

CMS Unveils Proposed Rule Regarding Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products

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On October 15, 2018, the Centers for Medicare and Medicaid Services (CMS) unveiled its [proposed rule](#) requiring direct-to-consumer television advertisements for prescription drug and biological products to contain the list price (defined as the Wholesale Acquisition Cost) if the product is reimbursable by Medicare or Medicaid. Medical devices are not included in the proposed rule, although CMS seeks comment on how advertised drugs should be treated if used in combination with a non-advertised device. If finalized, the requirement will be sweeping and only purports to exclude products costing under \$35 per month for a 30-day supply or a typical course of treatment.

CMS prescribes specific language for manufacturers to use at the end of an advertisement:

The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.

The list price is determined “on the first day of the quarter during which the advertisement is being aired or otherwise broadcast.” This pricing statement must be legible, “placed appropriately against a contrasting background for sufficient duration,” and must be in an easily read font and size. Manufacturers are permitted under the proposed rule, “[t]o the extent permissible under current laws,” to include a competitor’s current product list price, so long as the disclosure is done in a “truthful, non-misleading way.”

CMS proposes that drug and biological products in violation of the proposed rule would be publically listed on its website. Although CMS acknowledged that it was proposing no other HHS-specific enforcement mechanisms, CMS anticipates an influx in private actions under the Lanham Act as the primary enforcement mechanism if the proposed rule is finalized.

Health and Human Services Secretary Alex Azar emphasized the proposed rule’s intent to mitigate consumer out-of-pocket costs and reduce unnecessary Medicare and Medicaid expenditures. Interested stakeholders can submit comments online to the [regulations.gov docket](#) or by mail until December 17, 2018.

National Law Review, Volume VIII, Number 296

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