POINT OF VIEW

Proposed Regulation Mandates Drug Prices in DTC Advertising

Understand what this means for you

By Britt Thompson, EVP, Business Transformation
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For months there have been increasing rumors and conversation swirling around the hot-button issue of proposed legislation that will require pharmaceutical drug manufacturers to list drug prices in their Direct to Consumer (DTC) advertising in an effort to increase consumer transparency, and lower drug costs.

The buzz picked up over the weekend when the Secretary of the Department of Health and Human Services (HHS), Alex Azar, announced a press conference for Monday, October 15th to address the proposed drug price policy. Hours before the scheduled press conference, Pharmaceutical Research and Manufacturers of America (PhRMA) President, Stephen Ubl, proactively announced a pledge from the pharmaceutical industry to include messaging that directs consumers to a webpage to learn more about drug pricing in all DTC television advertising.

However, Secretary Azar rejected the industry proposal, and, in the Monday, October 15th press conference, announced a proposed regulation that requires pharmaceutical companies to include the list price of medicines in television advertisements to consumers.

So what does this mean for DTC television advertisements moving forward, and what happens next? **We have been following this news closely, and have included insights from our strategy, creative, and payer marketing teams to answer your top questions, which we will continue to update as more information becomes available.**

What does the proposed regulation say?

The proposed policy announcement by HHS Secretary Azar was drafted as a new federal regulation and states that **"in television advertising, drug manufacturers will need to state in writing the list price of a 30-day supply of any prescription drug or biological product that is covered through Medicare and Medicaid, and costs at least $35 a month."** The requirement affects all DTC advertising on broadcast, cable, streaming, and satellite television.

What kind of written statement needs to be included in advertising?

All advertising must contain a statement, or statements, indicating the Wholesale Acquisition Cost (WAC), referred to as the "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,

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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."

As for the "typical course of treatment," the federal regulation states, "the list price used should be the one for the "course of treatment" **associated with the primary indication addressed in the advertisement.**

Evoke's Executive Vice President, Creative Director, JC Parker, notes that the length of copy and precedence from Federal Trade Commission (FTC) guidelines likely mean this language will need to stay on-screen for a minimum of five seconds. He adds, "Of course legal supers are nothing new for pharma ads and I would expect this will follow similar guidelines, but the length of the required statement, in addition to required safety, starts to have implications for the brand story structure that will need to be considered."

Can any additional pricing language be included?

It's not entirely clear at this time if additional language can be included to help consumers understand pricing context but in addition to a drug's own list price, the regulation allows, to the extent permissible under current laws, **manufacturers to include an up-to-date competitor product's list price, so long as they do so in a truthful, non-misleading way.**

How will television creative be impacted?

The regulation provides high-level creative guidance proposing that "the required price disclosure 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."

Will other forms of advertising be impacted?

HHS states that they considered whether this regulation should apply to advertisements that are in other media forums such as radio, magazines, newspapers, Internet websites, and other forms of social media, but concluded that the purpose of this regulation is best served by limiting the requirements to only those identified herein (television).

Are any products excluded from the regulations?

The only excluded products include those with a list price of less than $35 per month for a 30-day supply or typical course of treatment.

What if a company violates the federal regulation?

The primary enforcement mechanism will be the threat of private actions under the Lanham Act Section 43(a), 15 U.S.C. Section 1125(a), for unfair competition in the form of false or misleading advertising. Additionally, for those in violation of the guidance, the HHS Secretary will publish a public list of drugs and biologics who are in violation of the rule, published at least annually.

What is the desired outcome for this policy?

Ultimately, HHS hopes this policy will increase transparency and understanding for consumers. Azar states, "Price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information, but for consumers of prescription drugs, including those whose drugs are covered through Medicare or Medicaid, both the list price and actual

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price to the consumer remain hard to find."

Evoke's Vice President of Payer Strategy, Jeff Carbone, explains, "Transparency into drug costs will be eye-opening for the general public who often get prescriptions filled at a pharmacy without knowledge or expectations of what their out-of-pocket spend will be. Health plans would likely support this type of legislation as it will give consumers insight as to why certain products are covered and others not covered."

