MEDICAID DRUG CLASSIFICATION: **CIVIL MONETARY PENALTIES**

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On April 18, 2019, the "Medicaid Services Investment and Accountability Act of 2019" was signed into law, bringing with it a significant change to the oversight and management of the Medicaid Drug Rebate Program (MDRP).[1,2] Effective immediately, this law enables the Center for Medicare and Medicaid Services (CMS) to impose civil monetary penalties on any manufacturer who incorrectly classifies their drugs. Manufacturers are then compelled to repay the resulting difference owed on any rebates for these products, regardless of whether the misclassification was purposely enacted. As with many of the changes to MDRP in recent years, the apparent intent is to better reimburse the states for the cost of drug coverage and close loopholes in the program's structure. While the misclassification of drugs does not appear to be an overly common issue, industry stakeholders will nonetheless want to familiarize themselves with the new law to ensure compliance and avoid the risk of incurring what could be substantial penalties.

BACKGROUND

MDRP Change History

Since its introduction via the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), the Medicaid Drug Rebate Program (MDRP) has been modified numerous times through various legislative acts. The program is intended to assist in covering the cost of medication to each state's eligible patient population. It does so by providing states with a standard reimbursement method for pharmaceutical products, similar to the way that manufacturers provide rebates for other large purchasers.[3] While this main principle has remained constant, several operational structures have been altered over the years, including changes to the rebate calculations for covered drugs, the addition of inflation penalties, and the incorporation of Medicaid Managed Care Organization (MCO) programs.[4] Since the program's inception, the reimbursement rates have been tied to certain drug categories.

Branded products, approved under a New Drug Application (NDA) or Biologics License Application (BLA) by the Food and Drug Administration (FDA), have been required to pay comparatively higher rebates than their generic counterparts. Products in this category are classified as either Single-Source ("S") or Innovator Multiple-Source ("I"). By contrast, generic products are defined as drugs approved under an Abbreviated New Drug Application (ANDA) by the FDA, and are categorized in MDRP as Non-Innovator Multiple Source ("N").

For all product categories, a standard formula is run each quarter by CMS to determine the Medicaid Unit Rebate Amount (URA), which is paid by manufacturers for all eligible utilization on covered outpatient drugs. Since 2010, the standard Medicaid Unit Rebate Amount (URA) formula for branded drugs, both "S" and "I", has been calculated as follows:[5]

Figure 1 – The chart below shows the steps necessary to calculate the URA for "S" and "I" drugs, as provided by the Center for Medicare and Medicaid Services (CMS)

Standard Unit Rebate Amount (URA) Calculation for Innovator Drugs	
1	Basic Rebate = (> of AMP * (23.1%) or AMP – BP)
2	Adjusted Baseline = (Baseline AMP / Baseline CPI-U) * Quarterly CPI-U
3	Additional Rebate = AMP – Adjusted Baseline, if AMP > Adjusted Baseline
4	Total Rebate = Basic Rebate + Additional Rebate
5	If Total Rebate > AMP, then Total Rebate reduced to = AMP
AMP = Average Manufacturer Price BP = Best Price CPI-U = Consumer Price Index Urban	

The AMP referenced in the grid above is the quarterly AMP, which is a weighted average of the three monthly AMPs reported to CMS. In addition, there are differences in the calculation for clotting factor drugs (CF), exclusively pediatric drugs (EP), and line extensions.

For most of the program's history, the URA formula was comparatively much simpler for generic products. These drugs were reimbursed at a rate 13% of AMP, without any additional rebate.[6] However, after concerns of so-called "price gouging" hit a boiling point in 2015, legislation was introduced that established inflation penalties for generic pharmaceutical products, the same as those in place for branded drugs.[7] [8] [9] The following year, CMS introduced a long-awaited "final rule" about MDRP which, among many other changes, attempted to clarify the difference between drug classifications and their reimbursement.[10] At the same time, another wave of public backlash had arisen over price hikes, this time concerning the EpiPen, which compelled lawmakers to request testimony from the manufacturer, Mylan pharmaceuticals.[11] [12] As a result of this increased scrutiny, it was noted that the EpiPen was classified as a generic product in MDRP, even though it had been marketed under an NDA.[13] [14] Consequently, rebates paid to states were at a lower rate than they would have been under a branded drug classification. While admitting no wrongdoing, Mylan agreed to a settlement with the government to correct for the difference.[15] As this scenario had been unfolding, the Office of the Inspector General (OIG) was asked by Congress to investigate the accuracy of manufacturer reported data in MDRP, the analysis which was completed by the end of 2017.[16] [17] Based on the findings of this study, which stated that a billion rebate dollars may have been lost in 2016 due to drug misclassification, Congress moved to implement a solution.[18] [19] This resulted in the inclusion of oversight powers for CMS in the aforementioned Medicaid Services Investment and Accountability Act of 2019. [20]

NEW LAW PROVISIONS

Civil Monetary Penalties

The new law states that, henceforth, manufacturers are subject to Civil Monetary Penalties (CMP) for knowingly misclassifying covered outpatient drugs. When infractions occur, the fine is set to be two times the difference between "the total amount of rebates that the manufacturer paid (and) the total amount of rebates that the manufacturer would have been required to pay." The document goes on to state that these penalties must be paid in addition to any others required by law.[1] This would include penalties under existing drug classification provisions of $100,000 for each infraction.

