

§ 149.710 Definitions.

For purposes of this subpart, the following definitions apply in addition to the definitions in § 149.30:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term “brand prescription drug” includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), and that is generally marketed under a proprietary, trademark-protected name. The term “brand prescription drug” includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this subchapter, in group health insurance coverage, or an individual who is covered by individual health insurance coverage, at any time during the reference year, and includes dependents.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, or for enrollees, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to individual health insurance coverage and fully-insured group health plans, earned premium as that term is defined in § 158.130 of this subchapter, excluding the adjustments specified in § 158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in § 158.130 of this subchapter, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under this subpart with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of this subpart.

Student market has the meaning given in § 158.103 of this subchapter.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic classification system provided by the Secretary, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in § 158.140 of this subchapter, excluding the adjustments specified in § 158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.