SECOND REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 2267

102ND GENERAL ASSEMBLY

4887H.03C DANA RADEMAN MILLER, Chief Clerk

AN ACT

To amend chapter 376, RSMo, by adding thereto three new sections relating to insurance coverage of pharmacy services, with penalty provisions.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 376, RSMo, is amended by adding thereto three new sections, to be known as sections 376.411, 376.414, and 376.415, to read as follows:

376.411. 1. For purposes of this section, the following terms mean:

(1) "Clinician-administered drug", any legend drug, as defined in section 338.330, that is administered by a health care provider who is authorized to administer the drug;

(2) "Health carrier", the same meaning given to the term in section 376.1350;

(3) "Participating provider", the same meaning given to the term in section 376.1350;

(4) "Pharmacy benefits manager", the same meaning given to the term in section 376.388.

2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health carrier or pharmacy benefits manager shall not:

(1) Impose any penalty, impediment, differentiation, or limitation on a participating provider for providing medically necessary clinician-administered drugs regardless of whether the participating provider obtains such drugs from a provider that is in the network including, but not limited to, refusing to approve or pay or reimbursing less than the contracted payment amount;

(2) Impose any penalty, impediment, differentiation, or limitation on a covered person who is administered medically necessary clinician-administered drugs regardless

EXPLANATION — Matter enclosed in bold-faced brackets **[**~~thus~~**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

of whether the participating provider obtains such drugs from a provider that is in the network including, but not limited to, limiting coverage or benefits; requiring an additional fee, higher co-payment, or higher coinsurance amount; or interfering with a patient's ability to obtain a clinician-administered drug from the patient's provider or pharmacy of choice by any means including, but not limited to, inducing, steering, or offering financial or other incentives; or

(3) Impose any penalty, impediment, differentiation, or limitation on any pharmacy, including any class B hospital pharmacy as defined in section 338.220, that is dispensing medically necessary clinician-administered drugs regardless of whether the participating provider obtains such drugs from a provider that is in the network including, but not limited to, requiring a pharmacy to dispense such drugs to a patient with the intention that the patient will transport the medication to a health care provider for administration.

3. The provisions of this section shall not apply if the clinician-administered drug is not otherwise covered by the health carrier or pharmacy benefits manager.

376.414. 1. For purposes of this section, the following terms mean:

(1) "340B drug", a drug that:

(a) Is a covered outpatient drug within the meaning of Section 340B of the Public Health Service Act, 42 U.S.C. Section 256b, enacted by Section 602 of the Veterans Health Care Act of 1992, Pub. L. 102-585;

(b) Has been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. Section 256b(a)(1); and

(c) Is purchased by a covered entity;

(2) "Covered entity", the same meaning given to the term in Section 340B(a)(4) of the Public Health Service Act, 42 U.S.C. Section 256b(a)(4);

(3) "Health carrier", the same meaning given to the term in section 376.1350;

(4) "Package", the same meaning given to the term in 21 U.S.C. Section 360eee (11)(A);

(5) "Pharmaceutical manufacturer", an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drugs, whether directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drugs;

(6) "Pharmacy", the same meaning given to the term in section 338.210;

(7) "Pharmacy benefits manager", the same meaning given to the term in section 376.388;

(8) "Third-party logistics provider", the same meaning given to the term in section 338.330;

(9) "Wholesale drug distributor", the same meaning given to the term in section 338.330.

2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health carrier or pharmacy benefits manager shall not discriminate against a covered entity or a pharmacy, including but not limited to by doing any of the following:

(1) Reimbursing a covered entity or pharmacy for a quantity of a 340B drug in an amount less than it would pay to any other similarly situated pharmacy that is not a covered entity or a pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or pharmacy or that the entity or pharmacy dispenses 340B drugs;

(2) Imposing any terms or conditions on covered entities or pharmacies that differ from such terms or conditions applied to other similarly situated pharmacies or entities that are not covered entities on the basis that the entity or pharmacy is a covered entity or pharmacy or that the entity or pharmacy dispenses 340B drugs including, but not limited to, terms or conditions with respect to any of the following:

(a) Fees, chargebacks, clawbacks, adjustments, or other assessments;

(b) Professional dispensing fees;

(c) Restrictions or requirements regarding participation in standard or preferred pharmacy networks;

(d) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles; and

(e) Any other restrictions, conditions, practices, or policies that, as specified by the director of the department of commerce and insurance, interfere with the ability of a covered entity to maximize the value of discounts provided under 42 U.S.C. Section 256b;

