MEDICAID

FROM A SIMPLE CONCEPT TO AN OPERATIONAL LABYRINTH

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The federal government created Medicaid in 1965 as a public insurance program to expand existing federal support for healthcare services. It has since ballooned from its basic insurance program roots. Today, Medicaid is a vital source of financial protection for the 1 in 5 Americans who receive healthcare coverage through it. It is also arguably the most complex and demanding government program in terms of potential impact and resources for participating drug manufacturers.

HOW DOES MEDICAID OPERATE?

Federal and state governments jointly fund and operate the Medicaid program. At the federal level, Title XIX of the Social Security Act and a large body of additional regulations govern the program, defining federal Medicaid requirements and state options and authorities. The Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (HHS) division is responsible for implementing Medicaid. The federal government funds the program by paying states a specific percentage of their expenditures called the Federal Medical Assistance Percentage (FMAP), which is at least 50% and varies by state.

State governments are responsible for outlining detailed coverage guidelines within their states and managing administration operations. States establish guidelines within the federal parameters to determine eligibility and determine healthcare delivery models and methods for paying physicians and hospitals. States administer various types of programs to support patient needs including Fee-for-Service (FFS), Managed Care Organization (MCO) and various supplemental programs for groups with unique needs. Depending on how a state has chosen to support their population and segment their programs by demographic, some states may have over 30 different Medicaid programs.

DRUG PRICES AND MDRP

Prescription drug coverage is a critical component of Medicaid, as many beneficiaries rely on medications for both acute conditions and for managing ongoing chronic or debilitating conditions. In response to rising drug prices and projected increased Medicaid spending, the Medicaid Drug Rebate Program (MDRP) was created in 1990 by the Omnibus Budget Reconciliation Act (OBRA).

The MDRP program requires drug manufacturers to have a National Drug Rebate Agreement (NDRA) with HHS in exchange for state Medicaid coverage on most of the manufacturers' drugs. Drug manufacturers with outpatient drugs are required to pay quarterly rebates based on the utilization of their products by Medicaid beneficiaries to various state programs. The rebates are then shared between state and federal governments to offset the overall cost of prescription drugs under the Medicaid program.

Participation for drug manufacturers in Medicaid, and by extension MDRP, means acceptance into the United States' vast pharmaceutical dispensing network and access to a significant proportion of prescription users in the U.S. However, it does add sizable reporting, operational and financial obligations to stay in compliance.

DRUG MANUFACTURER MDRP RESPONSIBILITIES

To support Medicaid participation, drug manufacturers must complete various actions to join and stay in compliance with CMS and the MDRP. Below is a list of critical reporting, operational and financial requirements necessary to participate in the program:

☐ Obtain Access and Agreements – One-Time Setup

In addition to signing and submitting a NDRA, drug manufacturers are required to enter into additional agreements with other federal programs to have their drugs covered under Medicaid; a pricing agreement for the Section 340B Drug Pricing Program[1], administered by the Health Resources and Services Administration (HRSA), and for branded drugs, a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule (FSS)[2].

Manufacturers also need to establish access to CMS reporting systems, state portals, and the Texas Formulary to ensure Medicaid claims are processed accurately.

☐ **Calculate and Report AMPs to CMS – Ongoing Monthly and Quarterly**

Manufacturers are required to calculate and submit an Average Manufacturer Price (AMP) to CMS on a monthly and quarterly basis for each dosage form and strength of a drug sold within Medicaid. AMP is a derived value intended to reflect the average actual market price for a drug sold, net of all eligible discounts (which is typically much lower than the published Wholesale Acquisition Cost (WAC). Manufacturers can reference guidance from CMS on what sales should be included in their AMP calculations, however they must use a consistent application of reasonable assumptions and document them in Standard Operating Procedures (SOPs) in the absence of clear directives.

The AMP value is then used to derive various government pricing values including Unit Rebate Amounts (URA) and PHS/340b pricing.

☐ **Calculate and Report Best Price – Ongoing Quarterly**

Branded drug manufacturers (including authorized generic manufacturers) must report Best Price, the lowest price made available to customers, for consideration in the calculation of the Unit Rebate Amount. If the Best Price is lower than what CMS would receive for a price using the standard calculated methodology, than CMS will calculate a rebate owed based upon the difference between AMP and Best Price.

