CMS' Proposed Rule Regarding Disclosure of Drug "List Prices" in Television Ads: Needed Transparency or Recipe for Confusion?

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On October 15, 2018, the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the Department of Health and Human Services, released a Proposed Rule that would require a direct-to-consumer ("DTC") television advertisement for a prescription drug that is covered by the Medicare or Medicaid programs to disclose the drug's "list price."[1] CMS is accepting comments on the Proposed Rule until December 17, 2018.

The Proposed Rule was contemplated as part of the Trump administration's "blueprint to lower drug prices" through market forces such as competition and transparency, rather than heavy-handed regulations such as price controls.[2] The Administration believes providing patients with drug price information will allow them to "price shop," much as consumers shop for other goods such as automobiles.

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While the Trump administration has long contemplated a pricing disclosure requirement for DTC prescription drug advertisements, the rationale for the requirement has changed. Originally, the administration contemplated that the Proposed Rule would be issued by the Food and Drug Administration ("FDA") pursuant to its authority under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to require "fair balance" in prescription drug advertising (to ensure, for example, that advertisements do not minimize risks or overstate efficacy).[3]

The Proposed Rule, however, was issued not by FDA but rather by CMS. Presumably, the administration recognized that the FFDCA does not authorize price disclosures in prescription drug advertising. Such disclosures would not come within the "fair balance" rubric as prices are unrelated to drug safety or efficacy. Instead, the administration justifies the Proposed Rule under CMS' authority, claiming that the rule would enhance the efficient administration of the Medicare and Medicaid programs and reduce expenditures for the government programs and their beneficiaries.

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1 https://www.federalregister.gov/documents/2018/10/18/2018-22698/medicare-and-medicaid-programs-regulation-to-require-drug-pricing-transparency.

2 https://www.debevoise.com/insights/publications/2018/05/the-white-houses-drug-pricing-blueprint.

3 *See, e.g.*, 21 C.F.R. 202.1.

The Proposed Rule, if enacted, is vulnerable to legal challenge for multiple reasons, including that it violates the First Amendment, and CMS lacks legal authority to issue rules regarding prescription drug advertising. As a result, there is a significant likelihood that a court would enjoin CMS from enforcing the Proposed Rule. Additionally, even if the Proposed Rule were allowed to come into effect in its current form, it would affect only the small number of prescription drugs that are advertised on television. The Proposed Rule would not apply to advertisements in other media including print media, social media and radio.

Provisions of the Proposed Rule

- The Proposed Rule applies to DTC television advertisements for prescription drugs that: (i) are covered under the Medicare or Medicaid programs; and (ii) have a "list price" of more than $35 for a 30-day supply or a typical course of treatment.

- It defines "list price" as a drug's Wholesale Acquisition Cost ("WAC"). The WAC price is a drug-pricing measure specified by federal regulations that is intended to estimate the price at which a drug is offered to wholesalers or direct purchasers, without taking into account rebates and discounts.

- It would require the following disclosure in DTC television advertisements: "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." Where the price for the typical course of treatment varies by treatment, the list price should reflect the course of treatment described in the advertisement. CMS has indicated that it believes disclosure of this information solely on a drug manufacturer's website is insufficient. The Proposed Rule does not purport to restrict the use of additional voluntary qualifying language or disclaimers as such restrictions would likely violate the First Amendment.

- It would require the disclosure to be displayed 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." This standard is similar to the Federal Trade Commission's "clear and conspicuous" requirement for the disclosure of material information.

- The Proposed Rule would define "television" to include broadcast, cable, streaming and satellite communications. The Proposed Rule would not apply, for example, to radio or social media.

- The Proposed Rule would include only one regulatory consequence for failure to satisfy the disclosure requirements: inclusion on a public list, maintained by CMS, of drugs that are advertised in violation of this provision. CMS' commentary to the Proposed Rule, however, states that it contemplates that the Proposed Rule would be enforced through lawsuits brought by competitors under Section 43(a) of the Lanham Act (a federal statutory provision governing false advertising). Additionally, the Proposed Rule includes a provision that is designed to preempt claims brought under state law.

Potential Issues with the Proposed Rule

First Amendment Issues

The regulatory preamble accompanying the Proposed Rule contemplates a challenge by pharmaceutical manufacturers and others on the basis that a compelled disclosure in a DTC prescription drug advertisement violates the First Amendment. CMS argues that the Proposed Rule is constitutional and does not violate the First Amendment because "[w]hen the government requires accurate disclosures in the marketing of regulated products under appropriate circumstances, it does not infringe on protected First Amendment interests," and the Proposed Rule's "required disclosures consist of purely factual and uncontroversial information about a firm's own product, namely the list price of the drug . . . ."

