_____ BILL NO. _____

INTRODUCED BY _____
(Primary Sponsor)

A BILL FOR AN ACT ENTITLED: “AN ACT ESTABLISHING REQUIREMENTS FOR PRESCRIPTION DRUG BENEFITS OFFERED UNDER A HEALTH BENEFIT PLAN; ESTABLISHING THE METHOD OF DETERMINING THE PAYMENT FOR BRAND-NAME AND GENERIC PRESCRIPTION DRUGS; REQUIRING HEALTH INSURANCE ISSUERS TO USE COMPENSATION FOR PRESCRIPTION DRUGS TO LOWER CONSUMER HEALTH INSURANCE COSTS; PROHIBITING CONFLICTS OF INTEREST IN DEVELOPING FORMULARIES; PROVIDING DEFINITIONS; PROVIDING RULEMAKING AUTHORITY; PROVIDING PENALTIES; AND PROVIDING A DELAYED EFFECTIVE DATE.”

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

NEW SECTION. **Section 1. Definitions.** For the purposes of [sections 1 through 10], the following definitions apply:

(1) "Average wholesale price" means the price calculated in accordance with [section 5].

(2) "Brand-name drug" means a prescription drug that is:

(a) marketed under a proprietary name or a registered trademark name;

(b) under patent protection; and

(c) listed as a brand-name drug on a published, independent national pricing source that is readily available to any person.

(3) "Commissioner" means the commissioner of insurance for the state of Montana.

(4) "Compensation" means any direct or indirect financial benefit, including but not limited to:

(a) rebates, discounts, or credits;

(b) fees;

(c) grants; or

(d) any other form of remuneration or item of value.

(5) "Cost-sharing amount" means the amount due from a covered person to a provider for a

prescription drug at the point of sale.

(6) "Covered person" means a policyholder, subscriber, certificate holder, enrollee, or other individual who is participating in a health benefit plan.

(7) "Dispensing fee" means the price a provider has agreed to accept for dispensing a prescription drug for a covered person.

(8) "Formulary" means a list of the prescription drugs and their related coverage and benefit levels that a health insurance issuer will cover under a health benefit plan.

(9) "Generic drug" means a prescription drug, whether identified by its chemical, proprietary, or nonproprietary name, that is:

(a) therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance, and intended use;

(b) not under patent protection; and

(c) listed as a generic drug on a published, independent national pricing source that is readily available to any person.

(10) "Health benefit plan" means health insurance coverage offered to individuals in the individual market.

(11) "Ingredient cost" means the price a provider has agreed to accept for a prescription drug, excluding the dispensing fee and cost-sharing amount.

(12) "Labeler" means a person who is engaged in the practice of labeling prescription drugs as governed by 21 U.S.C. 321 and 21 CFR, part 201.

(13) "Manufacturer" has the meaning provided in 37-7-602.

(14) "Maximum allowable cost" means the maximum amount a health insurance issuer will pay a provider for a generic drug or a brand-name drug that has at least one generic alternative available.

(15) "Prescription drug" has the meaning provided in 37-7-101.

(16) "Provider" means:

(a) a pharmacist licensed pursuant to Title 37, chapter 7;

(b) a pharmacy subject to regulation under Title 37, chapter 7;

(c) a pharmacy located outside this state that:

(i) ships, mails, or delivers by any lawful means a prescription drug to a resident of this state pursuant to a legally issued prescription;

(ii) provides to a resident of this state information on drugs or devices that may include but is not limited to advice relating to therapeutic values, potential hazards, and uses; or

(iii) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs; or

(d) any other person licensed under Title 37 or Title 50 to dispense prescription drugs for remuneration, subject to the limitations of 37-2-102 and 37-2-103.

(17) "Repackager" has the meaning provided in 37-7-602.

(18) "Retail pharmacy network" means the providers who:

(a) have contracted with an entity that is providing or administering a health benefit plan to fill and sell prescription drugs under the health benefit plan; and

(b) have a physical, storefront location in this state.

(19) "Wholesale distributor" has the meaning provided in 37-7-602.

NEW SECTION. **Section 2. Applicability and scope.** [Sections 1 through 10] apply to health insurance issuers that provide prescription drug benefits under a health benefit plan.

