October 19, 2018

Trump Administration Issues Drug Price Transparency Proposed Rule

On October 15, the Trump Administration published a proposed rule that, if finalized, would require prescription drug makers to include drug price information in broadcast advertising. This controversial proposal would implement an idea first broached in the Administration's drug pricing Blueprint (for more information about the Blueprint, see Manatt Health's summary).

The proposal is subject to a 60-day public comment period that will likely generate significant input. Some stakeholders are challenging the proposal as insufficient in its ability to address concerns with drug prices while others, including some members of Congress and consumer groups, are applauding the proposal as a useful step. The drug industry immediately attacked the proposal and, just hours before its release, announced its own voluntary plan to provide consumers with more access to price information.

The Proposed Rule

Although previous regulation of prescription drug advertising has come from the U.S. Food and Drug Administration (FDA), this proposal comes from the Centers for Medicare & Medicaid Services (CMS). The Agency writes in the preamble to the proposal that its goal is to "reduce the price to consumers of prescription drugs and biological products" and "improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also unreasonable expenditures borne by Medicare and Medicaid…"

The proposal would apply to broadcast ads, not print or other advertisements, for drugs that are paid for by Medicare or Medicaid. It would require the sponsors of ads to disclose the Wholesale Acquisition Cost (WAC) for a 30-day supply or for "a typical course of treatment," whichever is "most appropriate" and only for drugs where such supplies are more than $35 a month. The disclosure would come in text at the end of the ad. For drugs that have more than one indication (use approved by the FDA), the disclosure must be the price associated with the primary indication addressed in the advertisement.

It is important to note that the WAC is not the price that a consumer without insurance or with a deductible would pay at a pharmacy. Instead, it is a "list" price used as a benchmark to negotiate how much a pharmacy or other purchasers might pay for a drug. CMS claims that this price is an "anchor price" that "acts as a point of comparison when judging the reasonableness of prices offered for potential substitute products."

The rule also proposes to allow a drug advertiser to include in the ad "an up-to-date competitor product's list price, so long as they do so in a truthful, non-misleading way." This potentially raises issues with FDA rules that regulate how a manufacturer can discuss a competitor in its ads.

CMS is not proposing any penalties for noncompliance. Instead, it will publish a list of those drug ads not in compliance. CMS expects competitors to enforce the requirement by suing under the Lanham Act, a law that allows competitors injured by false or deceptive advertising to sue for damages.

CMS is seeking public comment on most of the major provisions of the proposal, including whether CMS should expand the proposal to other media or advertising. In its regulatory analysis of the proposal, CMS could not provide an estimate of its economic benefits.

It is likely that, if finalized, the rule would be subject to litigation challenging its statutory basis and raising objections that the rule violates the First Amendment by compelling speech. The proposal contains a vigorous defense of its constitutionality, but many observers question whether the argument would be upheld, especially given the conservative turn of the courts including the Supreme Court.

The Industry Plan

Also on October 15, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced that its members had agreed to abide by a voluntary plan to provide more price information about their drugs. PhRMA CEO Steve Ubl wrote that the "Administration and Congress have called on our industry to provide cost information in DTC advertisements, and our members are voluntarily stepping up to the plate."

The plan, an amendment to PhRMA's 2006 Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines, provides that: "all DTC television advertising that identifies a medicine by name should include direction as to where patients can find information about the cost of the medicine, such as a company-developed website, including the list price and average, estimated, or typical patient out-of-pocket costs, or other context about the potential cost of the medicine."

Each company will develop its own plan to implement the new, voluntary commitment. Critics of the PhRMA move cite its voluntary nature and the fact that the ads themselves will not contain price information. In response, PhRMA believes its approach would be more helpful by providing context on list prices.

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