

White Paper

Deconstructing Managed Care Rebate Processing Challenges

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Introduction

Managed Care rebate contracting between Pharmacy Benefit Mangers (PBM) and drug manufacturers is constantly changing to keep pace with shifting market dynamics. Continuous pressure from government, consolidations within PBMs, patent cliff, and the availability of more generic drugs in the industry have led to a focus on reducing costs from both sides. As a result, contracting strategies between manufacturers and PBMs are becoming more complex and payment terms are more aggressive. Although current industry revenue management systems have flexibility to process most rebate scenarios, manufacturers are facing increased pressure to operate around calculation variations both efficiently and accurately — with or without automated functionality.

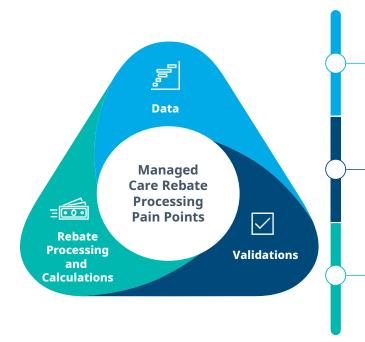
Before examining this topic, it is important to note that rebate processing steps vary considerably based on the data source. With the push to make prices more affordable to patients, Managed Care contracting has expanded to offer discounts on drugs typically administered under medical benefit coverage. These claims are usually submitted in different formats and with varying data elements. For this discussion, the focus will be on the developments in contracting for traditional pharmacy benefit utilization.

The challenges and scenarios shared in this article are based on the IQVIA Global Pricing & Contracting (GPC) team's experience in handling the obstacles that arise when working on a multitude of Managed Care engagements ranging from system assessments, full scale implementations, and production support, to collaborative efforts for developing solutions, processes, and system customs for unmet client needs in the areas outlined below. Through working with a wide range of manufacturers, it has been observed that most Managed Care pain points are found within the standard workflow of scrubbing, validating, and calculating rebate payments. The pain points discussed are grouped into the following topics:

- 1. Data challenges
- 2. Validation challenges
- 3. Rebate processing and calculation challenges



Many of the Managed Care pain points exist in the standard workflow for rebate processing. Summarized below are the common challenges faced by manufacturers. Determining a solution for each problem area will be unique to a manufacturer's requirements, technologies, and use cases.



Data challenges

- Unexpected file formats for submitted utilization and market share data typically require pre-processing before it can be loaded into a script scrubber system.
- Complex PBM rebate terms will require additional data formatting and research on records submitted to ensure accurate payments.

Validation challenges

- Contract terms and PBM requirements attribute to complex validation setups and create gaps for current script scrubber tools.
- Difficulty exists in flagging Puerto Rico scripts which is needed to avoid miscalculations with government pricing.
- No current script scrubber validation for ineligible plan/product combinations.

Rebate processing and calculations challenges

- Retroactive contract changes affect the amount of rework needed for rebate processing.
- No simple way to reprocess a subset of scripts in the event of formulary adjustments.
- Intricate price protection setups create issues for current systems.
- · Aggressive payment terms increase the risk of late fees.

Data challenges

One of the most challenging areas of Managed Care rebate processing occurs at the very beginning of the workflow – the receipt of claim data from a PBM. Although industry standards do exist for utilization data submissions, there are many variables that dictate special handling or pre-processing before it can be loaded into a scrubbing system. Some of these differences are expected because of contract terms, but others are related to the PBM's system and their preferences. In any event, an analyst will need to understand the data and may see any of the following scenarios:

New or unexpected formats

Submitted utilization files can be sent in new formats that do not follow the standard fields defined in the National Council for Prescription Drug Programs (NCPDP) format. PBMs can use different versions of the NCPDP format or decide to use their own conceived layouts which could be unfamiliar to the manufacturer. They are also prone to change formats as they merge or contract out their rebate adjudication process. Format changes usually do not come with an advanced notice or explanation of the updates. These unexpected formats are typically not caught until there is a failure in loading the data or when incorrect rebate calculations are made. Analysis is then required to verify the correct data fields and to edit a mapping set as needed. This can be a time-consuming process due to the lack of supplementary information and the fact that most utilization files are large data sets.

Multiple rebate files

A rebate period may include multiple files in its utilization submission. Although there can be valid reasons to submit and process separate rebate files, this situation usually requires some pre-processing outside of systems. The most challenging scenario is when a PBM submits overlapping data in multiple files. To comply with rebate terms, manufacturers are forced to create a merged file that combines the invoiced amounts from each so the full amount due/paid can be reconciled at a script level. Issues can arise easily since the two files are not necessarily identical, so additional tools and technical expertise are required to automate the process. PBMs also submit data in multiple files to separate adjustments to previous invoices. Depending on the script scrubber used, preprocessing may then be needed to create a single file.

