CMS Final Rule Requires Prescription Drug Pricing Transparency in DTC Advertising

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Background

On May 8, 2019, the Centers for Medicare & Medicaid Services ("CMS") finalized the regulation ("Final Rule" or "DTC Rule") requiring direct-to-consumer ("DTC") prescription drug television advertisements to include the wholesale acquisition cost ("WAC") or list price of a drug or biological product directly or indirectly paid by the Medicare or Medicaid programs. This is one of the first final rules to be issued following President Trump's Drug Pricing Blueprint issued in May 2018. Secretary Azar commented on the DTC Rule that "[m]aking those prices more transparent is a significant step in President Trump's efforts to reform our prescription drug markets and put patients in charge of their own healthcare."

We previously published an alert on the proposed rule discussing the impact of the DTC Rule on Medicaid and Medicare Programs and the implications of enforcement under the Lanham Act. The Final Rule largely adopts the provisions of the proposed rule, requiring manufacturers to disclose in DTC television advertisements the WAC of drugs and biologics with a list price over $35 for a 30-day supply or a typical course of treatment. Notably, CMS acknowledges that "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public." Instead, the agency relies upon the private right of action under the Lanham Act and upon the basis of unfair competition in the form of false or misleading advertising as the primary enforcement mechanism.

Although the DTC Rule finalizes these requirements, it slightly modifies the proposed 42 C.F.R. § 403.1204(b) related to state preemption and notes technical changes to 42 C.F.R. § 403.1202 to improve clarity surrounding commentary on whether changes to or expiration of list prices should be disclosed.

The rule is effective in July 2019 following 60 days after the date of publication in the Federal Register. However, finalizing the Final Rule likely will give rise to litigation challenges on First Amendment free speech grounds.

Below is a summary of key features adopted by the Final Rule, the modifications from the proposed rule and notable commentary.

Requirements for Drug Pricing Transparency in DTC Advertisements – 42 C.F.R. §§ 403.1200-403.1203

The Final Rule applies to any advertisements for prescription drugs or biological product distributed in the U.S. for which payment is available, directly or indirectly, under Medicaid and Medicare. Drugs and biologicals under $35 per month for a 30-day supply or typical course of treatment will be exempt from the transparency requirements.

Specifically, advertisements on television (including broadcast, cable, streaming, and satellite) for certain prescription drug or biological products must contain a statement indicating the current WAC (list price) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. The list price disclosure must be conveyed in legible textual statement at the end of the advertisement, placed "appropriately" and "presented against contrasting background for sufficient duration in a size and style of font that allows the information to be easily read."

The regulation also sets forth the model DTC language as follows:

> "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."

Enforcement and Compliance – 42 C.F.R. § 403.1204

Lanham Act as the Primary Enforcement Mechanism

As noted above, CMS lacks enforcement authority. The Final Rule states that CMS will publicize manufacturers that create false or misleading ads, but primary enforcement will be left to the industry itself. CMS relies on Section 43(a) of the Lanham Act ("Act") to be the primary vehicle for enforcement for failure to comply with the DTC Rule. No other HHS-specific enforcement mechanism was proposed. In the preamble, CMS supports its position on the Lanham Act as an appropriate mechanism for enforcing trade deceptive practices by highlighting the fundamental statutory premise of protecting consumers from false and misleading advertising. Since Section 43(a) requires a "false or misleading description of fact, or false or misleading representation of fact," omission of pricing information makes an advertisement false and thus, actionable.

The Agency dismisses concerns about litigation costs by asserting the commercial-friendly nature of the statute. Since sophisticated parties would be involved, CMS argues, the likelihood of meritless lawsuits is low and the Lanham Act as an enforcement mechanism is appropriate to deter drug manufacturers from raising prices to account for the costs in defending against meritless litigation.

The Final Rule adopts the proposed compliance regulation at § 403.1204(a) providing that the Secretary will maintain and annually update a public list of drugs and biologicals that violate this rule.

Notable Commentary from the Final Rule

CMS addressed many stakeholder comments related to the use of WAC and to First Amendment concerns.

Disclosure of WAC as Potentially Misleading

CMS disagreed with comments generally opposing the use of WAC based on the concern that it was not a meaningful measure of what a patient would pay for a drug and is therefore, misleading and confusing. In response, the Agency elaborated that consumers would be better able to approximate their out-of-pocket (OOP) costs for expensive drugs if they were provided information on the WAC. Finding support in a 2019 *Journal of the American Medical Society* (JAMA) study, CMS found that subjects realistically determined their OOP costs based on WAC disclosure. Subjects who were informed that the WAC for a drug was $15,000 expected their OOP costs to be substantially larger ($2,787) than those who were not provided such disclosure ($78).

Discussion Related to the Use of WAC as List Price

The Final Rule also addressed concerns related to whether WAC is an appropriate reflection of the list price for purposes of price transparency. As some commenters noted, the WAC is non-standardized and varies by National Drug Code (NDC). CMS disagreed with the notion that WAC is non-standardized as it has been used in Medicare Part B drug payment policies "for more than a decade without significant concern that it is not a meaningful price point." Additionally, the negotiated prices in Medicare Part D are largely a function of pharmacy-level charges which are expressed in network pharmacy contracts as a function of WAC.

With respect to variations between NDC and WAC, CMS clarifies, "[t]o the extent an NDC reflects an amount of the manufacturer's product other than a 30-day supply or typical course of treatment, the manufacturer will need to use reasonable assumptions to determine the appropriate list price for a 30-day supply or typical course of treatment."

First Amendment Considerations

CMS addressed many of the First Amendment concerns raised by commenters. At the outset, the Agency noted, "the speech here at issue does not implicate core First Amendment interests." CMS found the *Zauderer* standard as an appropriate framework in support of First Amendment concerns.

Under that standard, "the government may, consistent with the First Amendment, require disclosure of factual information in marketing commercial products where the disclosure is justified by a government interest and does not unduly burden protected speech." As the Agency highlighted, "the government interest is clear." According to CMS, the dramatic increase in prescription drug spending has

impacted the nation's health care spending and drug pricing transparency enables market efficiencies by helping consumers make informed choices. The Agency concludes that the brief disclosure at the end of DTC television advertisements is narrowly tailored to achieve this result.

Additionally, CMS concludes the required disclosure to not be unduly burdensome because the Agency deems the WAC to be a truthful statement of objective fact that is uncontroversial. As CMS further notes, "all drug manufacturers provide this information voluntarily to companies who publish this information in compendia or databases available to the public . . . []."

CMS' Response to the Use of PhRMA's Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines (hereinafter, PhRMA's Guidelines)

Finally, CMS addresses comments asserting that the required disclosure was unnecessary because many prescription drug manufacturers have begun voluntarily providing pricing information on their websites pursuant to PhRMA's Guidelines. The Guidelines as revised in October 2018, included principles to recommend that prescription drug broadcast advertisements include directions to where patients can find information about the cost of medicine.

CMS pointed to inadequacies of PhRMA's Guidelines indicating: (1) that the principles are voluntary and not binding on PhRMA members, (2) there is nothing to prevent PhRMA from revising its principles at any time, and more importantly, (3) including direction to where price information can be found is not as impactful as including information in the advertisement itself.

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