

NCHA Financial Feature



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CMS Proposes to Require Manufacturers to Disclose Drug Prices in Television Ads

The Centers for Medicare and Medicaid Services (CMS) have released a proposed rule that is intended to reduce the price to consumers of prescription drugs and biological products. This rule would require direct-to-consumer (DTC) television advertisements for prescription drug and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product.

The 45-page rule is scheduled for publication in the Oct. 18, 2018 *Federal Register*. A copy is available at: <https://bit.ly/2q2qAfo>. The proposal provides a 60-day comment period ending Dec. 17, 2018.

Provisions of Proposed Regulation (§§403.1200, 403.1201, 403.1202, 403.1203, and 403.1204)

CMS is proposing to amend subchapter A, part 403 by adding a new subpart L.

Proposed §403.1202 sets forth the requirement that advertisements for certain prescription drug or biological products on television (including broadcast, cable, streaming, and satellite), must contain a statement or statements indicating the Wholesale Acquisition Cost (referred to as the “list price”) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: “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.”

Manufacturers set the Wholesale Acquisition Cost, also known as list price, for their products. The Department recognizes that other prices may be paid by distributors, pharmacies, patients, and others in the supply chain. Because these other prices vary by contracts established by payors or others, only the Wholesale Acquisition Cost is certain to be known by the manufacturer when creating DTC ads.

The price stated in the advertisement must be current as of the date of publication or broadcast. This provision would specify that where the price is related to the “typical course of treatment,” and the course of treatment varies depending on the indication for which the drug is prescribed, the list price used should be the one for the “course of treatment” associated with the primary indication addressed in the advertisement.

To the extent permissible under current laws, manufacturers would be permitted to include an up-to-date competitor product’s list price, so long as they do so in a truthful, non-misleading way. In §403.1200(b),

CMS is proposing an exception to the requirement at proposed §403.1202(a) to provide that an advertisement for any prescription drug or biological product and that has a list price of less than \$35 per month for a 30-day supply or typical course of treatment will be exempt from these transparency requirements.

In publishing this proposed rule, CMS is seeking comment on several specifics. In particular, CMS seeks comment on whether Wholesale Acquisition Cost is the amount that best reflects the “list price” for the stated purposes of price transparency and comparison shopping under this proposed regulation. CMS also seeks comment on whether 30-day supply and typical course of treatment are appropriate metrics for a consumer to gauge the cost of the drug. Further, CMS seeks comment on how to treat an advertised drug that must be used in combination with another non-advertised drug or device. And, CMS seeks comment as to whether the cost threshold of \$35 to be exempt from compliance with this rule is the appropriate level and metric for such an exemption.

CMS is also proposing that §403.1200 set forth the scope of applicability to specify that this requirement will apply to any advertisement for a prescription drug or biological product distributed in the United States, for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act.

Comments

Regrettably, the proposal does not specify when the rule would become effective.

Our Washington liaison, Larry Goldberg of Larry Goldberg Consulting, provided NCHA with this summary. Please contact Jeff Weegar, NCHA, at 919-677-4231, jweegar@ncha.org or Ronnie Cook, NCHA, at 919-4225, rcook@ncha.org if you have questions.