Market share data files

Competitor data tends to pose challenges or create additional work because of the format and volume. If that data is needed to calculate performance rebates, it is critical to validate that the competitor-submitted data is correct and complete. Market Share (performance) strategies are less common these days, but that does not diminish the interest in this data for analytics. There continues to be a push to load competitor data into revenue management systems so it can be organized according to contract terms. Regardless of the end use for competitor data, there tend to be complications to overcome before it can be loaded and processed. Sometimes this involves formatting files prior to import, and other times it requires separate file layouts. Another recent challenge is getting the competitor data submitted in a consumable format. Some large PBMs refuse to submit Market Share files, pointing to the information provided in their data portals to satisfy contract terms.

Complex rebate terms/Multiple rates

There are scenarios that require more prework on the claim data due to PBM-specific rebate requirements and the associated fees. The complexity is due to how some of the bigger PBMs are structured. For example, a single plan can have several sub members and each of those members can earn different rebate rates. To bucket the lines in a revenue management system appropriately, additional data fields need to be identified. Sometimes, multiple fields are mapped and concatenated so the right rebate/fee is paid. Another common scenario is related to value-based or outcomebased rebates to provide an additional discount on a subset of previously paid utilization. In these cases, the period of evaluation is usually long (i.e., a full year of compliance), and manufacturers need to ensure that the sales are not doubled and that the scripts passed initial validations.

These variations require thorough understanding of a contract's terms, research on the records submitted, and different data formatting for each PBM. As PBMs continue to merge and grow, the issue with rebate terms will continue to be a problematic area for manufacturers.



Validation challenges

When manufacturers receive rebate invoices and load utilization data into their system, the next key step is validation of the raw data. This is an integral part of the process since it ensures that the calculations are correct and the data is eligible for rebates. To accomplish this, script validation applications must be configured appropriately to align with the contract terms, but also have the flexibility to account for nuances specific to each PBM. For the purposes of this document, we have identified three common scenarios to review since they have proven to be difficult for script scrubber tools.

Through IQVIA GPC's work with various manufacturers, we have determined most of the validation challenges can be handled if the proper planning is in place. Work-arounds and specific configurations can be set up with the support of subject matter experts in the system tools. Out-ofthe box functionality for script scrubbers and revenue management systems are still evolving to capture business needs, but we have seen a trend towards custom requests to meet the validation gaps. Consistently raising the issue of these validation challenges increases the chances of these features becoming part of standard out-of-the-box functionality for script scrubber tools.

Validation set up

Before validation of the received claims begin, configurations must be done to ensure the data is

scrubbed per the contract terms. This may be perceived as a simple first step, however the amount of validation set-up and complexity correspond to the contract and PBM. Contracts terms can differ greatly between PBMs, which can impact the time and expertise needed to correctly set up the validations required. Differences between contracts can exist in the number of backbill periods required, and depending on the script scrubber used, those differences may involve multiple validation configurations to cover what is required per PBM. Varying contract terms can also determine if Puerto Rico scripts need to be included or excluded in a claim. These details require not just a clear understanding of the contract, but how the scrubber system must be configured, including any system limitations if workarounds need to be created to meet this requirement. With more intricate set-ups, there is then greater awareness around which validations to select when processing claims.

Another important aspect of validation set-up are the requirements behind 340B claims. Manufacturers reference different internal and external sources for scrubbing out 340B duplicate discounts to ensure claims are not paid out twice. Currently available tools only allow a specific source of data to be used for 340B validations. This limits manufacturers' options for utilizing other data sources to maximize their ability for scrubbing 340B data. Therefore, the validation set up for 340B becomes more involved and will usually require customizations to a script scrubber system.



Validations for Puerto Rico scripts

Validating scripts for plans originating in U.S. territories, most often Puerto Rico, require special consideration. Typically, the effort is focused on configuring a validation to flag and exclude Puerto Rico scripts to avoid issues with government calculations. However, recently there has been a change in rules for some government calculations and PBMs are negotiating contracts in which Puerto Rico lines may be included in a claim. The new pain point that arises from this scenario is if the product has its own Puerto Rico Department of Consumer Affairs Wholesale Acquisition Cost (PR DACO WAC) that differs from the U.S. WAC. Although the Puerto Rico claims would be allowed, those with a different WAC would still need to be flagged to calculate the correct rebate amount and avoid issues with government best price calculations. It has proven difficult to flag and group Puerto Rico lines without relying on the PBM to submit additional information to clearly identify Puerto Rico scripts.

