Prescription Drug Price Relief Act – Section by Section Summary

Section 1 – Short Title

This Act may be cited as the Prescription Drug Price Relief Act of 2021.

Section 2 – Identification of Excessively Priced Drugs

This Act requires the Secretary of Health and Human Services to annually identify the list of "excessively priced" patented, brand name drugs that are being sold in the U.S. at prices higher than the median price in Canada, the United Kingdom, Germany, France, and Japan.

If the Secretary is unable to determine the median price of a drug in other countries, or if the Secretary believes that a drug is unaffordable even though its domestic price does not exceed the median price in other countries, the Secretary may still label the drug "excessively priced" after considering the following factors:

(1) The size of the affected patient population
(2) The value of the drug to patients, including whether the price impacts access to the drug
(3) The Federal Government subsidies and investments related to the drug
(4) The costs associated with developing the drug
(5) Whether the drug provided a significant improvement in health outcomes when approved
(6) The cumulative global revenues generated by the drug
(7) Whether the price of the drug increased during any annual quarter by more than CPI-U
(8) Other factors the Secretary determines appropriate

Anyone may petition the Secretary to review the price of a patented brand name drug. The Secretary must respond within 90 days and make the response and rationale publicly available.

The Secretary shall establish a process to carry out the annual drug price review described in this section not later than one year after the date of enactment of this Act.

Section 3 – Ending Government-Granted Monopolies for Excessively Priced Drugs

If the U.S. price of a patented brand name drug exceeds the median price of the drug in other countries, or if the Secretary otherwise determines the drug to be excessively priced, the Secretary shall allow generic drug manufacturers to make more affordable versions of the drug.

Specifically, if a brand name drug price is excessive, the Secretary shall (1) waive or void any exclusive rights granted to the drug's manufacturer by the government to make or sell the drug, and (2) regardless of any applicable patents, grant open, non-exclusive, and compulsory licenses so that any person, organization, or company may make, import, or sell the drug in the U.S.

The Secretary shall review and act upon applications for generic versions of excessively priced brand name drugs within eight months of submission.

Any price increases of drugs deemed to be excessively priced during the time period between official designation of excessive price and the first generic competitor beginning manufacturing will be subject to civil action.

Section 4 – Excessive Drug Price License

Any entity accepting a license to make a generic version of an excessively priced brand name drug under this Act shall pay a reasonable royalty to the holder(s) of the original drug patent.

The Secretary shall set the royalty rate to a level that is consistent with making drugs available to purchasers, including Federal, State, local, and nongovernment purchasers and individuals, at prices that are affordable and reasonable. Under no circumstances shall the royalty rate be so high as to cause the generic drug to be sold at an excessive price.

Section 5 – Public Excessive Drug Price Database

The Secretary is required to create a public "excessive drug price database" listing each patented brand name drug, whether the U.S. drug prices exceed the median prices in other countries, and other information. The Secretary must update the database within 30 days of receiving the annual drug manufacturer reports required by this Act.

Within 60 days of completing the annual drug price review, the Secretary shall submit to Congress and make publicly available a report summarizing the year's price review activities.

Section 6 – Drug Manufacturer Reporting

Drug manufacturers must submit annual reports to the Secretary that include domestic and international pricing information for each brand name drug they manufacture. The first annual report is due by January 15 of the year following the date of enactment of this Act.

Any manufacturer that fails to submit the required information in a timely manner or that knowingly provides false information to the Secretary shall be liable for a civil monetary penalty; collected funds shall support competitive research grant programs of the National Institutes of Health.

Section 7 – Prohibition of Anticompetitive Behavior

No drug manufacturer may engage in anticompetitive behavior that would interfere with this Act or run contrary to the public interest in the availability of affordable prescription drugs.

Section 8 – Definitions.