WEST VIRGINIA LEGISLATURE

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Introduced

House Bill 4583

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[Introduced January 29, 2020; Referred to the
Committee on Health and Human Resources then
Government Organization]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §33-53-1, §33-53-2, §33-53-3, §33-53-4 and §33-53-5, all relating to enacting the Requiring Accountable Pharmaceutical Transparency, Oversight, and Reporting Act; providing a short title; providing for definitions; outlining reporting requirements drug manufacturers and health benefit plan issuers to the Auditor; outlining the required pharmaceutical data required by the Auditor; directing the Auditor to create a searchable pharmaceutical transparency website; protecting confidentiality of patient information; providing registration requirements to drug manufacturers and health benefit plan issuers; and outlining penalties when a health benefit plan or drug manufacturer submits inaccurate or fails to submit information to the Auditor.

Be it enacted by the Legislature of West Virginia:

ARTICLE 53. REQUIRING ACCOUNTABLE PHARMACEUTICAL TRANSPARENCY, OVERSIGHT, AND REPORTING ACT.

§33-53-1. Short title.

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

§33-53-2. 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 insurance company, health maintenance organization, government agency, or hospital and medical services corporation that issues and manages a health benefit plan, government health plan for public employees, or Medicaid or Medicare program within the state.

"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.

"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 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.

§33-53-3. 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 sold in the state directly by the drug manufacturer or a wholesale drug distributor: *Provided*, That the requirements of this section only applies 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 (WAC) 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 (NDC) 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.

§33-53-4. 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 frequency 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.

§33-53-5. 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 available to the public at no cost, containing the information specified in §33-53-3 and §33-53-4 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 §33-53-3 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.

NOTE: The purpose of this bill is to require drug manufacturers and health benefit plan issuers who sell prescription drugs in West Virginia to provide cost information, changes in cost information, and prescription drug statistics to the State Auditor. The bill requires the Auditor to publish this information on a searchable transparency website available to the public and disclose identities of drug manufacturers and health benefit plan issuers who fail to comply with the requirements of the article.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.