The Untapped Potential of Script-Level Data Validation:

Optimizing Government Prescription Drug Program Compliance

Model N

What's Happening Out There?

Pharmaceutical manufacturers have long faced challenges with revenue leakage caused by chronic inaccurate payments on rebates for both commercial and government program rebates. Managing rebating effectively and ensuring accuracy in payment execution is accomplished through properly validating rebate claims before payment – eliminating overpayments, ineligible payments, and duplicate payments.

Systems and strategies for validating claims data at the prescription level enable manufacturers to achieve maximum accuracy and recover the most revenue. But manufacturers that participate in government drug pricing programs – including Medicaid, the 340B Drug Pricing Program ('340B'), and Medicare Part D – face additional challenges, such as maintaining compliance, adapting to ever-changing requirements, and managing disputes.

Government-sponsored health care programs are continually evolving, now more than ever – and often, in real time. As a result, pharmaceutical manufacturers must consistently evaluate and analyze requirements for these programs. To ensure successful participation in government-sponsored rebate programs, manufacturers must assess their capabilities to manage program compliance and their ability to manage and execute rebate payments accurately and effectively.

Without the proper controls and strategies in place to manage program participation, manufacturers will experience serious consequences, including:

- Financial Loss
  When manufacturers are processing incorrect payments for government programs – like Medicaid and the 340B Drug Pricing Program ('340B'), not only do they face increased revenue leakage, but risk non-compliance as well, which can be accompanied by steep financial penalties. The bottom line is always at risk.

- Administrative Burden
  Manufacturers' operations around managing rebates and discounts for government programs are hindered by complex requirements. Executing rebate payments and maintaining

- High Costs
  The recent mandate in the Affordable Care Act (ACA) to supplement the Medicare Part D Coverage Gap ('Coverage Gap') further increases the financial burden on manufacturers already managing tight budgets for government programs. Manufacturers need access to data at the most detailed level to gain incremental value and savings from improved management of rebates and disputes.

The negative financial and administrative impacts are what drive manufacturers to seek improved strategies and solutions for rebate claims validation. Manufacturers must control costs of participation in government programs and streamline operations to achieve more efficient, accurate, and timely payments of rebates.

To prevent ineligible payments and recapture erroneous payments, manufacturers need automated solutions to validate eligible entities and transactions.

This e-book will identify the unique challenges faced by manufacturers participating in government rebate programs and examine what manufacturers need to streamline operations, manage disputes, and achieve and maintain program compliance. It will outline how to improve processes and increase efficiencies for three government program initiatives:

- Medicaid Drug Rebate Program
- 340B Drug Pricing Program
- Medicare Part D Coverage Gap Discount Program

Covering the Donut Hole

By participating in the Medicare Coverage Gap Discount Program, pharmaceutical manufacturers provide cost-savings directly to qualified Medicare recipients. These manufacturers offer discounts on brand-name drugs to Medicare participants who reach the coverage gap, known as the "donut hole". At the same time, the manufacturer is driving sales and revenue by expanding access to drugs for more patients.

Program requirements and guidelines can present challenges to manufacturers. Manufacturers must remit payments within narrow time frames, leaving little time to validate claims for payment, determine eligibility, and execute payments accurately.

Utilization data is often limited. Restrictions on data from participants can further hinder the ability for manufacturers to validate appropriate claims. Impending increase of eligible individuals, due in large part to an aging population, will increase the volume of discount claims and thus increase the administrative burden on manufacturers to process all claims in a timely manner. Accuracy of payments will suffer when claims validations are rushed.

The complex nature of manufacturers' business portfolio includes a wide array of branded drugs and diverse channels, which also increases the administrative burden on manufacturers to execute claims validation accurately.

If manufacturers cannot overcome these challenges, revenue dollars are wasted: the cost of a few, intermittent errors quickly snowball over time as ineligible claims continue to be paid without due diligence. Without an automated system, the process to identify erroneous payments and recapture revenue adds additional burden and cost to the manufacturer. Moreover, manufacturers also bear the burden of proof to recapture erroneous or duplicate payments from third party administrators (TPAs).

To identify and manage disputed claims, manufacturers must start by determining the following:

- Who is eligible?
- Which claims are valid?
- How can validity be proven?

THE SOLUTION?

Automated support of 340B claims can shorten the dispute cycle, enabling manufacturers to recapture revenues faster. Pharmaceutical manufacturers should seek the implementation of an automated solution for validating discount claims on prescription-level data.

A system with specific data fields and data maps will help to separate coverage gap claims from other submissions. These added data fields will also provide enhanced validation accuracy and will constitute common support criteria.

