and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

§ 403.1105 Definitions.

For purposes of this subpart—

Applicable titles means Titles XVIII, XIX, or XXI of the Act.

§ 403.1110 Evaluation of models.

(a) *Evaluation*. The Secretary conducts an evaluation of each model tested under section 1115A of the Act. Such evaluation must include an analysis of the following:

(1) The quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.

(2) The changes in spending under the applicable titles by reason of the model.

(b) *Information*. Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including ''protected health information'' as that term is defined at 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

SOURCE: 84 FR 20757, May 10, 2019, unless otherwise noted.

§ 403.1200 Scope.

(a) *Covered pharmaceuticals*. Except as specified in paragraph (b) of this section, this subpart applies to advertisements 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.

(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