WEST VIRGINIA CODE: §33-54-3

§33-54-3. Drug manufacturer reporting requirements.

(a) Not later than January 15 of each calendar year, a drug manufacturer shall submit a report to the Auditor stating the following information for each brand-name, specialty, and generic drug manufactured by the drug manufacturer and sold in the state directly by the drug manufacturer or a wholesale drug distributor: *Provided*, That the requirements of this section only apply to:

(1) Generic, brand-name, or specialty drugs with a wholesale acquisition cost of at least $100 for a 30-day supply; and

(2) A generic, brand-name, or specialty drug manufactured by a drug manufacturer that recognizes a wholesale acquisition cost increase of 40 percent or greater over the preceding three calendar years, or 15 percent or greater in the previous calendar year.

(b) The report shall include:

(1) The name of the drug;

(2) Whether the drug is a brand-name drug or generic drug;

(3) The effective date of any change or any reportable change in the wholesale acquisition cost price;

(4) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration;

(5) The national drug code for the specific drug;

(6) Aggregate company-level research and development costs for the most recent calendar year for which final audit data is available;

(7) The name and annual U.S. sales/revenue of each drug manufacturer’s prescription drugs that lost patent exclusivity in the United States in the previous three calendar years; and

(8) A statement regarding the factor or factors that caused any increase in the wholesale acquisition cost.

(c) If the drug manufacturer is subject to reporting requirements established by the Securities and Exchange Commission, the quality and types of information submitted to the Auditor under this section must be consistent with the information that the drug manufacturer includes in the drug manufacturer’s annual report submitted on Form 10-K to the Securities and Exchange Commission.

WV Legislature