RCW 43.71C.060 Manufacturers—Notice of new drug applications.

(1) Beginning October 1, 2019, a manufacturer must submit written notice, in a form and manner specified by the authority, informing the authority that the manufacturer has filed with the FDA:

(a) A new drug application or biologics license application for a pipeline drug; or

(b) A biologics license application for a biological product.

(2) The notice must be filed within sixty days of the manufacturer receiving the applicable FDA approval date.

(3) Upon receipt of the notice, the authority may request from the manufacturer the following information if it believes the drug will have a significant impact on state expenditures:

(a) The primary disease, condition, or therapeutic area studied in connection with the new drug, and whether the drug is therapeutically indicated for such disease, condition, or therapeutic area;

(b) Each route of administration studied for the drug;

(c) Clinical trial comparators for the drug;

(d) The date at which the FDA must complete its review of the drug application pursuant to the federal prescription drug user fee act of 1992 (106 Stat. 4491; P.L. 102-571);

(e) Whether the FDA has designated the drug an orphan drug, a fast track product, or a breakthrough therapy; and

(f) Whether the FDA has designated the drug for accelerated approval, priority review, or if the drug contains a new molecular entity.

(4) A manufacturer may limit the information reported pursuant to this section to that which is otherwise in the public domain or publicly reported.

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