several audits is unlikely to be familiar with the variance of typical business operations between PBMs. As these are compliance reviews and not financial audits subject to accounting standards, an accounting background is unnecessary. Knowledge of the industry is what is essential.

TECHNOLOGY

Receiving accurate and complete claims data is the heart of a PBM compliance audit. If the data received is bad, incomplete, or loaded incorrectly then the audit results are worthless. The PBM's pharmacy claim record itself contains hundreds of fields and not requesting the right fields can compromise and even invalidate audit findings. The firm you select should have a dedicated data staff

with experience loading pharmacy claims data and a tested process for validating the data received before the audit process begins. You should also verify that it has the space and resources to handle the size of your claims data.

As a Business Associate, the audit firm selected must comply with all HIPAA requirements, including HITECH standards, to ensure the confidentiality of Protected Health Information (PHI). A demonstrated knowledge of HIPAA should be verified as well as the training of all staff in HIPAA requirements. A Business Associate agreement must also be in place before the audit process begins.

The audit process used by the firm should be able to replicate the key areas of claim adjudication being reviewed. Pricing should be verified with an independent source such as Medi-Span or First DataBank to ensure the AWP or WAC applied by the PBM was accurate. The independent source should also be used to verify the brand or generic status of the NDC dispensed. Claim edits such as quantity limits and PA requirements, copays, deductibles and other accumulators all should be independently applied by the auditor to ensure the PBM's application of the benefit was correct.

INTEGRITY

Auditor independence should be verified. Many firms offering PBM compliance auditing also offer PBM sourcing and other consulting services. PBMs are often reluctant to share certain information with these firms because of their consulting work. The PBM's consider it unfair for the firm to use information gained during an audit for a PBM sourcing engagement. Because of this, access to perform rebate and other audit scope items may be denied by the PBM.

Some firms that perform PBM sourcing are paid a fee by the PBM ultimately selected during the RFP process. This monetary relationship with the PBM could influence which audit results get reported to you. Additionally, a firm that helped negotiate a PBM contract may not be eager to reveal any weaknesses in the language they approved that gets discovered when they perform an audit. The implications of the audit firm's previous work for your plan and any compensation they receive from PBM's should be thoroughly appraised.

COMPENSATION

Although many medical claims auditors work on a contingency basis, that model does not work well in pharmacy claim auditing. While perhaps the most readily apparent benefit of an audit would be an immediate discovery of overpayments, an equally valuable outcome is the possibility of future savings based on improvements to less than optimal contract wording. The issues exposed in a PBM compliance audit regularly result in a dispute over interpretation of contract language. Scheduling regular audits

will likely result in fewer and fewer recoveries each year. The ultimate goal is to eliminate errors from occurring. A firm working on contingency could be inclined to report unrecoverable findings in order to cover its own expenses. This is a situation to be avoided as it often leads to litigation.

CONCLUSION

Small errors in pricing, formulary implementation, and benefit design add up quickly to substantial increases in your pharmacy benefit costs. Incorporating a compliance audit of your Pharmacy Benefit Manager as part of your overall audit strategy is the most effective way to uncover errors and minimize costly oversights. In addition to recoveries, some of the most important findings will yield future cost savings through improvements in system edits and contract wording. Select a firm with a department dedicated to PBM auditing, demonstrated independence, and sufficient system capabilities.

[i] CMS allows only products with costs in excess of $600 per month be placed on the specialty copay tier of a Medicare plan sponsor's formulary.
[ii] A class action lawsuit against First DataBank and Medi-Span resulted in these companies reducing their published AWP on approximately 23,000 NDCs effective September 26, 2009. To keep pharmacy reimbursements neutral, PBMs reduced their AWP discounts to both clients and pharmacies.
[iii] US Census Bureau, 2009
[iv] Kaiser State Health Facts, 2009.
[v] Express Scripts, 2010.
[vi] Generic Dispensing Rate, CVS/Caremark, 2010.
[vii] Kaiser Family Foundation, 2010.
[viii] OIG Report, *Medicare Part D Pharmacy Discounts for 2008*, 2010.