WEST VIRGINIA CODE CHAPTER 33 ARTICLE 54

WV Legislature

§33-54-1. Short title.

This article shall be known and cited as the Requiring Accountable Pharmaceutical Transparency, Oversight, and Reporting Act.

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§33-54-2. Definitions.

For the purpose of this article:

"Auditor" means the State Auditor of West Virginia, by himself or herself, or by any person appointed, designated, or approved by the State Auditor to perform the service.

"Brand-name drug" means a prescription drug approved under 21 USC §355(b) or 42 USC §262.

"Drug" or "prescription drug" refers to a brand-name, specialty, or generic prescription drug.

"Drug manufacturer" means any entity that holds the national drug code for a prescription drug and is engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products, and is not a wholesale distributor of drugs or a retail pharmacy licensed under state law.

"Generic drug" means a prescription drug approved under 21 USC §355(j).

"Health benefit plan" means an individual, blanket, or group plan, policy, or contract for health care services issued or delivered by a health benefit plan issuer in the state.

"Health benefit plan issuer" means an entity subject to the insurance laws and rules of this state, or subject to the jurisdiction of the Insurance Commissioner, that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including government agencies and any insurer subject to §5-16-1 *et seq.*, §33-15-1 *et seq.*, §33-16-1 *et seq.*, §33-24-1 *et seq.*, §33-25-1 *et seq.*, and §33-25A-1 *et seq*. of this code. For purposes of this article, the term "health benefit plan issuer" does not include insurers or managed care organizations with respect to their Medicaid or CHIP plans or contracts which are reviewed and approved by the Bureau of Medical Services.

"Market introduction" means the month and year in which the manufacturer acquired or first marketed the drug for sale in the United States.

"National drug code" or "NDC" means the numerical code maintained by the United States Food and Drug Administration that includes the labeler code, product code, and package code.

"Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

"Total spending" means the total of allowed amounts associated with payment for a specified drug or drug group, for all covered lives.

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"Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

"Wholesale acquisition cost" or "WAC" is the manufacturer's list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include prompt pay or other discounts, rebates, or reductions in price. The current or proposed WAC is the amount that prompts reporting under this act. If reported by a drug group, it is the average WAC weighted by the relevant number of WAC units.

"Wholesale drug distributor" means an entity licensed by the West Virginia State Board of Pharmacy that is engaged in the sale of generic, brand-name, or specialty drugs to persons other than a consumer or patient.

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§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.

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§33-54-4. Health benefit plan issuer reporting requirements.

No later than March 1 of each calendar year, each health benefit plan issuer shall submit to the Auditor a report providing the following information for the immediately preceding calendar year: *Provided*, That nothing in this article should be construed as to requiring a health benefit plan issuer to disclose confidential health information protected by the Health Insurance Portability and Accountability Act:

(1) The names of the 25 most frequently prescribed prescription drugs across all plans;

(2) The percent increase in annual net spending for prescription drugs across all plans;

(3) The percent increase in premiums that were attributable to prescription drugs across all plans;

(4) The percentage of specialty drugs with utilization management requirements across all plans; and

(5) The premium reductions that were attributable to specialty drug utilization management.

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§33-54-5. Auditor's searchable pharmaceutical transparency website created.

(a) By July 1, 2021, the Auditor shall create a searchable pharmaceutical price transparency website, containing the information specified in §33-54-3 and §33-54-4 of this code, available to the public at no cost, and presented in a consumer-friendly, searchable format.

(b) Effective July 1, 2021, the Auditor shall update the information displayed on the searchable pharmaceutical price transparency website within 30 days of receiving updated or revised information from a drug manufacturer or health benefit plan issuer.

(c) Each drug manufacturer or health benefit plan issuer shall submit to the Auditor in writing contact information for those entities or individuals employed by the health benefit plan issuer or drug manufacturer responsible for complying with reporting requirements specified in §33-54-3 of this code, and shall notify the Auditor within 30 days of any changes to this information.

(d) The Auditor shall publish the identity of any drug manufacturer or health benefit plan issuer who fails to comply with the requirements of this article or who submits false or inaccurate information to the Auditor.

(e) The Auditor shall compile a report regarding information submitted pursuant to the provisions of §33-54-4 of this code and submit this analysis to the Legislative Oversight Commission on Health and Human Resources Accountability created pursuant to §16-29E-1 *et seq.* of this code beginning on December 30, 2022, and annually thereafter.

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