CMS' claim that disclosure of WAC price information is "purely factual and uncontroversial," however, is subject to significant criticism. The pharmaceutical industry is likely to argue that a compelled disclosure of WAC prices violates the First Amendment because it does not reflect the prices actually paid by consumers and therefore does not "directly advance[] the government interest asserted."[4]

As described below, the WAC price significantly overstates, in virtually all cases, the amount the consumer will pay out of pocket for the applicable drug. Therefore, a WAC price is irrelevant to most consumers and compelling disclosure may lead to significant confusion rather than transparency. Moreover, the resulting confusion may adversely

[4] *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980) (providing the Supreme Court's analysis of government restrictions that may impact commercial speech).

impact public health by dissuading consumers from purchasing essential prescription drugs because they mistakenly conclude the drugs are unaffordable.

Further, the Proposed Rule's reliance on WAC price sidesteps the complex web of relationships that determines prescription drug costs. Between the drug manufacturer and the patient, there are typically a number of intermediaries, including wholesalers, pharmacy benefit managers ("PBMs"), payors (commercial insurers or the government) and pharmacies. While the WAC price is the "list price" at which a drug is offered to wholesalers, the actual amount paid by wholesalers is often reduced by discounts and rebates. The price of a drug may further be affected by a combination of fees, payments, discounts and rebates paid by different downstream entities in the pharmaceutical supply chain. In addition, a consumer that is a covered by a government-sponsored or commercial healthcare plan is often responsible for only a fixed copayment or coinsurance, which is set as a percentage of the drug's cost.

In fact, the target audience of the Proposed Rule—individuals covered by the Medicaid and Medicare programs—rarely, if ever, pay the WAC price for prescription drugs:

- Medicaid: Beneficiaries with income below 150 percent of the federal poverty level are not responsible for a copayment of more than eight dollars. In the case of certain "non-preferred drugs," Medicaid beneficiaries pay 20 percent of CMS' cost—an amount that is typically far less than the WAC price.

- Medicare Part D: Many Medicare patients have prescription coverage provided by Part D. Part D plans are administered by private insurers, who employ PBMs to develop a tiered drug formulary and set cost-sharing requirements for each tier. In most cases, a Part D plan will negotiate with drug manufacturers by offering placement on a formulary in return for certain discounts and rebates (although Part D plans must cover all drugs in six therapeutic classes). Depending on the circumstances, a Part D beneficiary will either pay a fixed copayment or part or all of the drug's *negotiated* cost—not the WAC price. Further, after a beneficiary's prescription drug expenditures reach a "catastrophic" threshold, the beneficiary's cost-sharing requirement is capped at five percent of the drug's negotiated price.

- Medicare Advantage (Part C): Unlike traditional Medicare plans, Medicare Advantage plans cover a combination of hospital care, outpatient care and, if selected by the beneficiary, prescription drug coverage. These plans typically act as health management organizations or preferred provider organizations and employ certain types of cost containment measures. Medicare Advantage beneficiaries therefore usually pay fixed copayments for prescription drugs—not the WAC price.

The WAC price has little practical relevance even for individuals who are not beneficiaries of government healthcare programs. Like the Part D plans described above, commercial insurers generally establish multitiered formularies and limit out-of-pocket expenditures to a copayment or coinsurance. Even when a consumer is paying out of pocket (either because a deductible has not been met or because the consumer is uninsured), pharmacies typically make their own decisions regarding the price at which they sell prescription drugs. In some cases, either the drug's manufacturer or a PBM will offer discount or savings cards that reduce the out-of-pocket cost. Additionally, the recent enactment of two statutes banning "gag clauses," requirements that pharmacists not inform patients when it would be cheaper to purchase prescription drugs with cash instead of through insurance, provides patients with yet another source of information about how to make cost-effective prescription drug purchasing decisions.

CMS thus may have a difficult time defeating a First Amendment challenge. The agency will need to argue that the WAC price provides important data that directly advances a compelling government interest in educating consumers. For the reasons discussed, however, the facts do not appear to support this position. It is telling that CMS is seeking comment on whether the WAC price accurately reflects the "list price" for the purposes of consumer price transparency.

