FIRST REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 198

102ND GENERAL ASSEMBLY

0545H.02C DANA RADEMAN MILLER, Chief Clerk

AN ACT

To amend chapter 376, RSMo, by adding thereto four 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 four new sections, to be known as sections 376.411, 376.413, 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.

376.413. 1. For purposes of this section, the term "health carrier" shall have the same meaning given to the term in section 376.1350, and the term "pharmacy benefits manager" shall have 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) Discriminate, lower the reimbursement, or impose any separate terms upon an entity in any contract based, in whole or in part, on the entity's participation in the 340B drug pricing program as described in 42 U.S.C. Section 256b including, but not limited to:

(a) Requiring an entity participating in the 340B drug pricing program 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;

(b) Requiring a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim or imposing any billing or reporting requirements that identify whether a drug was purchased through the 340B drug pricing program;

(c) Excluding an entity from a network on the basis, in whole or in part, of the entity's participation in the 340B drug pricing program;

(d) Establishing or setting network adequacy requirements based, in whole or in part, on 340B drug pricing program participation by a provider or a pharmacy;

(e) Prohibiting an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing

from participating in the provider network on the basis, in whole or in part, of participation in 340B drug pricing;

(f) Offering a lower reimbursement for a drug purchased under the 340B drug pricing program than for the same drug not purchased under 340B drug pricing;

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

(h) Charging more than fair market value or seeking profit sharing in exchange for services involving the 340B drug pricing program; or

(2) Limit a patient's freedom to use an entity that participates in the 340B drug pricing program 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.

3. A pharmacy benefits manager shall not base drug formulary or drug coverage decisions upon the 340B drug-pricing status of a drug, including price or availability, or whether a dispensing entity participates in the 340B drug pricing program.

4. A pharmaceutical manufacturer shall not prohibit an entity from contracting or participating with an entity authorized to participate in the 340B drug pricing program by denying access to drugs that are manufactured by the pharmaceutical manufacturer or by denying the entity the ability to purchase drugs at 340B program pricing by substituting a rebate discount.

5. All pharmacy claims processed by a pharmacy that participates in the 340B drug pricing program are final at the point of adjudication.

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

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

(a) A covered outpatient drug as defined in 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; and

(b) Purchased under an agreement entered into under 42 U.S.C. Section 256b;

(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) "Pharmacy", an entity licensed under chapter 338;

(5) "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, not including a pharmaceutical manufacturer, 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 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) Requiring a covered entity or pharmacy to identify, either directly or through a third party, 340B drugs. However, a pharmaceutical manufacturer may enter into a contract to utilize an industry standard platform to identify a 340B dispensation no sooner than forty-five days after the point of sale of the 340B drug. A health carrier, pharmacy benefits manager, or agent or affiliate of such health carrier or pharmacy benefits manager may only use such identification information to comply with rebate transparency requirements of a pharmaceutical manufacturer;

(5) 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);

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

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

(8) 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. 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 this section. Such penalty shall not exceed five thousand dollars per violation per day.

4. The director of the department of commerce and insurance shall promulgate rules to implement the provisions 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, 2023, shall be invalid and void.

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.

✓