

CMS Publishes Long-Awaited Final Rule Requiring Drug Pricing Transparency

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On May 10, 2019, the Centers for Medicare & Medicaid Services (CMS) published its final rule, 42 CFR 403, requiring drug manufacturers to disclose the price of prescription drugs in direct to consumer (DTC) advertisements. Publication of the final rule was preceded by a lively comment period that commenced on October 18, 2018. The rule is “intended to 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” costs and expenditures.^[1]

The final rule generally requires television DTC advertisements for prescription drugs and biological products to include the list price of the product.^[2] Advertisements must contain a statement indicating the list price for a typical 30-day regimen or a typical course of treatment as determined on the first day of the quarter during which the advertisement is being aired (list price disclosure). The final rule also requires advertisements to contain the following verbiage, “[t]he list price for a 30-day supply/typical course of treatment of [name of product] is \$x. If you have health insurance that covers drugs, your cost may be different.”^[3] The statement must be presented against a contrasting background for a sufficient duration and must be written in a style and font that allow the information to be easily read.

The final rule’s requirements apply to any television advertisement for prescription drugs or biological products distributed in the United States for which payment is available, directly or indirectly, under Medicare or Medicaid, except for products that have a list price of less than \$35 for a 30-day supply or a typical course of treatment.^[4] However, when the price of a product varies based on indication, the list price stated in the advertisement should represent the typical course of treatment associated with the primary indication addressed in the advertisement.

Finally, the Secretary of Health and Human Services will maintain a public list of prescription drugs and biological products that have been advertised in violation of these requirements.^[5] However, CMS anticipates the primary enforcement mechanism will be the threat of private actions under the Lanham Act § 43(a)[6] for unfair competition in the form of false or misleading advertising.

It is anticipated stakeholders will raise First Amendment challenges in response to this final rule as well as other challenges related to the CMS's statutory authority. The rule will go into effect on July 9, 2019.

[1] <https://www.federalregister.gov/documents/2019/05/10/2019-09655/medicare-and-medicaid-programs-regulation-to-require-drug-pricing-transparency>.

[2] *Id.*

[3] 42 CFR 403.1202.

[4] *Id.* at 403.1200.

[5] *Id.* at 1204.

[6] 15 U.S. C. 1125(a).

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