

Summary: Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency

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Comments Due: December 17, 2018

On October 18, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a new proposed rule entitled [Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency](#). This proposed rule would require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products payable by Medicare or Medicaid to include the wholesale acquisition cost (WAC), or list price, of that prescription drug or biological product.

This proposed rule mirrors other efforts by the Administration to reduce the price of prescription drugs for consumers and to reduce expenditures for Medicare and Medicaid. CMS intends to decrease the cost of prescription drugs by introducing drug price transparency and therefore reducing the incentive for manufacturers to increase list prices. Additionally, the proposed rule aims to provide Medicare and Medicaid beneficiaries with critical information around the cost of advertised drugs and biologicals to better aid their decision making around significant out-of-pocket costs and selecting lesser cost alternatives. Overall, CMS hopes that the new transparency created by this rule will promote a more competitive environment and motivate manufacturers to take more caution when increasing prices. CMS expects that the final rule will take effect 30 days following its publication.

While AMCP supports efforts to encourage drug pricing transparency within health care, we strongly discourage advertising aimed at consumers that promotes the use of specific prescription drug products. In general, such advertising aims to increase a product's market share or create a new market for the products. AMCP advocates for the appropriate use of prescription drug products and encourages providers to select products based on the needs of the patient in conjunction with prescription drug benefit designs.

AMCP is reviewing this proposal to provide formal comments to CMS on this proposed rule and is seeking feedback from its members to inform the comments. Comments on this proposal must be submitted to CMS by December 17, 2018. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced. You may provide feedback via email to Afton Wagner, Director of Regulatory Affairs, at awagner@amcp.org by December 5 on provisions included in the proposed rule. AMCP's final comments to CMS will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is summary of provisions in the proposed rule that may be of interest to AMCP members:

The proposed rule would require that advertisements for prescription drugs or biologicals on television (including broadcast, cable, streaming, and satellite) payable by Medicare or Medicaid, must contain a statement or statements indicating the WAC (referred to as the "list price") for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate.

- The statement would read “The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”
- The list price would be determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast.
- CMS is proposing an exception to the requirement when the list price of the drug is less than \$35 dollars per month.
 - \$35 was selected as it represents the average copayment for a preferred brand drug.
- The “typical course of treatment” would be associated with the primary indication addressed in the advertisement.
- Manufacturers would be required to show the statement at the end of the advertisement in a legible manner, against a contrasting background, for a sufficient duration, and in a size and font that allows the information to be read easily.
- Manufacturers would be required to allow the U.S. Department of Health & Human Services (HHS) to publish a public list of drugs and biological products advertised in violation of these proposed requirements.
 - The list would be published publicly on a CMS website no less than once a year.
- CMS does not propose additional HHS-specific enforcement mechanisms and anticipates that the threat of private actions under the Lanham Act for unfair competition in the form of false or misleading advertising will be the primary enforcement mechanism for this proposed rule.
- CMS is proposing that this rule preempt any state-law-based claim which depends in whole or in part on any pricing statement required by this rule.

CMS is seeking specific input from stakeholders on the following:

- Whether Wholesale Acquisition Cost is the amount that best reflects the “list price.”
- Whether 30-day supply and typical course of treatment are appropriate metrics for a consumer to gauge the cost of a drug.
- How providing consumers with the list price of a medication may influence interactions with prescribers, the selection of drug products, and the perceived efficacy of the prescribed drug.
 - How benefit design influences these choices.
- On whether the final rule should include more specific requirements with respect to the textual statement, such as specific text size, contrast requirements, and/or duration and specifically what those requirements should be.
- Primary enforcement mechanism and other approaches to enforcing compliance.
- How to treat an advertised drug that must be used in combination with another non-advertised drug or device.
- Whether the cost threshold of \$35 to be exempt from compliance is the appropriate level, alternative approaches to the cost threshold and how often it should be updated.
- Content of the proposed pricing information statement.
- Whether this proposed regulation should be applied to other media formats such as radio, magazines, newspapers, websites, and other forms of social media.
- Whether compliance to this proposed rule should be a condition of payment, directly or indirectly, from these federal health programs.
- Other approaches to price transparency and informed decision making.
- What information, such as the list price, could be useful to include on the [CMS Drug Spending Dashboards](#).