RCW 43.71C.050 Manufacturers—Data reporting. (1) Beginning October 1, 2019, a covered manufacturer must submit to the authority the following data for each covered drug:

(a) A description of the specific financial and nonfinancial factors used to make the decision to set or increase the wholesale acquisition cost of the drug. In the event of a price increase, a covered manufacturer must also submit the amount of the increase and an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug;

(b) The patent expiration date of the drug if it is under patent;

(c) Whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug;

(d) The itemized cost for production and sales, including the annual manufacturing costs, annual marketing and advertising costs, total research and development costs, total costs of clinical trials and regulation, and total cost for acquisition of the drug; and

(e) The total financial assistance given by the manufacturer through assistance programs, rebates, and coupons.

(2) For all qualifying price increases of existing drugs, a manufacturer must submit the year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction.

(3) If a manufacturer increases the price of an existing drug it has manufactured for the previous five years or more, it must submit a schedule of wholesale acquisition cost increases for the drug for the previous five years.

(4) If a manufacturer acquired the drug within the previous five years, it must submit:

(a) The wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition; and

(b) The name of the company from which the drug was acquired, the date acquired, and the purchase price.

(5) Except as provided in subsection (6) of this section, a covered manufacturer must submit the information required by this section:

(a) At least sixty days in advance of a qualifying price increase for a covered drug; and

(b) Within thirty days of release of a new covered drug to the market.

(6) For any drug approved under section 505(j) of the federal food, drug, and cosmetic act, as it existed on July 28, 2019, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on July 28, 2019, if submitting data in accordance with subsection (5)(a) of this section is not possible sixty days before the price increase, that submission must be made as soon as known but not later than the date of the price increase.

(7) The information submitted pursuant to this section is not subject to public disclosure under chapter 42.56 RCW. [2019 c 334 s 6.]