

PUBLICATION

Proposed Rule on Drug Price Disclosure in TV Advertisements

Authors: Sheila P. Burke

October 2018

The Administration has continued its push to address the issue of high drug prices through the regulatory process. On October 15, 2018, the Department of Health and Human Services (HHS) issued a proposed rule to require drug manufacturers to disclose drug list prices in direct-to-consumer advertisements. HHS seeks to help Americans make better decisions on prescription drugs and to put pressure on drug manufacturers to bring drug prices down. According to HHS, the drug industry spent more than \$5.5 billion on advertising in 2017, including nearly \$4.2 billion on television advertisements.

Specifically, the proposed rule would require drug manufacturer advertisements to display a prescription drug's monthly wholesale acquisition cost (list price) or the cost of a typical course of treatment. The proposal would apply to drugs covered by Medicare or Medicaid that cost greater than \$35 per month for a 30-day supply. Advertisements would also have to include a statement that patients with health insurance may have different cost sharing for the drug. Of note, the Administration issued the proposal through the Centers for Medicare and Medicaid Services (CMS), relying on HHS's Medicare and Medicaid authority, rather than issuing the proposal through the Food and Drug Administration. HHS would list online the companies that violate the requirement, but the agency would not directly enforce compliance. Instead, HHS would rely on drug manufacturers to sue each other for violations. Some observers have questioned whether the Administration has the legal authority to issue such a requirement, particularly through CMS.

The drug industry strongly opposes the proposal and is expected to challenge the proposed rule in court. The Pharmaceutical Research and Manufacturers of America (PhRMA) stated that the proposal would violate the First Amendment by forcing drug manufacturers to "speak." PhRMA also claims that disclosing list prices without additional context is misleading, since patients with insurance do not pay the list prices, and may discourage patients from seeking needed medical care. In contrast, other groups praised the proposal as a step in the right direction to address high drug prices, including America's Health Insurance Plans (AHIP), the Pharmaceutical Care Management Association (PCMA), and the American Medical Association (AMA).

If you have questions or would like further information regarding the content of this alert, please contact [Sheila Burke](#).