**WAC 182-51-0700 Manufacturers—Notice of new drug applications and biologic license applications.** (1) On or before December 31, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1), following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 1, 2019, through October 15, 2020, for which the manufacturer has received an FDA approval date.

(2) Beginning October 16, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1), following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 16, 2020, within sixty calendar days of the manufacturer receiving the FDA approval date.

(3) The authority considers fifty thousand dollars per biennium to be a significant impact on state expenditures. Reporting entities may anticipate a request for additional information per RCW 43.71C.060(3) from the authority for products expected to exceed fifty thousand dollars per biennium. To improve efficiency in reporting, manufacturers who submit a new drug application or a biologics license application for a pipeline drug or a biologics license application for a biological product that is expected to cost the state more than fifty thousand dollars per biennium may submit the data elements in RCW 43.71C.060(3) at the same time they submit the notice of the new drug application.

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

(5) The agency 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 2019 c 334. WSR 20-19-079, § 182-51-0700, filed 9/15/20, effective 10/16/20.]