(3) Interfering with an individual's choice to receive a 340B drug from a covered entity or pharmacy, whether in person or via direct delivery, mail, or other form of shipment, by any means including, but not limited to, modifying a patient's payment limitations or cost-sharing obligations on the basis of participation, in whole or in part, in the 340B drug pricing program;

(4) Discriminating in reimbursement to a covered entity or pharmacy based on the determination or indication a drug is a 340B drug;

(5) Requiring a covered entity or pharmacy to identify, either directly or through a third party, a 340B drug sooner than forty-five days after the point of sale of the 340B drug;

(6) Refusing to contract with a covered entity or pharmacy for reasons other than those that apply equally to entities that are not covered entities or similarly situated pharmacies, or on the basis that:

(a) The entity is a covered entity; or

(b) The entity or pharmacy is described in any of subparagraphs (A) to (O) of 42 U.S.C. Section 256b(a)(4);

(7) Denying the covered entity the ability to purchase drugs at 340B program pricing by substituting a rebate discount;

(8) Refusing to cover drugs purchased under the 340B drug pricing program; or

(9) Requiring a covered entity or pharmacy to reverse, resubmit, or clarify a 340B-drug pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing, except as required by federal law.

3. A pharmaceutical manufacturer, wholesale drug distributor, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer, wholesale drug distributor, or third-party logistics provider, shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

4. The director of the department of commerce and insurance shall impose a civil penalty on any health carrier, pharmacy benefits manager, or agent or affiliate of such health carrier or pharmacy benefits manager that violates the requirements of subsection 2 of this section. Such penalty shall not exceed five thousand dollars per violation per day.

5. The commission of any act prohibited by subsection 3 of this section shall constitute an unlawful practice within the meaning of section 407.020, and any action authorized in sections 407.010 to 407.130 may be taken. Each package of 340B drugs determined to be subject to a prohibited act under subsection 3 of this section shall constitute a separate violation under subsection 3 of this section.

6. The board of pharmacy is authorized to investigate any complaint of a violation of subsection 3 of this section by an individual or entity licensed by the board of pharmacy, and to impose discipline, suspension, or revocation of the license of any such individual or entity.

7. The director of the department of commerce and insurance shall promulgate rules to implement the provisions of subsection 2 of this section. The board of pharmacy may promulgate rules to implement the provisions of subsection 3 of this section. Any

rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2024, shall be invalid and void.

8. Nothing in this section shall be construed or applied to be less restrictive than any federal law as to any person or entity regulated by this section. Nothing in this section shall be construed or applied to be in conflict with any of the following:

(1) Applicable federal law and related regulation; or

(2) Other laws of this state, if the state law is compatible with applicable federal law.

9. Limited distribution of a drug required under 21 U.S.C. Section 355-1 shall not be construed as a violation of subsection 3 of this section.

10. No covered entity shall intentionally act in a nefarious manner with the sole purpose of defrauding the 340B program. The department of health and senior services shall have sole authority to initiate suit pursuant to this section against a Missouri-based covered entity in a court of competent jurisdiction in Missouri. A finding by such court that a covered entity has intentionally acted in a nefarious manner with the sole purpose of defrauding the 340B program may result in the imposition of a fine not to exceed one million dollars for a covered entity with at least five hundred inpatient beds and not to exceed five hundred thousand dollars for all other covered entities. No action shall be initiated by the department pursuant to this section against a covered entity until the conduct and claims at issue are substantiated by the Office of Pharmacy Affairs within the Health Resources and Services Administration through a final, formal audit finding of intentional fraud against the 340B program by the covered entity with damages in excess of two hundred fifty thousand dollars; and such conduct and claims are fully and finally adjudicated and substantiated through all permissible or required administrative actions or hearings; and all available court challenges or appeals. Any fine paid pursuant to this section shall be submitted to the department of mental health to fund mental health services.

376.415. 1. For purposes of this section, the following terms mean:

(1) "Biological product", the same meaning given to the term in 42 U.S.C. Section 262(i);

(2) "Biosimilar", the same meaning given to the term in 42 U.S.C. Section 262(i);

(3) "Health carrier", the same meaning given to the term in section 376.1350;

(4) "Pharmacy benefits manager", the same meaning given to the term in section 376.388;

(5) "Reference product", the same meaning given to the term in 42 U.S.C. Section 262(i).

2. A health carrier, a pharmacy benefits manager, or an agent or affiliate of such health carrier or pharmacy benefits manager that provides coverage for a reference product or a biological product that is biosimilar to the reference product shall provide coverage for the reference product and all biological products that have been deemed biosimilar to the reference product. The scope, extent, and amount of such required coverage shall be the same including, but not limited to, any payment limitations or cost-sharing obligations.

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