CMS Proposes Requiring Prescription Drug Price Disclosure in Direct-to-Consumer Advertising

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Background

On October 15, 2018, the Centers for Medicare & Medicaid Services (CMS) published a Proposed Rule requiring disclosures by pharmaceutical manufacturers of the list price for certain drugs and biologicals directly or indirectly reimbursed by the Medicare and Medicaid programs. As part of the Trump Administration's drug pricing initiative, Health and Human Services (HHS) Secretary Alex Azar said the rule is intended "to create new incentives for drug companies to start lowering their list prices, rather than raising them."[1]

The Proposed Rule would require manufacturers to disclose in direct-to-consumer (DTC) television advertising (including broadcast, cable, streaming, and satellite) the "current list price," which CMS defines as the wholesale acquisition cost (WAC) of drugs and biologicals with a WAC over $35 for a 30-day supply or a typical course of treatment. Under the rule, the WAC would be provided in legible text at the end of the advertisement against a contrasting background for sufficient duration to be read easily. Notably, CMS proposes that, to the extent permissible under current laws, manufacturers would be permitted to include competitors' list prices in a truthful and non-misleading fashion.

Impacts on the Medicaid and Medicare Programs

While prescription drug DTC advertising is regulated by the Food and Drug Administration (FDA), the proposed rule was issued by CMS pursuant to sections 1102 of the Social Security Act, which broadly authorizes the Secretary to issue rules and regulations to administer the Medicaid and Medicare programs, and section 1871 of the Act, which authorizes the Secretary to issue rules and regulations to administer the Medicare program.

In the rule, CMS concedes "Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public," but claims that "Congress has explicitly directed HHS to operate Medicare and Medicaid programs efficiently." Arguing that "DTC advertising appears to directly affect drug utilization," CMS contends that disclosing drug list prices will lead to "[m]ore informed consumer decision making", which in turn "will impact not only each individual beneficiary's own finances, but also positively affect the shared taxpayer responsibility to fund the Medicare and Medicaid drug benefit programs."

It is uncertain whether disclosing the WAC for a prescription drug will help inform Medicaid and Medicare beneficiaries in a meaningful way, since, as the Congressional Budget Office points out, "The WAC often approximates the prices that retail pharmacies pay to wholesalers," rather than those typically paid for by consumers, including such beneficiaries. [2]

Enforcement

There are also significant questions regarding how the proposed rule would be enforced. CMS anticipates that the primary enforcement mechanism would 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. CMS would also maintain a public list of violations, with the information "posted publicly on a CMS internet website no less than annually." A purpose of this list apparently would be to set the violators up as targets for the anticipated Lanham Act false-advertising lawsuits.

This is the first time, to our knowledge, that a federal regulation has explicitly looked to private Lanham Act advertising litigation as its primary enforcement mechanism, and we see some reasons why it may not work the way the agency intends. Some of these reasons stem from the fact that the Lanham Act is not a consumer protection law, it is a competitor protection law.

Only competitors, or parties with a related commercial relationship to the violator, would have standing to sue for false advertising under the Lanham Act. A violator could not be sued by just any other drug company, but generally only by one with a competing product, so it could allege that the false advertising is diverting sales to the violator and causing the plaintiff commercial injury – an element of a Lanham Act case. That plaintiff would have to make out an argument, and prove with survey evidence, that non-disclosure of a drug's list price communicates some misleading message; the mere identification by the agency of the defendant as a violator would not likely establish deception as a matter of law in most courts. Then, the competitor would have to decide that it is losing enough sales because of the violator's non-compliance that it is worth investing, potentially, upwards of a million dollars, a year or two of litigation, and the risk of counterclaims, just to take a chance on stopping it. Lanham Act false-advertising litigation has declined in recent years as more companies have done this this calculus and found it not worthwhile.

Unintended Consequences?

The rule might even spawn the opposite kind of Lanham Act lawsuits to those intended. When companies disclose their list prices, they may be sued by competitors for falsely stating those list prices. This could be an easier theory of deception and injury than a claim based on the lack of price disclosure, and companies would be vulnerable to it whenever market conditions caused them to change their prices without being immediately able to revise their advertisements. A false-price-disclosure claim could even be raised as a counterclaim to a Lanham Act suit for price-non-disclosure.

The proposed rule would also preempt any state-law based claim which depends in whole or in part on any pricing statement required by this rule. This likely rules out any private enforcement of the Rule by litigation under state deceptive-practices laws such as California's Unfair Competition Law.

Finally, CMS solicited comments on a wide range of questions, including:

- How providing consumers with the list price of a medication may influence interactions with prescribers, the selection of drug products, and the perceived efficacy of the prescribed drug and how benefit design influences these choices.
- Whether the rule may provide a moderating force to counteract prescription drug increases by promoting efficient utilization of prescription drugs by consumers.
- What would be the effect of this potential advertising reduction on patient behavior, including as regards the information they seek out from their medical providers?

Looking Ahead

The proposed rule leaves the door open to other approaches to support drug price transparency, ranging from an enhanced CMS drug pricing dashboard, to a new payment code for drug pricing counseling. The Trump Administration is also pursuing other transparency initiatives for prescription drugs as well as for health care services, including hospital inpatient care. There is a 60-day comment period through December 17, 2018. Under the provision of the Social Security Act under which CMS issued the rule, CMS cannot issue a regulation in final form until there has been at least 60 days of public comment. Thus, even assuming that the agency could issue a final rule shortly after the comment period closes, this rule could not possibly take effect until late December, at the earliest.

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1. Centers for Medicare and Medicaid Services, "CMS Proposes to Require Manufacturers to Disclose Drug Prices in Television Ads", October 18, 2018, available here

2. Congressional Budget Office, Prescription Drug Pricing in the Private Sector, January 2007, available here

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