Validating plan and product combinations

When a rebate claim contains an ineligible plan and product combination based off the contract, the current script scrubber validation logic verifies if that plan and product exist separately in master data. This means if both the plan and product are found in the master data, the combination will pass through the script scrubber as eligible, even though it is not an eligible claim per the contract. Once the submission is created, validations in the revenue management system will usually catch ineligible plan and product combinations. However, the late timing is not an ideal solution. Ineligible claim data should be caught as early in the scrubbing process as possible, prior to creating the rebate submission, to allow for contract updates and to reduce the risk of paying on ineligible claims. Additionally, this current workflow places the script scrubber and revenue management systems out of sync with each other. The script scrubber maintains the ineligible lines of data as valid while revenue management systems exclude them, leading to discrepancies in the reconciliation. Having two systems that house out-of-sync utilization data can cause compliance and reconciliation issues as well as complicate processing of future adjustment claims.

Rebate processing and calculation challenges

After the claim data has been received and validated, challenges persist into the final phase of rebate processing. Changes to a contract and payment adjustments occur and calculation complexities exist. Handling the rebate processing and calculation challenges can be time consuming. Manufacturers face a time constraint from the time they receive the invoice until when the payment is due, so they are constantly under pressure to quickly remedy errors and meet deadlines.

Contract changes

Changes to contract terms are a normal occurrence and if handled proactively, are manageable, albeit time consuming. It is when contract changes are retroactive that it affects the amount of rework required to process rebates. Retroactive contract changes have become the new normal as it is taking longer to finalize a renewal contract. The increased processing times can be attributed to both parties having more difficulty finding middle ground when negotiating contract terms. Both sides feel pressure to reduce costs, but manufacturers are being left with less leverage as bigger PBMs have more negotiating power.

Formulary adjustments

Managed Care plans can switch from one formulary to another or remove/add restrictions that affect rebate eligibility. If the change is discovered after the rebate for a period is paid, it can require manual work depending on the system and PBM. For example, some PBMs may not have the system capabilities to send a reversal/ rebill script, while others do and frequently move scripts from one rebate bucket to another. The issue is even more complicated if it takes effect mid-period. In either case, manufacturers do not have a simple way to reprocess a subset of scripts after they are initially paid and processed to reverse the lines and adjust or recoup the paid amounts. In the event of a change that does not apply to the full period, additional issues arise because scripts are summarized when sent downstream. Correcting data is always challenging since rules are in place to control manipulation of data. The approach for correcting the data may also change by scenario. Beyond changing the dollar amounts, resulting impacts to GP, reporting, and data warehouses need to be considered.

Price protection

Another complex area within Managed Care is Price Protection - negotiated rebates to cover manufacturer increases on WAC over an agreed-upon increase for a specified period. This topic alone is extensive; however, in short, Price Protection is a standard part of rebate processing, but there are numerous variations that drive different calculations. While most scenarios can be handled by revenue management systems, the ones that are intricate and unique still pose a challenge for current systems and manufacturers. If this is a topic that interests you, please refer to IQVIA's Managed Care Price Protection blog, <u>Trends in Price Protection</u>.

Payment due dates

Regarding payment due dates, we have noticed that timeframes for processing payments are getting shorter. For example, we have seen several quarterly payment terms recently be modified to monthly. The payment window is shortening, but the work required for each claim remains complex as detailed in the above scenarios. Claim analysis not only ensures accurate rebate calculations, but it is also provided to the PBM to support why claims have been approved or denied. Finding an error this late in the rebate processing stage means going back through the lengthy process to rectify the issue, so a tight deadline becomes a recurring pain point. Shorter timeframes also increase the risk of late payments which can carry a hefty penalty fee for the manufacturer.



Solutioning

Although these challenges are commonly encountered by manufacturers, there is no one-size-fits-all solution to manage every one of these pain points. Finding out what works will be dependent on each manufacturer's requirements, technologies, and use cases.

Through IQVIA GPC's extensive experience with Managed Care, solutions have been implemented that minimize manual intervention, ultimately reducing risk of inaccurate rebate payments. If you are interested in learning how IQVIA can help address your organization's Managed Care needs or answer any questions on the topics in this article, please contact Heenal Patel at <u>heenal.patel@iqvia.com</u>.

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Lauren Campbell serves as a Principal in the Global Pricing & Contracting practice at IQVIA. With over 15 years of experience in the pharmaceutical industry, she has developed expertise in commercial contracting, Managed Care rebate adjudication, discount reallocation, and compliance. Lauren's recent achievements include successful project implementations of Model N (Powered by N & Flex), vendor evaluation assessments, and advisory engagements that focus on enhancing business processes, governance, and reducing revenue leakage. Before transitioning to her consulting role, Lauren was responsible for contract development, deal analytics, and negotiation while working for a Top 3 national Payer at a prominent pharmaceutical manufacturer.



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