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Client Alert

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For more information, contact:

John Shakow
+1 202 626 5523
jshakow@kslaw.com

Elizabeth Lindquist
+1 202 626 5585
elindquist@kslaw.com

David Farber
+1 202 626 2941
dfarber@kslaw.com

Brian Bohnenkamp
+1 202 626 5413
bbohnenkamp@kslaw.com

Seth Lundy
+1 202 626 2924
slundy@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

Congress Acts to Eliminate MDRP Misclassification

New Enforcement and CMPs for Drugs Improperly Claiming Noninnovator Status

President Trump on Thursday signed into law the most extensive set of amendments to the Medicaid Drug Rebate Program statute since the Affordable Care Act in 2010. The new law addresses the perception that drug manufacturers regularly mischaracterize their drugs to avoid Medicaid rebate liability. It gives the Centers for Medicare and Medicaid Services and other authorities power to unilaterally correct mischaracterizations and enforce compliance with the MDRP.

Section 6 of the "Medicaid Services Investment and Accountability Act of 2019" (that section previously known as the "Right Rebate Act," hereafter, the "Act"): subjects manufacturers that misclassify drugs to civil monetary penalties; exposes them to potential suspension from the MDRP; permits recovery of underpaid rebates due to drug category misclassification (whether made knowingly or not); gives the government the authority to require correction of misclassification; and makes technical changes to the definitions of drug category types (while preserving the "narrow exception" process). Moreover, the Act creates financial incentives for government enforcement efforts and requires public accounting of those efforts.

The Act's changes are effective immediately.

We encourage manufacturers to closely review their drug category classifications and other baseline information in the Drug Data Reporting system, and to quickly update them if necessary. This is an eight ball no one wants to get behind.

BACKGROUND

MDRP-participating manufacturers must pay a rebate to state Medicaid programs on each unit of covered outpatient drug reimbursed by a state program. The rebates due for innovator products (generally, brand-name drugs) are significantly higher than those for non-innovator drugs

(generally, generics). For instance, the minimum rebate percentage for most innovator products is 23.1%, but only 13% for noninnovator drugs.

Manufacturers self-report to CMS this innovator/noninnovator distinction in what is known as the "baseline information" for each product. There are innovator codes ("S" for "single source drug" and "I" for "innovator multiple source drug") and a noninnovator code ("N" for "noninnovator multiple source drug"). These terms are defined in the MDRP statute, regulations, and guidance.

The problem the Act purports to address is that manufacturers of "S" or "I" drugs may misclassify these products as "N" drugs, and in so doing inappropriately avoid paying the higher Medicaid rebate amount. Whether this is done intentionally, negligently, innocently, or because the terms are poorly defined in statute and regulation is a matter of debate. What is clear is that misclassification is rare, but that when it occurs, it can be costly to the Medicaid program. The HHS Office of Inspector General recently reported that "[t]he vast majority of the approximately 30,000 drugs in the Medicaid rebate program were classified appropriately," but found that 3% may have been misclassified, leading to approximately $1.3 billion in underpaid rebates over four years. *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Rebates*, OIG Report OEI-03-17-00100 (December 2017). We think this report overstates the problem. Nevertheless, as evidenced by the passage of the Act, it was persuasive.

NEW CIVIL MONETARY PENALTIES

The Act provides for new civil monetary penalties that can be levied on manufacturers of misclassified products.

Labelers that "knowingly" misclassify a covered outpatient drug will be subject to CMPs of two times the difference between (a) the total rebates they paid, and (b) the total rebates they would have been required to pay, had the drug been properly classified. As one can imagine, that delta can be quite large, particularly over many quarters and with substantial utilization. Double that could be a heavy penalty indeed (and the $100,000 per item of false information penalty that already prevails is *in addition* to this new CMP!). "Knowingly" in this context means with actual knowledge, with deliberate ignorance, or in reckless disregard of the truth. No proof of specific intent to defraud is required.

