

(b) *Excepted pharmaceuticals.* An advertisement for any prescription drug or biological product that has a list price, as defined in § 403.1201, less than \$35 per month for a 30-day supply or typical course of treatment shall be exempt from the requirements of this subpart.

§ 403.1201 Definitions.

For the purposes of this subpart, the following definitions apply:

(a) *Biological product.* Biological product means any biological product, as that term is defined in Public Health Service Act (“PHS Act”) section 351(i), that is licensed by the Food and Drug Administration pursuant to section 351 and is subject to the requirements of Federal Food, Drug, and Cosmetic Act (FDCA) section 503(b)(1).

(b) *Prescription drug.* Prescription drug means any drug, as defined in the FDCA section 201(g), that has been approved by the Food and Drug Administration pursuant to FDCA section 505 and is subject to the requirements of FDCA section 503(b)(1).

(c) *List price.* List price means the wholesale acquisition cost, as defined in paragraph (d) of this section.

(d) *Wholesale acquisition cost.* Wholesale acquisition cost means, with respect to a prescription drug or biological product, the manufacturer’s list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

§ 403.1202 Pricing information.

Any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) must contain a

textual statement indicating the current 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.” Where the price is related to the typical course of treatment and that typical course of treatment varies depending on the indication for which a prescription drug or biological product is prescribed, the list price to be used is the one for the typical course of treatment associated with the primary indication addressed in the advertisement.

§ 403.1203 Specific presentation requirements.

The textual statement described in § 403.1202 shall be presented at the end of an advertisement in a legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

§ 403.1204 Compliance.

(a) *Identification of non-compliant products.* The Secretary will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation of this subpart.

(b) *State or local requirements.* No State or political subdivision of any State may establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by this subpart.