NEW SECTION. **Section 3. Health insurance issuer oversight and contracting responsibilities.** (1) A health insurance issuer shall monitor all activities carried out by or on behalf of the issuer under [sections 1 through 10] and is responsible for ensuring that all requirements of [sections 1 through 10] are met.

(2) If a health insurance issuer contracts with another person to perform activities required under [sections 1 through 10], the issuer shall monitor the person's activities and ensure that the person meets the requirements of [sections 1 through 10].

(3) A health insurance issuer may not enter into any contract or agreement or allow a person acting on its behalf to enter into any contract or agreement that would prohibit a provider from:

(a) offering a covered person the option of paying the cash price for the purchase of a prescription drug if the cash price is less than the covered person's cost-sharing amount; or

(b) providing information to a state or federal agency, a law enforcement agency, or the commissioner when disclosure of the information is required by law.

(4) (a) A health insurance issuer shall provide an adequate retail pharmacy network for the provision of prescription drugs for its covered persons.

(b) An issuer may not include a mail-order pharmacy in its calculation of an adequate network.

NEW SECTION. **Section 4. Prescription drug payments -- confidentiality.** (1) A health insurance issuer shall, in accordance with the provisions of this section, establish the amount a health benefit plan pays a provider for a prescription drug covered by the plan.

(2) A health insurance issuer shall use a maximum allowable cost list to establish the maximum payment for a generic drug and for a brand-name drug that has at least one generic alternative available. The amount paid by a health insurance issuer for a prescription drug must be the same amount received by the provider.

(3) A health insurance issuer's maximum allowable cost list must be:

(a) reviewed and updated in accordance with 33-22-172;

(b) accessible to each provider in the issuer's retail pharmacy network at least once every 10 calendar days; and

(c) readily accessible by the commissioner upon request.

(4) A health insurance issuer shall use the average wholesale price to establish the maximum payment for:

(a) a brand-name drug for which a generic alternative is not available; or

(b) a prescription drug that is not included on a maximum allowable cost list.

(5) (a) The amount paid by a health insurance issuer to a provider under contract with the health insurance issuer or an issuer's designee for dispensing a prescription drug must:

(i) consist of the ingredient cost and the dispensing fee, less any cost-sharing amount; and

(ii) be calculated at the point of sale.

(b) Only the dispensing provider may retain the payment described in this subsection (5).

(6) A dispensing provider may not be denied payment or be subjected to a reduced payment

retroactively unless the original claim was submitted fraudulently or in error.

(7) If the commissioner accesses a health insurance issuer's maximum allowable cost list as allowed under [sections 1 through 10], the commissioner shall treat the maximum allowable cost list as confidential except:

(a) as provided in 33-1-311; or

(b) to the extent the commissioner uses a health insurance issuer's maximum allowable cost list in any examination or investigation of any activities governed by [sections 1 through 10].

NEW SECTION. **Section 5. Use of average wholesale cost -- calculations -- limitations.** (1) For the purposes of [sections 1 through 10], the average wholesale price of a prescription drug must reflect the price identified by a published, independent national pricing source for the quantity of the drug dispensed on the date it was dispensed.

(2) A health insurance issuer shall maintain records for each prescription drug transaction paid under a health benefit plan. The records must identify:

(a) the national drug code number for the prescription drug for the quantity of the prescription drug that was dispensed; and

(b) the average wholesale price listed by the published, independent national pricing source for the identified drug on the date it was dispensed.

(3) If a health insurance issuer uses the average wholesale price to establish the cost of the drug for the purposes of [section 4], the issuer:

(a) except as provided in subsection (4), may use only one published, independent national pricing source during each calendar year;

(b) shall use the same published, independent national pricing source when negotiating payment rates for each provider; and

(c) shall identify on its website the name of the published, independent national pricing source used to determine the average wholesale price.

(4) An issuer may use more than one published, independent national pricing source in a calendar year only if the original national pricing source is no longer available.

NEW SECTION. **Section 6. Use of compensation to lower premiums.** (1) All compensation remitted by or on behalf of a manufacturer, labeler, repackager, or wholesale distributor that is directly or indirectly related to a health benefit plan must be remitted to and retained by the health benefit plan and used to lower health benefit plan premiums for covered persons.

(2) Beginning March 1, 2023, a health insurance issuer shall file with the commissioner on or before March 1 of each year an annual report in a manner and form established by rule demonstrating how the health insurance issuer has complied with subsection (1).

