CMS Finalizes Rule Requiring Prescription Drug Price Information in Direct-to-Consumer Television Advertisements

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On May 10, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a final rule requiring that direct-to-consumer television advertisements for prescription drugs and biological products include certain pricing information for products covered under the Medicaid or Medicare programs.[2] The final rule follows CMS's proposed rule published on October 18, 2018.[3] After considering public comments, the agency decided to publish the final rule largely as proposed, with one modification regarding state law preemption, and other smaller changes to improve clarity. The final rule will take effect on July 9, 2019.

We briefly summarize the rule below. We also note some other efforts to address drug pricing that are underway at both the federal and state level.

CMS Rule on Drug Pricing Information in TV Ads

The new CMS rule applies to any television advertisement for a prescription drug or biological product covered under Medicare or Medicaid that is distributed in the United States, with the exception of prescription drugs or biological product that have a list price of less than $35 per month for a 30-day supply or typical course of treatment. The new rule requires that television advertisements (including broadcast, cable, streaming, and satellite advertisements) for such products contain a statement indicating the Wholesale Acquisition Cost ("WAC" or list price) for a typical 30-day regimen or for a typical course of treatment, as determined on the first day of the quarter during which the advertisement is being aired or broadcast. The rule also provides a model statement to make this disclosure: "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." In addition, the final rule provides that the list price disclosure must be conveyed in a "legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily."[4]

According to the final rule, CMS anticipates that the primary enforcement mechanism to ensure compliance will be challenges from industry via private actions under the Lanham Act for unfair competition by way of misleading or false advertising. The agency also intends to maintain a public list that will include products advertised in violation of the requirements. CMS notes that the agency did not intend for the rule to impose varying disclosure requirements on television advertisements that air in different states, noting that the rule was not intended to create a regulatory "floor" above which the states could add additional requirements. To ensure that prescription pharmaceutical advertisements on television would not have to vary from state to state, CMS modified the preemption language in the final rule from that in the proposed rule to say that the rule preempts

1 With research assistance from Laura Dona, Summer Law Clerk.

2 CMS, Medicare and Medicaid Programs; Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency (final rule), 84 Fed. Reg. 20732-20758 (May 10, 2019).

3 CMS, Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency (proposed rule), 83 Fed. Reg. 52789-52799 (Oct. 18, 2018). Also see our previous article regarding the proposed rule, Arnall Golden Gregory, S. Ray, C. Kirk, and G. Razick, "CMS Issues Proposed Rule to Require List Prices of Drugs and Biologics in Direct-to-Consumer Television Ads" (October 25, 2018), available at: https://www.agg.com/CMS-Issues-Proposed-Rule-to-Require-List-Prices-of-Drugs-and-Biologics-in-Direct-to-Consumer-Television-Ads-10-25-2018/.

4 84 Fed. Reg. 20732-20758 at p. 20732.

any state-law-based claim that depends in whole or in part on any pricing statement required by the rule. Further, no state or political subdivision of any state may establish or continue in effect any requirement related to a disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by the new rule.

CMS has indicated that the impetus behind the final rule is drug pricing transparency. In particular, the rule is intended to help ensure that consumers have relevant information, including information about the costs of prescription drugs and biological products, in order to make informed decisions to minimize their out-of-pocket costs and expenditures that are reimbursed by the Medicare and Medicaid programs. While public comments included both support for and opposition to the proposed rule, observers expect that the rule may be challenged in court.[5] Some notable concerns raised about the rule include:

- Whether the rule would cause consumer confusion rather than increase transparency, given that prices can vary widely from the WAC, depending on a consumer's individual insurance coverage;
- First Amendment concerns regarding the scope of the rule, and
- Concerns regarding whether the proposed rule improperly inserts CMS regulation into prescription drug advertising, an area normally regulated by the U.S. Food and Drug Administration (FDA), rather than CMS.