Labelers that do not knowingly misclassify, but fail to correct misclassifications when instructed to do so by the Secretary, are subject to another CMP. These recalcitrant manufacturers may have to pay 23.1% of the AMP of a misclassified drug times every unit of the drug reimbursed by a state program for as long as they fail to reclassify.

In a twist worth noting, the Act permits HHS to retain, from amounts collected under these CMP provisions, (a) its investigation, enforcement, and litigation costs; and (b) 25 percent of the total amount collected each year. Interesting incentive. These funds must be repurposed for oversight and enforcement of the MDRP.

OTHER MISCLASSIFICATION ENFORCEMENT AUTHORITY

The Act gives CMS the explicit ability to require manufacturers to pay states the "correct" rebate amount in the event of misclassification. Where the government determines that a misclassification has occurred (knowingly or otherwise), it must "notify the manufacturer of the misclassification and require the manufacturer to correct the misclassification in a timely manner."

Presumably this discovery of misclassification would occur during an OIG audit, or through CMS inquiry with the manufacturer. Perhaps OIG/CMS would initiate a misclassification inquiry if DDR and the FDA Structured Product Labeling data elements file were found to disagree as to approval type/drug category code?

"Timely manner" is not defined in the Act. CMS may put pressure on manufacturers to correct apparent misclassification by imposing the 23.1% CMPs described above, or by suspending the misclassified drug from the MDRP (blocking federal financial participation funds for the NDC) until the drug is properly classified. Additionally, CMS may "correct the

misclassification … on behalf of the manufacturer." One wonders why CMS would ever take the former two actions if the latter were available to it.

OTHER INTERESTING MDRP CHANGES IN THE ACT

In addition to the misclassification enforcement provisions described above, the Act makes several other changes to the MDRP statute that are worth considering:

- The Act "clarifies" that a drug approved under **any** NDA is an "innovator" for the purposes of rebate calculations (subject to the second bullet, below). Savvy drug pricing professionals will recall that the innovator provisions of the statute had often modified "new drug application" with variants of the word "original," adding confusion to our understanding of what constituted a single source or innovator multiple source drug. Indeed, we suspect that understandable confusion about this adjective's place in the statute led to many of the instances of supposed "misclassification" in the OIG's 2017 report.
- Recognizing that not all NDAs were created equal(ly), however, the Act preserves the "narrow exception" arrangement put in place by CMS in 2016. Manufacturers of drugs that were technically approved via NDA, but are more appropriately treated as noninnovators (*e.g.,* paper NDAs), were permitted to petition CMS for noninnovator treatment in the MDRP. To our knowledge, the vast majority of those applications, pending at CMS for over two years, have yet to be ruled upon. Nevertheless, we are relieved to see that this "narrow exception" exception was not written out of existence in this Act (as was the case when the legislation was first presented in the House earlier this year).
- The definition of "single source drug" was amended to explicitly include drugs approved via biologics license applications (BLAs). Biosimilars, approved under 351(k) BLAs, would appear, therefore, to be "S" drugs.
- The Act requires CMS to submit an annual report to Congress – which must also be made public – detailing (a) the drugs found to have been misclassified, (b) steps taken to reclassify those drugs, (c) actions CMS has taken to ensure appropriate rebate payments have been made for misclassified drugs, and (d) how money collected under the CMP provisions has been spent. One hopes that pressure to publicly report on these efforts will not cause CMS/OIG to be more aggressive than is warranted, and will not inappropriately influence any of the pending "narrow exception" applications.

CONCLUSION

This development puts manufacturers on notice that improper classification of covered outpatient drugs in Medicaid will not be tolerated, and may lead to federal enforcement actions and substantial monetary penalties. Drug makers should take immediate action to review their product masters to ensure alignment between the basis for approval (NDA (BLA)/ANDA) and internal understanding of innovator/non-innovator. They should confirm that the proper "drug category" codes for each of their NDCs are reflected in DDR. If there are discrepancies, disclose, correct, and remediate in Medicaid and 340B.

We at King & Spalding stand ready to assist you with any questions related to this Act; with any drug pricing or price reporting concerns; and with any other legal matter associated with the development, approval or marketing of a drug product.

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