Court Strikes Down Regulation Requiring Price Disclosure in TV Ads for Prescription Drugs

July 11, 2019

On July 8, 2019, Judge Amit Mehta of the United States District Court for the District of Columbia granted a motion to stay a rule established by the Centers for Medicare and Medicaid Services ("CMS") that would have required drug manufacturers to provide the wholesale acquisition cost ("WAC") of certain drugs in television advertisements, effectively nullifying the rule.[1] We have previously written about this rule here and here. The Court granted a motion filed by three members of the innovator pharmaceutical industry and the National Association of Advertisers to stay the rule, which otherwise would have gone into effect on July 9, 2019.

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The "Wholesale Acquisition Cost Disclosure Rule" would require drug manufacturers to disclose the list prices of 30-day supplies of their drugs in any television advertisements marketing the drugs. This rule was issued as part of the Trump Administration's efforts to reduce drug prices through market forces and transparency.

In enacting this rule, CMS relied on its general rulemaking authority in the Social Security Act, which empowers CMS to make any rules necessary for the efficient administration of the Medicare and Medicaid programs. CMS argued that disclosures of WAC prices would allow Medicare and Medicaid beneficiaries to make more informed choices about which prescription drugs are cost effective and thereby limit costs to the government.

As anticipated, the WAC Disclosure Rule was challenged on the basis that CMS lacked statutory authority to issue the rule and that the rule violated the First Amendment because it is compelled speech. Judge Mehta stayed the rule based on the first argument. He explained that the Social Security Act does not grant either explicit or implicit authority to CMS to require the disclosure of drug prices in television advertisements. The rule would therefore have impermissibly regulated the conduct of drug manufacturers who are not participants in the Medicare and Medicaid programs. Judge Metha expressed concern that upholding this rule could lead to a slippery slope, allowing CMS to enact any rule that could indirectly lead to cost savings for the

[1] *Merck & Co., Inc. v. United States Dep't of Health and Human Svcs.*, No. 19-cv-01738 (D.D.C. July 7, 2019).

government through the Medicare and Medicaid programs. As the court resolved the matter on statutory grounds, it did not address the challengers' First Amendment argument.

The implications from this ruling extend beyond this particular rule. In light of the Trump Administration's inability to reach agreement with Congress on healthcare reform or drug pricing measures, the Trump administration has turned to administrative rulemaking by CMS and other agencies as a means to achieve at least some of its objectives. In some cases, the regulations proposed by the Administration appear to reach the outer limits of the relevant agency's administrative authority. This ruling suggests that courts will also look closely at other rulemaking efforts and will not uphold rules simply because they are based on amorphous objectives such as transparency and cost savings to the federal government (or beneficiaries of federal healthcare programs) unless Congress clearly delegated such authority to the agency.

What Happens Next. The Trump Administration is likely to appeal the ruling. That said, the district court's ruling is well reasoned and seems positioned to be upheld on appeal.

In the meantime, the Trump Administration is continuing to move forward with another rulemaking also intended to address drug prices. This potential rule, which we discussed here, would limit the prices that Medicare Part B pays for certain drugs administered directly by healthcare providers in outpatient settings, in part by tying them to an index of international prices for each drug. This proposal would also change acquisition of Part B drugs from the current system where healthcare providers purchase them directly from distributors to a system where regional or national vendors would negotiate purchases and then distribute the drugs to providers.

Although the proposal was highly publicized by the Trump Administration when it was originally released, the Trump Administration has not advanced the rulemaking process for months. This delay has sparked speculation that the threat of this proposal is being used as a cudgel to exact concessions from the pharmaceutical industry. Alternatively, the Administration may have recognized that if the proposal is implemented without sufficient planning, it could adversely impact the distribution of Part B drugs.

The Trump Administration had also proposed another new regulation that would have precluded Medicare Part D pharmacy benefit managers ("PBMs") from retaining rebates that they obtain from pharmaceutical manufacturers. The proposed rule would have required those rebates to be passed on to consumers at the point of sale. The proposed rule, however, was heavily criticized by PBMs and others, who argued that the rule could lead to increases in premiums for Part D plans and indeed could lead to the cost of

some drugs rising. The Administration announced on July 11, 2019 that it is withdrawing its proposal, leaving the current system in place.

Judge Mehta's ruling on the TV advertising regulations and the impending 2020 elections may increase pressure on Congress and the Administration to enact legislation related to drug pricing. There are multiple ongoing efforts to craft such legislation in both the House and the Senate. We are skeptical that any of these proposals will be able to pass both houses and survive a potential Presidential veto, given the need for bipartisan, bicameral agreement and the wide divergence in approaches being considered.

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Please do not hesitate to contact us with any questions.

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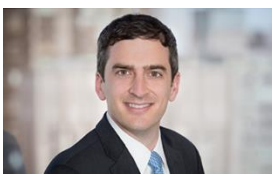

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