

## § 403.1100

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

### Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

SOURCE: 79 FR 68001, Nov. 13, 2014, unless otherwise noted.

#### § 403.1100 Purpose and scope.

The regulations in this subpart implement section 1115A of the Act. The intent of that section is to enable CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, 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

## 42 CFR Ch. IV (10–1–24 Edition)

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