☐ **Calculate URAs – Ongoing Quarterly**

The URA (Unit Rebate Amount) is a calculated value used to determine the amount of rebates a manufacturer will owe to government entities to offset some of the cost for Medicaid. To generate the URA, manufacturers follow formulas to compute the Base URA, Inflation Penalty and ultimately the Total URA, which is then reported to CMS on a quarterly basis.

State programs compile utilization, which includes all drug claims, point-of-sale pharmacy prescriptions and medical outpatient drug claims dispensed to Medicaid patients during the prior calendar quarter. The total number of units is then multiplied by the URA (provided by CMS) for each product to calculate the total rebate amount owed by the drug manufacturer.

☐ **Process, Validate and Pay Rebates to 300+ State Medicaid Entities – Ongoing Quarterly**

At the end of each calendar quarter, over 300 Medicaid programs across various states will submit invoices to participating manufacturers for rebates due. Invoices can be downloaded from various state portals and/or mailed to manufacturers. Overall invoice volume for a manufacturer far exceeds the number of U.S. states and can vary for the following reasons:

- States issue multiple invoices to each labeler for **unique programs** that serve specific subsets of the population.
- **Participation in voluntary rebate programs** such as SPAPs, supplemental and other ancillary programs may increase the volume of invoices a manufacturer gets, as they're invoiced separately.
- States issue separate invoices for both **current quarters and past quarter utilization** and/or utilization changes. Manufacturers are required to file Reconciliations of State Invoice (ROSI) forms in response to current quarter invoices, and Prior Quarter Adjustment Statement (PQAS) forms in response to adjustments in past quarter utilization or URAs. It's important to note that there is no expiration on when states are required to stop issuing past quarter adjustments. Invoices can be added and/or adjusted going back to a drug's first quarter of sale.
- Drug manufacturers with **multiple labeler codes** will have separate invoices issued, as states issue invoices by labeler code.
- Invoice volume for a manufacturer can range widely. It is not unusual to receive 500 – 1,000+ per quarter for **high-utilization** drugs.

Prior to processing Medicaid rebate payments to various state entities, manufacturers should validate rebate amounts based on URA calculations and, if necessary, claim level detail to ensure they are paying the correct rebate amounts. While CMS has issued standard electronic formats for states to utilize, they are not universally adopted by all of Medicaid's 300+ programs resulting in many different formats. Therefore, a manufacturer will be required to review invoices in various formats, which makes the validation processes complicated and time-consuming across the multitude of states and programs.

Following validation, Medicaid rebate invoices must be processed and paid by the manufacturer within 37 calendar days after the postmarked date on the original invoice to avoid paying interest. The 37 days includes time that an invoice was in mail transit, so this can reflect a tight window with which to adjudicate invoices. Payments can, in some cases, be grouped by jointly managed programs using checks and ACH transactions in a small number of instances. With so many operational challenges to processing Medicaid rebates, manufacturers need to have strict time management and standard operating procedures in place to ensure they remain in compliance and pay accurate rebate amounts to Medicaid agencies.

☐ Research and Resolve State Rebate Invoice Discrepancies - Ongoing

Drug manufacturers also need to resolve any discrepancies that arise, including incorrect utilization on the invoices, payments not allocated correctly, and duplicate invoices received. The MDRP agreement allows pharmaceutical manufacturers to dispute claims they believe are invalid by indicating units to be disputed with the applicable CMS dispute code(s) on the ROSI or PQAS report upon payment. Manufacturers can also dispute claims retroactively. The disputes consume a tremendous amount of state and manufacturer resources to reach resolution.

Manufacturers need to have a strong knowledge of the nuances of the 300+ Medicaid programs and establish partnerships with state processing contacts to effectively resolve discrepancies.

☐ Monitor Medicaid Program Changes and Adapt SOPs as Required - Ongoing

Legislative and/or compliance changes at the federal and state level are common and require monitoring to ensure manufacturers stay in compliance and appropriately plan for operational and financial changes. Within the last year alone, broad scope changes for drug manufacturers participating in Medicaid have come from the Inflation Reduction Act and the American Rescue Plan Act.

YOUR SIMPLE SUMMARY

Participation in Medicaid is crucial for drug manufacturers wanting to have widespread access and utilization for their drugs in the United States. However, successful participation and management of the program requires drug manufacturers to diligently manage monthly, quarterly, and ongoing operational/financial requirements while keeping a keen eye on legislative changes that will impact their futures.

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