Weekly Checkup

New Rules, New Concerns

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Late last weekend, the Centers for Medicare and Medicaid Services (CMS) released a collection of updates for a final rule to the Medicaid Drug Rebate Program (MDRP) – which helps offset the federal and state costs of outpatient prescription drugs dispensed to Medicaid patients – **in response to several concerns raised by industry stakeholders during the rule's comment period.** In its update, CMS opted to "decline to finalize" several of the most contentious previously proposed alterations from its original May 2023 rule – including Best Price stacking and a new definition of "manufacturer." But, of note, CMS opted to retain provisions that redefined components of "Covered Outpatient Drug[s]" (COD) and "Internal Investigation[s]," among others. **Let's review these two important term changes in the MDRP final rule to better understand their implications.**

The long-standing statutory definition of COD excludes:

> any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as (and for which payment be made under this title as part of the payment, but not a direct reimbursement) certain health care settings or situations described in section 1927(k)(3).

Historically, CMS' definition of COD has been used as a justification to prevent the issuance of rebates when a drug and service payment are bundled together – to prevent double-dipping – but CMS' updated final rule relaxes this standard by changing the definition of "direct reimbursement." Per CMS:

> In order for the drug to satisfy the COD definition [per the clarified direct reimbursement definition], the drug must be identified, the charge for the drug must be itemized on the claim form, and the payment must be consistent with the reimbursement methodology for CODs in an approved State plan…[furthermore, these requirements may] apply to drugs that are always used in the bundled services and to drugs for which this is not the case.

The important takeaway is that, in further clarifying its definition of "direct reimbursement," CMS circumvented previous language and will now allow both bundled and non-bundled drugs to receive reimbursement. **While this change does remove a significant hurdle that unnecessarily prevented some bundled drugs and services from being eligible for Medicaid rebates, there is also the concern that this new alteration could extend coverage too far in the opposite direction, resulting in a drastic increase in the number of drugs subject to Medicaid rebates**. Such a redefinition could subsequently incentivize state Medicaid programs to "game" this new provision for increased rebates. **Considering the MDRP is also used to determine if a drug is subject to 340B pricing, there are also some concerns that this new revision to COD could be the hypothetical match needed to set the 340B Program ablaze by further ballooning spending for the already massive program.**

Regarding CMS' revisions to the term "Internal Investigation," as outlined under the Social Security Act, manufacturers typically receive a 12-quarter window to make restatements (more commonly known as revisions) to one or more of their previously filed financial statements to correct errors. Outside of this official window, manufacturers can also file restatements following an "internal investigation." In its original 2023 MDRP final rule, CMS sought to restrict manufacturers' ability to file these restatements outside of the

prescribed 12-quarter window but limited the "internal investigation" clause to only apply when an investigation results in a finding by the manufacturer of fraud, abuse, or a violation of law or regulation. **With some commenters expressing concerns that this alteration punished good-faith attempts by manufacturers to comply with complicated reporting obligations and that a successful "internal investigation" could be interpreted as an admission of guilt, CMS reclarified this provision to remove any legal ramifications of a successful investigation.**

It is good that CMS altered the language in its final rule to address these legal concerns, yet this provision will still substantially reduce the number of successful restatements filed by manufacturers, potentially eroding the accuracy of pricing data moving forward. In this provision, CMS also emphasized that a change of ownership would no longer be a valid reason to file restatements outside the 12-quarter window. **This additional language will significantly impact those looking to buy or invest in manufacturing companies, requiring them to perform a high level of due diligence and to seek stronger warranty agreements before purchasing.**

While it will take time for the more significant impacts of these revisions to the MDRP to present themselves, **it's imperative that CMS remain vigilant and be prepared to act quickly should manufacturers or other stakeholders identify downstream negative implications.**