Key Functionality to Look for:

- Track and monitor submitted disputes
- Evaluate status
- Make updates to submitted claims
- View final dispositions across TPAs

How the Donut Hole is Changing

Prior to the Affordable Care Act, Medicare Part D coverage worked like this: Patients paid out-of-pocket for premiums until the $310 deductible was reached. After, the patient pays only 25% until total spending on drugs reaches $2,800 - the Donut Hole. They are now responsible for the full cost of drugs until the yearly out-of-pocket limit of $4,550 is reached. Then the patients pay a nominal amount, usually 5%.

For most patients, the donut hole presented serious financial challenges. The ACA introduced important changes to help relieve this burden.

- When patients enter the Part D donut hole, they will receive a one-time, $250 rebate check.
- Patients receive a 50% discount on brand-name drugs while in the donut hole
- In 2011, patients started to pay less and less for generic drugs in the donut hole
- In 2013, patients paid less and less for brand-name drugs in the donut hole
- By 2020, the coverage gap will be closed, meaning there will be no more “donut hole,” and patients will only pay 25% of the costs of drugs until the yearly out-of-pocket spending limit is reached.

340B Rebates: No Double Dipping!

Under the Affordable Care Act, the 340B Drug Pricing Program is growing. The ACA expands the number of entities qualified to participate and allows for use of outside, contracted pharmacies to managed 340B prescriptions.

This gets complex for manufacturers that provide discounts through rebates for drugs on commercial plans' formularies to wholesalers and pharmacies that also serve Medicaid patients. After a prescription has been paid and the rebate issued under Medicaid, the script could also be defined as a valid 340B prescription and, in theory, eligible for a 340B discount. If a discount is paid again under the 340B program, that is considered a "double dip".

When double dipping occurs, manufacturers lose revenue. To prevent revenue leakage, manufacturers must prevent issuing discounts on the same prescription under Medicaid and 340B.

THE SOLUTION?

Many manufacturers already have strategies or systems in place to ensure payments are rendered in compliance with the 340B program. But double-dipping is an added risk that many manufacturers may not have considered. They must develop cohesive approach to discern program eligibility and render payments accurately, and only one time, to avoid the double dip. With a system that will more accurately and efficiently store, manage, and provide access to standard pharmacy data.

An automated solution that leverages multiple data files and data sources for claims validation will keep track of pharmacy eligibility by type and optimize validation checks. When these files are easily integrated into the validation system, manufacturers more easily identify 340B transactions and can avoid double dipping. Moreover, a system that allows users to track changes and store a history of reliable history of changes to address potential audit requirements.

A robust automated solution will minimize instances of double payments, reducing revenue lost and eliminating administrative burden of corrective action that must be taken to recoup revenue. With these capabilities, manufacturers can realize cost- and time savings, with more efficient processing – minimizing errors, associated disputes, and back-end administrative tasks required to correct and reprocess 340B rebates.

Key Functionality to Look for:

- Import of the National Council for Prescription Drug Programs (NCPDP) Services Offered Information file
- Automated basic checks on validity of incoming data
- Definition, storage, and prioritization of data sources for pharmacy services information
- View of related pharmacy master information
- Automated and streamlined updates of information, based on most recent changes and manufacturers' prioritization

The 340B Expansion

The ACA expanded the types of hospitals eligible to participate in the program and instituted new programs for ensuring that both pharmaceutical manufacturers and covered entities comply with 340B program requirements.

For the first time, hospitals excluded from the Medicare payment system, like children's hospitals, cancer hospitals, and critical access hospitals, are eligible to participate in the 340B program. Rural referral centers and sole community hospitals will also be able to participate by meeting an adjusted set of requirements.

As many as 1,500 new hospitals are being added to the list of 340B covered entities.

Turn Up The Volume

With the large numbers of covered patients in the Medicaid program, participation is essential for pharmaceutical manufacturers' success. Manufacturers must balance the increase in sales from participation in the program by carefully managing associated costs.

Medicaid is one of the largest expenditures for manufacturers. The Office of Inspector General (OIG) estimated that Medicaid recouped between 29 and 38 percent of its expenditures for prescription drugs each year between 2006-09 from manufacturers, yielding about $8 billion yearly1.

The costs continue to rise for manufacturers. Program eligibility is set to expand every year under the ACA through 2017. Significant increases in eligibility equate to significant increases in volume of rebate claims for manufacturers to process. The potential for inaccurate payments or payments on ineligible claims gets higher with increased volume.

Plus, rebate criteria, rules, and regulations will continue to evolve. This all presents a burden to manufacturers, making it difficult to validate every claim accurately without proper tools to do so – which ultimately leads to revenue loss and failure to comply with Medicaid requirements, which can result in serious penalties.