The Proposed Rule may also face a First Amendment challenge because it is not a content-neutral requirement that applies to all advertisements. Instead, the Proposed Rule singles out one category of speech for regulation: DTC television advertisements for certain prescription drugs. If so, the regulation would be subject to the First Amendment "strict scrutiny" test—meaning there must be a compelling government interest, and the statute must be narrowly tailored to meet that interest. It would be very difficult for CMS to meet those criteria when there is no other set of circumstances in which the government argues that the absence of pricing information necessarily renders a prescription drug advertisement deceptive or misleading. For example, there is no comparable disclosure requirement for DTC communications in media not covered by the Proposed Rule, such as radio, print or social media, or for prescription drugs not covered by Medicare or Medicaid, or for medical devices.

Administrative Procedure Act ("APA") Issues

The Proposed Rule may also be subject to challenge under the APA for being arbitrary and capricious for two interrelated reasons.

First, CMS arguably lacks statutory authority to issue these regulations. The regulatory preamble to the Proposed Rule does not cite any statute that expressly authorizes CMS to issue regulations requiring prescription drug price disclosures in advertising. Instead, CMS relies on amorphous authority to promote efficient administration of Medicare

and Medicaid. It is far from clear that this generalized authority is sufficient to allow CMS to issue regulations that have nothing to do with CMS' authority to address what drugs are covered under Medicare and Medicaid and how they are reimbursed—but rather how such drugs are *advertised* on television. DTC drug advertisements historically have been regulated by FDA, not CMS, and therefore are arguably subject to FDA primary jurisdiction.

Second, CMS' contention that the Proposed Rule would promote the effective administration of Medicare/Medicaid rests on the assertion that arming consumers with WAC price information would allow them to make informed choices about the cost-effectiveness of various prescription drugs and thus save the programs money. But this is unlikely to be true for a variety of reasons, including:

- Medicaid patients typically pay small copayments and therefore have no incentive to make decisions about which drugs are cost-effective.

- For Medicare patients, WAC prices could actually lead them to make the *wrong* decision because while a WAC price for one drug may be higher than that of a potential substitute, the patient's actual out-of-pocket cost could actually be substantially lower. That could occur, for example, if the drug with the higher WAC price was included in a preferred tier of a Part D plan's formulary, but the other drug was not.

- Overall healthcare costs could increase if the disclosure of WAC price data leads Medicare and Medicaid beneficiaries to forego necessary prescription drugs because they mistakenly believe those drugs are unaffordable, leading to the worsening of untreated conditions.

Thus, it may be challenging for HHS to posit a rational basis for assuming that the Proposed Rule would reduce prescription drug expenditures.

Lanham Act Issues

CMS argues that if the Proposed Rule went into effect, it could be enforced though Lanham Act lawsuits brought by competitors who claimed that they suffered commercial injury because a DTC television advertisement included incorrect WAC price information or omitted WAC price information altogether. In such litigation, the burden would be on the plaintiff to establish a false or misleading description of fact

relating to the nature, characteristics, qualities or geographic origin of the goods or services in question.[5]

Assuming that the advertisement complies with FDA regulations and is accurate, the omission of price information may not itself be sufficient to render the advertisement false, though, depending on the total circumstances, one might still be able to show that the omission of pricing information is impliedly false. Accordingly, it may be difficult to bring an omission case without additional supporting evidence regarding the accuracy of statements in the advertisement in question. (In contrast, one can easily imagine a viable Lanham Act suit in which the advertisement discloses WAC prices, but a competitor challenges them as inaccurate.)

Defendants in Lanham Act litigation may challenge whether certain types of plaintiffs have standing. Patients and consumers do not have standing to bring an action pursuant to Section 43(a) of the Lanham Act as standing is limited to competitors who suffer a commercial injury. Accordingly, to bring an action under the Lanham Act, a competitor would have to establish that it suffered some form of commercial harm.

Other Potential Methods of Enforcing the Proposed Rule

It is possible that a consumer, industry watchdog group or pharmaceutical company could challenge a competitor's DTC television advertisements that included an allegedly incorrect WAC price disclosure with the National Advertising Division of the Better Business Bureau ("NAD"), the self-regulatory forum for advertising disputes. If NAD agreed with the petitioner that the WAC price disclosure is materially incorrect and deceptive, the NAD likely would recommend that the advertiser discontinue dissemination of the incorrect WAC price; if the advertiser declined to do so, NAD may refer the matter to the FDA and/or the Federal Trade Commission for possible enforcement proceedings.

It is also conceivable that state attorneys general, other federal regulators or private plaintiffs may attempt to enforce an advertising price disclosure requirement through consumer protection laws (including laws prohibiting unfair business practices). However, any state law claims are likely to be preempted, and plaintiffs asserting federal law claims would likely face many of the same challenges described above.

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Please do not hesitate to let us know if you have questions.

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[5] 15 U.S.C. § 1125(a).

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