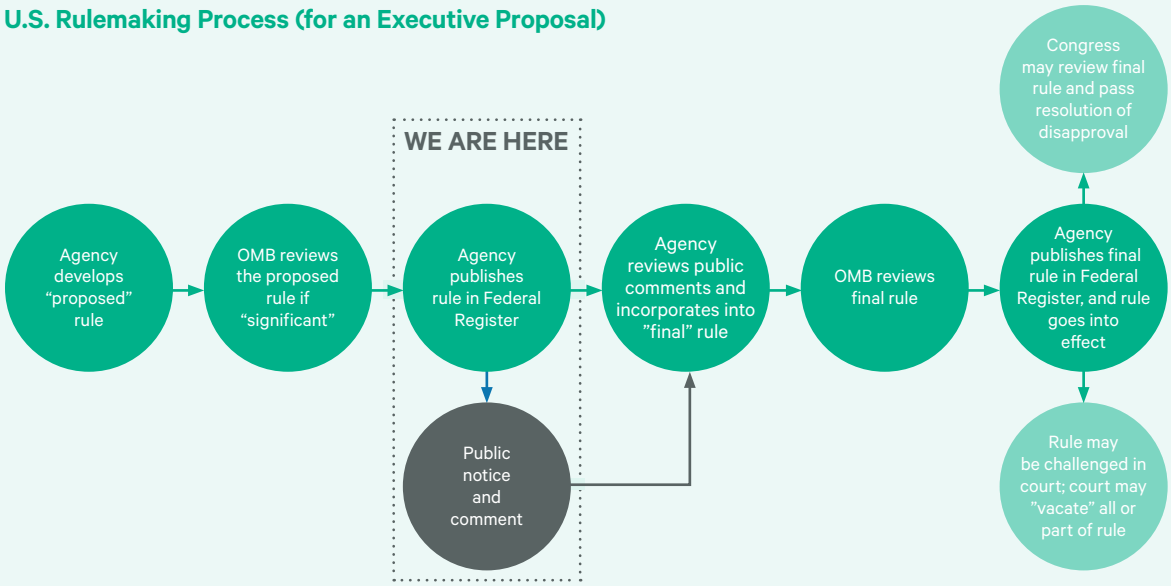
Additionally, language included in the proposed regulation implies that HHS hopes this policy will deter pharma companies from advertising as frequently. The policy reads, "*We believe that this rule may also have impacts along other dimensions. In particular, it may affect the number of televised DTC advertisements, the rate at which televised DTC advertisements are updated, prices for prescription drugs, the set of pharmaceutical products available for sale, and utilization of various prescription drugs. A possibility not reflected in the quantitative estimates above is that, with this proposed rule, drug companies would find the cost of revising their ads to be prohibitively expensive (for example, if they change their WACs so frequently that there is extensive monitoring and revision necessary to ensure that ads airing on a particular day match the WAC for that day). In this case, TV drug advertising would be reduced.*"

What happens next?

PhRMA is taking a hard stand against the policy, and, while they say it's too early to mention litigation, they feel that prior case law shows a regulation like the one the administration is proposing is a serious First Amendment violation: "If the government is compelling companies to speak, then that violates the First Amendment," Jim Stansel, Executive Vice President, General Counsel for PhRMA, told reporters.

Stephen Ubl, President of PhRMA, has also argued that disclosing only the list price of a medication in a television ad would be "very confusing, misleading, lacks appropriate context and isn't what patients want or need." He predicted that the price, which wouldn't reflect what most people would pay, might deter patients from seeking medical care, because patient's out-of-pocket costs vary depending on their insurance plans.

U.S. Rulemaking Process (for an Executive Proposal)



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Officially, what happens next is that the federal regulation will be published in the Federal Register. Public comments will then be accepted for 60 days. After these comments have been reviewed, a draft version with response to comments will be published. The final draft will go through several process steps and, if it is ultimately approved, one of three things will happen: The rule will take effect, it can be challenged legally, or it can be overruled by Congress through a vote of disapproval. **Timing wise, this means it would be at least three months before any formal law would take effect.**

How should brands prepare?

It is likely that some version of this regulation will ultimately be approved, and we will need to find effective ways to communicate this pricing information compliantly and minimize negative impact.

With this regulation, the devil will be in the regulatory details. However, **proactive brands and manufacturers can take immediate steps to prepare for eventual requirements.** Oren Eisenberg, Associate Director, Strategy at Evoke, recommends companies take a few key steps in the next 60 to 90 days to prepare for the final policy:

- **Work with regulatory and legal teams on proactive solutions** to providing better context for list price.
- **Conduct focus groups with patients, prescribers, and payers** to understand overall attitude towards cost.
- **Initiate message testing** to explore what types of pricing messages resonate with desired patients and what type(s) of supporting language may be needed to make the information useful.
- **Initiate ad format testing** to understand impressions of price information based on where it appears in an advertisement, how long it appears in the unit, and how ad format may influence the user's ability to process the information.
- **Explore ways of integrating financial support information** into existing creative.
- **Establish a creative management process.** If approved, the television creative must be up to date with the listed price, on a quarterly basis. "Brands will need to establish creative management guidelines to properly manage creative updates and re-traffic television creative," advises JC Parker, Evoke EVP, Creative Director.

The goal of these steps is to mitigate the negative impact of price disclosure and help brands address new regulatory requirements sooner. Stay tuned for more updates, and reach out to your Evoke Client Services lead or **business@evokegroup.com** if you'd like to discuss how this regulation may affect your brand.