HOUSE BILL NO. 345

INTRODUCED BY K. SULLIVAN

A BILL FOR AN ACT ENTITLED: “AN ACT REQUIRING THE DISCLOSURE OF AGREEMENTS DELAYING THE PRODUCTION AND INTRODUCTION OF GENERIC-NAME PRESCRIPTION DRUGS IN MONTANA; PROVIDING FOR ENFORCEMENT; PROVIDING PENALTIES; REQUIRING REPORTS; PROVIDING DEFINITIONS; AND PROVIDING RULEMAKING AUTHORITY.”

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Short title.** [Sections 1 through 5] may be cited as the "Prescription Drug Pay-for-Delay Transparency Act".

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 5], the following definitions apply:

(1) "Brand name" means the proprietary or the registered trademark name given to a prescription drug product by its manufacturer, labeler, or distributor and placed on the drug, its container, label, or wrapping at the time of packaging.

(2) "Generic name" means the chemical or established name of a drug product or drug ingredient published in the latest edition of an official compendium recognized by the board of pharmacy provided for in 2-15-1733.

(3) "Health insurance issuer" has the meaning provided in 33-22-140.

(4) "Manufacturer" means:

(a) a person approved by application to the United States food and drug administration to manufacture a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262;

(b) a person who manufactures a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262 that is not the subject of an

approved application or license by the United States food and drug administration;

(c) a colicensed partner of a person described in subsection (4)(a) or (4)(b) that obtains the product directly from a person described in subsection (4)(a), (4)(b), or (4)(d); or

(d) an affiliate of a person described in subsection (4)(a), (4)(b), or (4)(c) that receives the product directly from a person described in subsection (4)(a), (4)(b), or (4)(c).

(5) "Pharmacy benefit manager" means a person who contracts with pharmacies on behalf of a health insurance issuer, third-party administrator, or plan sponsor to process claims for prescription drugs, provide retail network management for pharmacies or pharmacists, and pay pharmacies or pharmacists for prescription drugs.

(6) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.

NEW SECTION. **Section 3. Prescription drug manufacturer disclosure.** (1) Each manufacturer of a brand-name prescription drug that is transacting business in this state or whose brand-name prescription drugs are otherwise sold or distributed in this state shall notify the attorney general if the manufacturer enters into an arrangement, through agreement or otherwise, with another manufacturer for the purpose or effect of delaying or preventing the other manufacturer from introducing a generic-name drug as a substitute for the brand-name drug in the Montana market.

(2) The notice must disclose:

(a) the name and wholesale price of the brand-name drug;

(b) the disease or diseases for which the brand-name drug is commonly prescribed to treat;

(c) the manufacturer of the brand-name drug;

(d) the name of the manufacturer of the generic-name drug; and

(e) the length of the delay to which the manufacturers have agreed.

(3) The notice must be provided to the attorney general:

(a) no later than 30 days after the manufacturer has entered into the agreement; and

(b) in the form and manner prescribed by the attorney general by rule.

(4) No later than 30 days after receiving the notice, the attorney general shall share the information with all health insurance issuers and pharmacy benefits managers transacting business in the state. The information must be shared in a format and manner prescribed by the attorney general by rule.

(5) The attorney general shall report annually to the board of pharmacy provided for in 2-15-1733 and, in accordance with 5-11-210, to the economic affairs interim committee on all notices sent pursuant to this section. The report must include the prescription drug, cost, disease, and manufacturer both for the brand-name prescription drug and the generic-name prescription drug.

NEW SECTION. **Section 4. Penalty.** (1) A manufacturer that fails to provide the required notice is subject to:

(a) for a first violation, a fine of no less than $5,000 for each day the manufacturer fails to properly provide notice; and

(b) for each subsequent violation, a fine of no less than $10,000 for each day the manufacturer fails to properly provide notice.

(2) The penalties are payable to the attorney general for deposit in the general fund. The attorney general may file a civil action to recover the penalties.

(3) The fines provided for in this section are in addition to all other penalties imposed by the laws of this state.

NEW SECTION. **Section 5. Rulemaking authority.** The attorney general may adopt rules necessary to implement the provisions of [sections 1 through 5].

NEW SECTION. **Section 6. Codification instruction.** [Sections 1 through 5] are intended to be codified as an integral part of Title 30, chapter 14, and the provisions of Title 30, chapter 14, apply to [sections 1 through 5].

NEW SECTION. **Section 7. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications,

the part remains in effect in all valid applications that are severable from the invalid applications.

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