NEW SECTION. **Section 7. Prescription drug formularies -- development -- prohibition on conflicts of interest -- availability.** (1) A health insurance issuer shall prohibit conflicts of interest for any committee or other entity established to develop a formulary for a health benefit plan by ensuring, at a minimum, that:

(a) no person involved with the committee or entity:

(i) is employed or compensated by a manufacturer, labeler, repackager, or wholesale distributor while serving on the committee or entity;

(ii) was employed or compensated by a manufacturer, labeler, repackager, or wholesale distributor in the 12-month period before the person's involvement with the committee or entity; or

(iii) receives any other remuneration, funding, or other item of value from a manufacturer, labeler, repackager, or wholesale distributor during the person's involvement with the committee or entity; and

(b) the committee or entity does not receive any remuneration, funding, or other item of value from a manufacturer, labeler, repackager, or wholesale distributor.

(2) A health insurance issuer shall provide electronic access to the formulary developed for a health benefit plan and covered persons.

(3) The information provided for a formulary must include:

(a) an indication of whether each drug on the formulary is a preferred drug for purposes of coverage under the plan;

(b) an indication of whether each drug on the formulary requires prior authorization or is subject to

other limitations on coverage; and

(c) if the issuer uses a tiered formulary, the tier in which the drug has been placed.

(4) The information provided for applicable benefit levels must include:

(a) the cost-sharing amount, if any, for each drug; and

(b) whether the drug is subject to a deductible, and if so, the amount of the deductible.

(5) The information required under subsections (3) and (4) must be made available to a covered person in writing upon request.

(6) A health insurance issuer shall review brand-name drugs newly approved by the United States food and drug administration for inclusion on the formulary of a health benefit plan no later than 90 days after approval by the United States food and drug administration.

NEW SECTION. **Section 8. Health insurance issuer data -- audits.** (1) (a) A health insurance issuer shall maintain and have access to all data related to the administration and provision of prescription drug benefits under a health benefit plan, including but not limited to:

(i) the names, addresses, member identification numbers, protected health information, and other personal information of covered persons; and

(ii) all contracts, documentation, and records, including transaction and pricing data, related to the dispensing of prescription drugs for covered persons.

(b) An issuer is entitled to audit all transaction records related to the administration and provision of prescription drug benefits at a location of its choosing and with an auditor of its choosing.

(2) Any sale or transaction involving the transfer of records, information, or data described in subsection (1) must be made in accordance with the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq., and related federal regulations and the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. 17921, et seq., and related federal regulations.

(3) A health insurance issuer shall retain all records, contracts, documents, and data governed by [sections 1 through 10], including the records, contracts, documents, and data described in subsection (1) and any related audit records, for at least 5 years in accordance with prudent standards of insurance recordkeeping.

(4) The commissioner may access a health insurance issuer's records, contracts, documents, and

data upon request or for examination, audit, or inspection. Any confidential information contained in the records, contracts, documents, and data remains confidential as required by law except that the commissioner may use the records, contracts, documents, and data in any proceedings involving the health insurance issuer, the issuer's designee, or any other person performing an activity governed by [sections 1 through 10].

NEW SECTION. **Section 9. Rulemaking.** The commissioner shall adopt rules establishing:

(1) the retail network adequacy requirements of [section 3];

(2) the manner for filing and form of the report required under [section 6]; and

(3) the requirements for online publication of a health insurance issuer's formulary.

NEW SECTION. **Section 10. Penalties.** The commissioner may impose a fine in accordance with 33-1-317 and 33-1-318 for:

(1) a violation of [sections 1 through 10]; or

(2) the refusal or failure of a health insurance issuer, an issuer's designee, or any other person performing an activity governed by [sections 1 through 10] to:

(a) provide records, contracts, documents, or data governed by [sections 1 through 10] within 30 business days of the commissioner's request; or

(b) submit to an examination, audit, or inspection by the commissioner.

NEW SECTION. **Section 11. Codification instruction.** [Sections 1 through 10] are intended to be codified as an integral part of Title 33, chapter 22, and the provisions of Title 33, chapter 22, apply to [sections 1 through 10].

NEW SECTION. **Section 12. Saving clause.** [This act] does not affect rights and duties that matured, penalties that were incurred, or proceedings that were begun before [the effective date of this act].

NEW SECTION. **Section 13. 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.

NEW SECTION. **Section 14. Effective date.** [This act] is effective January 1, 2022.

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