Eligibility Expansion

Medicaid enrollment is projected to increase by 17 million covered individuals by 20221. A high level of churn is also anticipated, with 38% of individuals moving in or out more than four times between 2014-2018. Only 19% will be continually eligible over the same span.

1 Higher Rebates For Brand-Name Drugs Result In Lower Costs For Medicaid Compared To Medicare Part D," Department Of Health And Human Services, Office Of Inspector General, Aug. 2011

THE SOLUTION?

To keep erroneous payments under control, manufacturers need an advanced solution that will efficiently process all Medicaid rebate claims– to ensure on-time, accurate payments. Automated processes will enable manufacturers to clearly identify Medicaid pharmacies and transactions, apply details of script-level data, manage changes, and validate claims for payment. Manufacturers will have increased insight and clarity around transactions.

KEY FUNCTIONALITY TO LOOK FOR:

- Configurable security requirements to adjust user access as appropriate to commercial, Medicaid, or both types of transactions
- Inclusion of new fields, i.e., third party liability, dispensing fee tables
- Multiple import and export formats for improved accuracy

A Solution for Every Program

Preventing revenue leakage associated with rebate payments and maintaining compliance with government programs go hand in hand. Manufacturers must process payments for government plans efficiently and accurately.

With a specifically-targeted solution that addresses the unique demands of claims validation for government programs, manufacturers are enabled not only to prevent revenue loss but manage resolve disputes while maintaining compliance.

A SOLUTION FOR MEDICARE PART D COVERAGE GAP

- Specific data fields, data maps, and security required to help separate Coverage Gap claims from other transactions
- Script-level claims validation that supports disputes and the ability to work through the dispute process

A SOLUTION TO BETTER IDENTIFY AND VALIDATE 340B SCRIPTS

- Easy accessibility and streamlined maintenance of standard pharmacy data to discern eligibility
- Management of specific data validation requirements to render rebates accurately

A SOLUTION TO VALIDATE MEDICAID PRESCRIPTION REBATES

- Clear identification of Medicaid pharmacies and transactions
- Validations of Medicaid script data to clearly identify outliers, duplicates, and pending reversals

Revolutionizing Data Validation

NEW MODULES FOR MODEL N VALIDATA

Using Model N Validata, pharmaceutical manufacturers are now equipped to save potentially millions of dollars in rebate overpayments. Model N research has demonstrated the manufacturers are saving 3-10% of rebate exposure by:

- Performing up to 56 script-level validations on incoming line items
- Reducing errors in processing data, preventing over-paying rebates and administrative fees
- Staying current with NCPDP standards for claim detail and reconciliation formats
- Easily defining and managing multi-format incoming prescription validation files and outgoing export files using mapping sets

Now, manufacturers can leverage new modules to enhance compliance with the Medicare Part D Coverage Gap Discount Program, the 340B Drug Pricing Program, and the Medicaid Drug Rebate Program. Plus, manufacturers using the modules will gain incremental operational savings and by reducing the administrative burden of managing complex and program-specific program requirements.

MODEL N COVERAGE GAP DISPUTE lets companies track and dispute overpayments associated with Medicaid Part D "donut hole" transactions. With narrow payment windows, pharmaceutical companies need a solution to manage payments on time, and identify disputed submissions. This module addresses scrubbing script-level data, providing documented facts to support disputes, and working through the dispute resolution to return dollars faster.

MODEL N 340B VALIDATION facilitates and improves how pharmaceutical companies validate 340B-designated pharmacies and transactions, saving wasted payments to ineligible entities, which may result in resetting best price for a product and avoiding high administrative costs in managing rework and recoveries. Using the 340B designation provided by NCPDP and optionally other sources, as well as examining segment qualifier information at the script level, pharmaceutical companies can verify whether or not the transaction is 340B-eligible.

MODEL N MEDICAID SCRIPT VALIDATION supports storing and managing Medicaid pharmacy IDs using industry-standard formats. This module brings in Medicaid script-level data with flexible data formats to better flag those claims eligible for benefit coordination and those that should be flagged as invalid payments.

New rules automate validations for average rebates per unit and total reimbursement amounts to assess exposure and manage costs. With this enhanced capability, pharmaceutical manufacturers can avoid paying duplicate or ineligible submissions, as well as provide necessary supporting information for resolution of Medicaid rebates payment disputes.

About the Author

Model N is the leading provider of enterprise-class solutions for channel and contract management, on premise and in the cloud. Model N solutions enable organizations to accelerate revenue through diverse, multi-level sales channels and attain maximum value from contracts. For over 25 years, Model N has empowered companies in channel-intensive industries to achieve best-in-class performance and sustainable competitive advantage.

For more information, please visit www.modeln.com.