Other Federal and State Initiatives Regarding Drug Pricing and Promotion

Sponsors of prescription drugs and biologics should be aware that this new CMS rule is just one of a number of recent and pending federal and state initiatives to address high drug prices, lack of drug pricing transparency, and drug marketing and promotion. For example:

- *U.S. Congress.* Multiple bills addressing prescription drug pricing and related issues are currently pending in Congress. Just this week, pricing and transparency issues have been considered by a House Committee, and these issues continue to be under review by two Senate Committees.[6]
- *Federal Agencies.*
  - The Department of Health and Human Services (HHS) has announced a concerted effort to address high drug prices, including, but not limited to drug pricing transparency. The agency and its operating divisions, such as CMS and FDA, have indicated that they are taking a look at whether there are appropriate regulatory actions to be taken in areas such as competition in the brand and generic marketplace and drug price negotiation for programs such as Medicaid and Medicare.
  - The Federal Trade Commission (FTC) continues to bring enforcement actions regarding unfair competition and to work closely with FDA in identifying and addressing violations of applicable marketing and promotion laws (FTC and FDA each enforce different statutes, but often work together).
- *State Litigation.* Earlier this month, multiple state attorneys general filed a lawsuit against a number of pharmaceutical companies, alleging, among other things, a price-fixing conspiracy in the generic drug space.
- *State and Local Legislative Action.* A number of states, and some local jurisdictions, have considered or enacted legislation addressing drug pricing, transparency, drug promotion, and other related issues.

5 Public comments on the proposed rule may be viewed at www.regulations.gov (see Docket No. CMS-2018-0123).

6 See, e.g., U.S. House, House Committee on Energy and Commerce, Health Subcommittee, Hearing, "Improving Drug Pricing Transparency and Lowering Prices for American Consumers" (May 21, 2019), hearing webpage available at: https://energycommerce.house.gov/committee-activity/hearings/hearing-on-improving-drug-pricing-transparency-and-lowering-prices-for; see also, U.S. Senate, Statement from Senator Lamar Alexander, Chairman of the Senate Committee on Health, Education, Labor, and Pensions (HELP Committee), "Alexander Statement on Administration Rule to Require Drug Companies to Disclose to Consumers List Prices on TV Ads" (May 9, 2019), available at: https://www.help.senate.gov/chair/newsroom/press/alexander-statement-on-administration-rule-to-require-drug-companies-to-disclose-to-consumers-list-prices-on-tv-ads (noting that the Chairman supports the new CMS rule and related legislation, and that the Committee held multiple hearings on health costs last year and has held four hearings to explore the cost of prescription drugs); and U.S. Senate, Committee on Finance, Hearing, "Drug Pricing in America: A Prescription for Change, Part III" (April 9, 2019), hearing webpage available at: https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-iii (this hearing was the most recent in a series of related hearings).

AGG Observations

- The CMS final rule represents the current Administration's latest step aimed at drug pricing, and we expect to see further scrutiny and action in the area.
  - The CMS rule applies to certain televised prescription drug and biologics advertising, but does not amend or replace FDA advertising and promotion rules that apply to such ads. The interaction between the new CMS rule and existing FDA laws and guidance regarding prescription drug advertising may be of interest or concern. While the rule text does not address this issue, and CMS disagreed with a comment raising concern about the interaction, the preamble does note that FDA requirements are not superseded by the CMS rule.
  - To date, companies have taken a variety of approaches to how they plan to comply with the new rule. For example, one trade association's members have begun a voluntary program to reference a website where pricing information is available, and at least one company has already included list price information in a television ad (as noted above, the rule takes effect in July 2019).
- Both federal and state legislators and regulators are actively considering measures to address drug pricing, and there are multiple pending or recently passed measures addressing a number of related issues (e.g., transparency, competition, and negotiation).
  - This is a rapidly changing area, and affected companies should follow developments closely.
  - Companies may need to consult state or local law as well as federal law to determine if there are specific requirements regarding drug pricing and price disclosure.

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