Figure 2 – The chart below depicts a hypothetical breakout of an originally paid rebate amount, the adjusted amount, and civil monetary penalty

Product A	URA	Units	Rebates	Difference	CMP
"I" Class	$ 34.65	100,000	$3,465,000.00	$1,515,000.00	$3,030,000.00
"N" Class	$ 19.50		$1,950,000.00		

Rebate Reimbursement

As described in the congressional summary of the bill, manufacturers are also now "required to compensate for rebates that were initially underpaid as a result of misclassification." Interestingly, while the civil monetary penalties are to be imposed only in cases where there was deliberate misclassification, it makes the point of stating that this repayment must occur "whether or not such misclassification was committed knowingly."[1] While the law does not explicitly state the protocol to be used, one may assume that OIG would investigate these claims at the behest of CMS, who would then order repayment to occur from a manufacturer.

NEXT STEPS

Considerations

While drug classifications are often clear cut, they may not be straightforward in all instances. In the OIG's report, the potentially misclassified drugs are listed as such because the categorizations are inconsistent in MDRP and FDA data. However, this discrepancy may be explainable for reasons other than ignorance or deliberate malfeasance. In the case of the EpiPen for example, the active ingredient is epinephrine, which is a non-innovator multiple source product and approved under an ANDA. However, the auto-injector device supplying this substance is a patented product, approved under an NDA.[14] In these instances, a "narrow exception" process allows for manufacturers to submit their rationale to CMS for a drug to be classified in a certain manner under MDRP. Although, as this occurs on a case-by-case basis for each drug, it is difficult to predict what will be accepted in each circumstance.

It is worth noting that the purported incidence of intentional misclassification also does not appear to be as prevalent as the legislation states. In the OIG's report, it states that manufacturers "may have misclassified a small percentage of drugs in the Medicaid rebate program."[17] Of the more than 30,000 drugs reviewed by the agency, it determined that 95% of drugs were classified correctly. Furthermore, of the 3% of drugs that were potentially misclassified, a number of manufacturers had submitted narrow exception requests that may have explained their status in the listed category.[17]

Figure 3 – The table below shows the results of the OIG analysis of Medicaid and FDA classification data for covered outpatient drugs in 2016[17]

Classification Determination	Number of Drugs	Percentage of Drugs	Medicaid Reimbursement
Appropriately Classified	28,945	95%	$58,690,484,856
Potentially Misclassified	885	3%	$813,324,981
Unable to Determine	339	1%	$139,138,150
Missing from FDA Files	300	1%	$19,049,845
Total	30,469	100%	$59,661,997,832

Recommendations

Manufacturers will want to consult with their legal counsel and government pricing teams to reexamine the classification of any covered outpatient drugs within MDRP to ensure that categorizations are accurate. For any products that are determined to be inappropriately classified, updates should be made in the CMS Drug Data Reporting (DDR) system as soon as possible. New products in development or those about to launch should be similarly scrutinized as well. This is particularly critical for products that are harder to classify, like those that have multiple active ingredients or use unique delivery mechanisms. Given the lack of specific guidance from CMS, classifications are best made on reasonable assumptions of the existing legislation. In certain circumstances, it may be warranted to file for a narrow exception with CMS in order to secure approval for a classification that may otherwise be questioned.

To maintain compliance with the regulations around government price calculation and reporting, most pharmaceutical manufacturers use a Revenue Management System (RMS) designed to operate within a given methodology. Any drug makers with products affected by the law will need to determine how their software needs to be updated to reclassify drugs and calculate any rebate change claims. For many platforms, this adjustment may constitute a simple configuration change or formula alteration, while others will require more extensive modifications. In all cases, proactive evaluation will be necessary to ensure that the system-generated values match expected results. Otherwise, manual calculations may have to be employed as a workaround for any disparities.

Further downstream, manufacturers needing to reclassify their products will also want to revise their forecasting models, accrual workbooks and price reporting, as they will likely require updates to account for additional rebate dollars incurred. Concurrently, prospective gross-to-net calculations will have to factor in the change in Medicaid rebate calculation for any affected products. In the short term, discrepancies in rebate payments will need to be incorporated into any models, and in the long term, the higher liability presented by branded drug rebates presents a more significant impact to bottom-line revenue.

Additionally, any pricing that is derivative of Medicaid rates will have to be examined as well. For example, the 340B ceiling price, used to set discounts for institutions covered under the 340B drug pricing program, is calculated as the current quarter Medicaid URA subtracted from the current quarter AMP. Consequently, 340B prices for line extension products will decrease as Medicaid URAs become higher. As a result, any Medicaid reimbursement required for a misclassified product will have to be accounted for in the 340B program as well.

Most importantly, companies should stay apprised of any forthcoming guidance from CMS around this new law, its handling of drug classification investigations, or modifications to the "narrow exception" review policy to ensure they remain compliant and can adapt their systems and processes effectively.

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Robert Blank is a managing consultant at EVERSANA, working extensively in revenue management software solutions for the pharmaceutical and medical device industries. His expertise includes Medicaid and Managed Care rebates, chargebacks, and membership management. He has developed custom client solutions around value based contracting, formulary validation, discount reallocation, and the 340B Drug Pricing Program. In his speaking engagements and published articles, Robert focuses on outlining industry trends and the impacts of legislation upon commercial operations.

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