

PROPOSED CMS RULE TARGETS PBM PRICE TRANSPARENCY FOR MEDICAID MANAGED CARE ORGANIZATIONS

In the latest effort to increase price transparency and lower prescription drug costs, the Centers for Medicare & Medicaid Services (“CMS”) issued a **proposed rule** (“Proposed Rule”) that, in part, intends to reveal the actual cost of drugs covered by Medicaid.

The Proposed Rule includes two new initiatives:

1. A Medicaid managed care organization (“MCO”) transparency initiative requiring pharmacy benefit managers (“PBMs”) to report to Medicaid MCOs the amount of the fees the PBM receives from the Medicaid MCO that go directly to paying for the dispensation or administration of prescription drugs covered by the Medicaid MCO and the amount of the fees that the PBM receives from the Medicaid MCO that the PBM retains; and
2. A drug pricing survey requiring pharmaceutical manufacturers who participate in the Medicaid Drug Rebate Program (“MDRP”) to annually disclose information regarding the costs associated with certain Medicaid covered outpatient drugs (“CODs”), the results of which may be made public.

The stated goal of both initiatives is to provide further transparency into the actual costs associated with prescription drugs offered through the Medicaid program.

PBM PRICE TRANSPARENCY

The Proposed Rule aims to provide greater clarity into the actual cost state Medicaid programs are paying for the dispensation or administration of covered prescription drugs. Most states utilize MCOs to administer all or part of the state’s Medicaid benefits. These MCOs in turn often contract with PBMs to manage and administer the Medicaid prescription drug benefit on behalf of the MCO. In addition to providing other administrative services, these PBMs contract with pharmacies to negotiate and establish the rates at which pharmacies are reimbursed for the prescriptions dispensed to the Medicaid MCO’s members.

As CMS notes in the Proposed Rule, due to a PBM practice known as “spread pricing,” it is often difficult for a state Medicaid agency or a Medicaid MCO to know the actual price the Medicaid MCO or state Medicaid agency is paying for prescription drugs provided to its members. “Spread pricing” is the practice by which a PBM pays a lesser amount to its contracted pharmacies for the dispensation or administration of a prescription drug than it receives from its contracted MCO and then retains the “spread” as a profit. Importantly, there is currently no federal requirement for PBMs to report to the MCO the exact cost the PBM pays to a pharmacy for prescription drug provided to the MCO’s members. CMS explains that this makes it difficult “for health plans or Medicaid managed care plans to know how much they are paying for the actual cost of the drug compared to the fees for administering the benefit.” Consequently, unless a state regulation mandates disclosure of this information, this margin or “spread” may only be known by the PBM. Because such state regulations are rare, there is an information deficit resulting in a lack of accountability and transparency to the Medicaid program, which CMS believes is “contrary to proper and efficient operation of the State Medicaid program and potentially creates conflicts of interest in connection with payment for CODs.”

In light of the non-transparent nature of the amount the PBMs pay for prescription drugs, CMS issued the Proposed Rule that will require Medicaid MCOs to include in their contracts with any PBMs a requirement that the PBM report separately: (1) any administrative costs incurred by the PBM (including any retained “spread”), and (2) the amounts paid to providers or pharmacies for dispensing or administering a covered outpatient drug. Ultimately, this will provide greater transparency to the MCOs and state Medicaid programs, not only to the “spread” the PBM is retaining as profit, but also into what the actual cost of the Medicaid prescription drugs are.

Further, CMS clarifies that providing greater transparency into the actual cost PBMs pay for prescription drugs, as differentiated from the “spread pricing” administrative expense retained by the PBM, will provide greater accuracy when determining an MCO’s Medical Loss Ratio (“MLR”) calculation - a calculation that is used by CMS to determine the actual amount of funds being used by an MCO for the payment for provision of services to beneficiaries, which ultimately assists CMS and state Medicaid agencies in determining the amounts to be paid to Medicaid MCOs for the coverage of Medicaid beneficiaries.

MANUFACTURER SURVEY REQUIREMENTS

Second, the Proposed Rule aims to provide greater transparency into the actual cost associated with the manufacturing and distribution of certain expensive prescription drugs covered by the Medicaid program. The MDRP is a program under which CMS and state Medicaid agencies enter agreements with drug manufacturers to reduce the cost of most outpatient prescription drugs dispensed to Medicaid beneficiaries. The program requires drug manufacturers to enter into National Drug Rebate Agreements (“NDRAs”) with the Department of Health and Human Services (“HHS”) in exchange for state Medicaid coverage for most of the manufacturer’s drugs.

Under the MDRP, CMS is responsible for verifying participating manufacturer prices for CODs made available to Medicaid beneficiaries. In light of this responsibility, the Proposed Rule creates a new process by which CMS will issue surveys to manufacturers and wholesalers to verify prices and charges of certain CODs. CMS stated that the survey process “should provide CMS and the States a clearer understanding into a manufacturer’s pricing for its [COD] to verify those prices and charges, and ensure that Medicaid payments are made in an economical and efficient, as well as sufficient manner, to provide access to care.” Moreover, to the extent CMS determines that such information is not confidential or a trade secret, such information will be made publicly available to provide further transparency into the cost of Medicaid covered prescription drugs.

Annually, CMS will compile a list of single source CODs that may be subject to the survey based on enumerated criteria, including the COD which has the highest Medicaid drug spend per claim and the highest one-year price increase among single source CODs. No more than 10 CODs will remain on the survey list each year. The survey will then be sent to the applicable manufacturers and wholesalers and will request in a standard reporting format specific information that will include:

1. The wholesale acquisition cost of the COD, including the types of discounts available to purchasers on the market or for a wholesaler or pharmacy affiliates with the manufacturer or wholesaler;
2. Average price of the drug to wholesalers and other direct purchasers for sales outside of the U.S.;
3. Actual or expected utilization of the drug in the U.S.;
4. Public prices for the drug to other federal agencies;
5. Information related to the cost of distribution of the drug;
6. Costs of production, research and marketing for the drug; and
7. Total revenue and net profit generated from the drug for each calendar year sing drug approval.

Failure of a manufacturer or wholesaler to provide the requested survey information could result in a \$100,000 civil monetary penalty.

PRACTICAL TAKEAWAYS

The Proposed Rule demonstrates the federal government’s continued push towards greater price transparency in the U.S. health care industry and overall increased scrutiny into the amounts federal health care programs pay for prescription drugs. If adopted, the Proposed Rule has the potential to significantly change the amounts state Medicaid agencies and Medicaid MCOs pay for certain prescription drugs, which may ultimately create a ripple effect and eventually impact the amounts that other federal government programs and private payors pay for covered prescription drugs.

Additionally, the Proposed Rule demonstrates the overall national increased scrutiny of PBMs – an industry that has been relatively unregulated at the federal level up to this point. The Proposed Rule is a first step in creating stronger federal control over what many view as problematic PBM practices. Although the Proposed Rule only looks to have PBMs report “spread pricing” practices to MCOs at this point, it could open the door for further federal regulation of PBM practices that impact federal government programs and the overall cost of prescription drugs.

Interested parties can submit comments on the Proposed Rule by using this [link](#). The deadline to comment is July 25, 2023, at 11:59 PM EDT.

For more information on federal and state laws related to pharmacy and PBM matters, or for assistance preparing a comment on the Proposed Rule, please contact:

- [Julie Lappas](#) at (317) 977-1490 or jlappas@hallrender.com;

- Ben Fee at (720) 282-2030 or bfee@hallrender.com;
- Matt Reed at (317) 429-3609 or mreed@hallrender.com; or
- Your primary Hall Render contact.

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