

WAC 182-51-0600 Manufacturers—Data and price reporting. (1) On or before December 31, 2020, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070, following the guidelines set in the authority's applicable data submission guide for each new covered drug introduced to market, or a covered drug that had a qualifying price increase between and including October 1, 2019, and October 15, 2020.

(2) Beginning October 16, 2020, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070, following the guidelines set in the authority's applicable data submission guide, for each covered drug as follows:

(a) Sixty days in advance of a qualifying price increase for a covered drug already introduced to market; or

(b) Within 30 days of a new covered drug introduced to market.

(3) For any drug approved under section 505(j) of the federal Food, Drug, and Cosmetic Act as it existed on August 18, 2020, or a biosimilar approved under section 351(k) of the federal Public Health Service Act as it existed on August 18, 2020, if submitting data in accordance with subsection (2)(a) of this section is not possible 60 days before the price increase, that submission must be made as soon as known but no later than the date of the price increase.

(4) The information submitted according to this section is not subject to public disclosure under chapter 42.56 RCW.

(5) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1100.

[Statutory Authority: RCW 41.05.021, 41.05.160, and 43.71C.110. WSR 22-17-075, § 182-51-0600, filed 8/16/22, effective 9/16/22. Statutory Authority: RCW 41.05.021, 41.05.160, 43.71C.010, 43.71C.050, 43.71C.100, and 43.71C.110. WSR 21-10-008, § 182-51-0600, filed 4/22/21, effective 5/23/21. Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-0600, filed 9/15/20, effective 10/16/20.]