

# CMS Proposed Rule to Require Drug Pricing Transparency

October 19, 2018 – Dorsey Health Law

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On October 18, 2018, the Centers for Medicare and Medicaid Services (“CMS”) proposed a new rule (“Proposal”) that would require direct-to-consumer (“DTC”) television advertisements of prescription drugs paid for by Medicare or Medicaid to include the drug’s wholesale acquisition cost (“List Price”). The Proposal comes as part of the current administration’s promise and attempt to both lower the cost and increase the transparency

of prescription drug prices. As the Proposal notes, prescription drug prices have seen a dramatic increase over the past decade due to factors such as lack of competition and lack of relevant product information. The Proposal aims to address these factors in an attempt to improve the efficient administration of the Medicare and Medicaid programs and lower the cost of prescription drugs.

Prescription drug prices are variable and largely unknown to everyday consumers. Typically, a consumer knows the price of a product before making an informed decision on purchasing that product. That is not the case with prescription drugs where the consumer often makes purchase decisions without knowing much, if any, information about the drug’s price. By mandating the inclusion of a prescription drug’s List Price, CMS hopes to make prescription drug prices more transparent in a fashion similar to the “sticker” price on a new car.

The List Price is the price set by drug manufacturers. It can play a major role in price negotiations between payors (e.g., an employer providing a prescription drug benefit plan to its employees or the government providing Medicare and Medicaid coverage), pharmacy benefit managers, and manufacturers. These negotiations impact a benefit plan’s cost sharing and the ultimate drug price paid by the consumer. The price paid by the consumer for prescription drugs can vary widely based on these individual

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negotiations, but the underlying element of every price is the static List Price. Currently, there is no market pressure for manufacturers or pharmaceutical companies to compete based on the List Price, but the Proposal argues that mandating its inclusion in DTC television advertising will eventually lead to lower prices through increased competition and consumer knowledge.

There are at least three main critiques with this Proposal, all of which are pre-emptively addressed by the Proposal:



- The first is that the Proposal will not lower drug prices but rather make the market for prescription drugs more confusing to consumers. The argument is that since the List Price is rarely the price paid by consumers (in fact, it is largely only paid by those without any coverage), advertising a high List Price will only deter potential consumers instead of create competition. The Proposal states that even though the List Price is typically not the price paid, it is a basic piece of factual information that the consumer should know in order to have at least one metric for comparison shopping.
- The second critique is that the Proposal will not withstand First Amendment scrutiny; namely, that this mandate is unreasonably compelled speech by the government. The Proposal states that the List Price is simply a required disclosure of factual information in a commercial speech setting, thus requiring a lower level of First Amendment scrutiny.
- The third main critique is that the Proposal lacks an enforcement mechanism. If a prescription drug advertiser violates the Proposal, their name is only added to a list of violators on the CMS website. The Proposal assumes that enforcement will come from private actions for false or misleading advertising under the federal Lanham Act.

In order to better address the critiques outlined above, CMS is accepting comments on the Proposal until December 17<sup>th</sup>, 2018. In addition to the above critiques, CMS is seeking comments regarding the requirements of the price disclosure among other specific aspects of the Proposal. If you would like to submit comments, one of the authors or your regular Dorsey attorney would be happy to assist you.