CMS Issues Proposed Rule to Require List Prices of Drugs and Biologics in Direct-to-Consumer Television Ads

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On October 18, 2018, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that would require direct-to-consumer (DTC) television advertisements for prescription drugs and biological products for which payment is made through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC, or the "list price") of the drug or biological product.[1]

According to CMS, the impetus behind the proposed rule is to ensure that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so that informed decisions can be made to minimize out-of-pocket costs and the expenses to the Medicare and Medicaid programs. CMS notes that, "markets operate more efficiently when consumers have relevant information about a product, including its price, as well as alternative products and their prices, before making an informed decision whether to buy that product or, instead, a competing one."[2]

There may be some skepticism as to how the proposed rule will increase transparency and enable consumers to make informed decisions, given that consumers' insurance providers may have negotiated a different price for the drug or biological product than the list price. CMS notes, however, that in its view, several factors make the list price relevant across a number of drug benefit designs. First, over 40% of beneficiaries in the commercial market are in high deductible plans, requiring the beneficiary to pay the full list price of the product until they meet the deductible. Second, the negotiated rebate rate is not paid until months after the product was dispensed. Third, co-insurance has become a standard payor mechanism applicable to high cost drugs, which requires the patient to pay a percentage of the list price. Finally, very few drugs have coverage on all formularies throughout the country. If a plan does not have coverage for a particular drug or biological product, the patient may have to pay the full list price for the medication.

AGG Observations

- PhRMA and other industry associations have already issued press releases and other communications opposing the rule, as well as an industry-initiated approach to drug pricing information, and are likely to submit comments in opposition to the proposed rule. We expect that other groups will submit comments in support of the rule.

- While the proposed rule would affect prescription drug advertising, it does not amend any FDA rules, just CMS rules.

- The interaction with FDA statutes and regulations governing prescription drug advertising is not addressed in the proposed rule, but may be of interest or concern.

Interested stakeholders may submit comments until December 17, 2018. If you have any questions about the proposed rule, or are interested in submitting comments, please contact Seth Ray, Christine Kirk, or Genevieve Razick.

1 Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency, 83 Fed. Reg. 52789-52799 (Oct. 18, 2018).
2 Medicare and Medicaid Programs, 83 Fed. Reg. at 52789.

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