FIRST REGULAR SESSION

SENATE BILL NO. 433

99TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time February 16, 2017, and ordered printed.

ADRIANE D. CROUSE, Secretary.

1935S.02I

AN ACT

To repeal section 208.227, RSMo, and to enact in lieu thereof four new sections relating to the MO HealthNet pharmacy program.

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

Section A. Section 208.227, RSMo, is repealed and four new section enacted in lieu thereof, to be known as sections 208.227, 208.228, 208.229, and 208.231, to read as follows:

208.227. **[**Fee for service eligible policies for prescribing psychotropic medications shall not include any new limits to initial access requirements, except dose optimization or new drug combinations consisting of one or more existing drug entities or preference algorithms for SSRI antidepressants, for persons with mental illness diagnosis, or other illnesses for which treatment with psychotropic medications are indicated and the drug has been approved by the federal Food and Drug Administration for at least one indication and is a recognized treatment in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature and deemed medically appropriate for a diagnosis. No restrictions to access shall be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression.**] 1. The MO HealthNet division shall establish a pharmaceutical case management or polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs or medications. The division shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-supported prescription practices. The division**

EXPLANATION–Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

shall communicate with providers, as such term is defined in section 208.164, whose prescribing practices deviate from or do not otherwise utilize best medical evidence-supported prescription practices. The communication may be telemetric, written, oral, or some combination thereof. These programs shall be established and administered through processes established and supported under a memorandum of understanding between the department of mental health and the department of social services, or their successor entities.

2. The provisions of this section shall not prohibit the division from utilizing point-of-sale clinical edits to ensure clinical best practices, including, but not limited to:

(1) Drug safety and avoidance of harmful drug interactions;

(2) Compliance with nationally-recognized and juried clinical guidelines from national medical associations using medical evidence and emphasizing best practice principles;

(3) Detection of patients receiving prescription drugs or medications from multiple prescribers; and

(4) Detection, prevention, and treatment of substance use disorders.

3. The division shall issue a provider update no less than twice annually to enumerate treatment and utilization principles for MO HealthNet providers, including, but not limited to:

(1) Treatment with antipsychotic drugs or medications, as with any other form of treatment, should be individualized in order to optimize the patient's recovery and stability;

(2) Treatment with antipsychotic drugs or medications should be as effective, safe, and well-tolerated as supported by best medical evidence;

(3) Treatment with antipsychotic drugs or medications should consider the individual patient's needs, preferences, and vulnerabilities;

(4) Treatment with antipsychotic drugs or medications should support an improved quality of life for the patient;

(5) Treatment choices should be informed by the best current medical evidence and should be updated consistent with evolving nationally-recognized best practices guidelines; and

(6) Cost considerations in the context of best practices, efficacy,

and patient response to adverse drug reactions should guide antipsychotic medication policy and selection once the preceding principles have been maximally achieved.

4. If the division implements any new policy or point-of-sale clinical edit for an antipsychotic drug or medication, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug or medication that they utilize and on which they are stable or that they have successfully utilized previously and have been reasonable adherent to the prescribed therapy. The MO HealthNet prescription drug formulary shall adhere to the following:

(1) If an antipsychotic drug or medication listed as "non-preferred" is considered clinically-appropriate for an individual patient based on the patient's previous response to the drug or medication or other medical considerations, prior authorization procedures, as such term is defined in section 208.164, shall be simple and flexible;

(2) If an antipsychotic drug or medication listed as "non-preferred" is known or found to be safe and effective for a given individual, the division shall not restrict the patient's access to that drug or medication. Such non-preferred drug or medication shall, for that patient only and if that patient has been reasonably adherent to the prescribed therapy, be considered "preferred" in order to minimize the risk of relapse and to support continuity of care for the patient;

(3) A patient shall not be required to change antipsychotic drugs or medications due to changes in medication management policy, prior authorization, or a change in the payor responsible for the benefit; and

(4) Patients transferring from state psychiatric hospitals to community-based settings, including patients previously found to be not guilty of a criminal offense by reason of insanity or who have previously been found to be incompetent to stand trial, shall be permitted to continue the medication regimen that aided the stability and recovery so that such patient was able to successfully transition to the community-based setting.

5. The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug Administration-approved antipsychotic drugs or medications that have substantially the same clinical differences and adverse effects that are predictable across individual patients and whose manufacturers

have entered into a federal rebate agreement with the Department of Health and Human Services. Clinical differences may include, but not be limited to, weight gain, extrapyramidal side effects, sedation, susceptibility to metabolic syndrome, other substantial adverse effects, the availability of long-acting formulations, and proven efficacy in the treatment of psychosis. The available drugs or medications for an individual patient shall include, but not be limited to, the following categories:

(1) At least one relatively weight-neutral atypical antipsychotic medication;

(2) At least one long-acting injectable formulation of an atypical antipsychotic;

(3) Clozapine;

(4) At least one atypical antipsychotic medication with relatively potent sedative effects;

(5) At least one medium-potency typical antipsychotic medication;

(6) At least one long-acting injectable formulation of a high-potency typical antipsychotic medication;

(7) At least one high-potency typical antipsychotic medication; and

(8) At least one low-potency typical antipsychotic medication.

6. Nothing in subsection 5 of this section shall be construed to require any of the following:

(1) Step therapy or a trial of a typical antipsychotic drug or medication before permitting a patient access to an atypical drug or antipsychotic medication;

(2) A limit of one atypical antipsychotic drug or medication as an open-access, first-choice agent; or

(3) A trial of one of the eight categories of drugs or medications listed in subsection 5 of this section before having access to the other seven categories.

7. The department of social services may promulgate rules and regulations 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, 2017, shall be invalid and void.

8. The department shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department determines are necessary to implement the provisions of this section.

208.228. 1. The drug utilization review board, established under section 208.175, shall annually identify up to ten prescription drugs on which the state spends significant health care dollars and for which the wholesale acquisition cost has increased by fifty percent or more over the past five years or by fifteen percent or more over the past twelve months, thereby creating a substantial public interest in understanding the development of the drugs' pricing. The drugs identified shall represent different drug classes. The board shall provide to the attorney general and the department of social services the list of prescription drugs developed under this section and the department shall make the information available to the public on its website.

2. For each prescription drug identified, the attorney general shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug in a format that the attorney general determines to be understandable and appropriate. The manufacturer shall submit to the attorney general all relevant information and supporting documentation necessary to justify the manufacturer's wholesale acquisition cost increase, which may include, but not be limited to, the following:

(1) All factors that have contributed to the wholesale acquisition cost increase;

(2) The percentage of the total wholesale acquisition cost increase attributable to each factor; and

(3) An explanation of the role of each factor in contributing to the wholesale acquisition cost increase.

Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent

permitted under state or federal law.

3. The attorney general, in consultation with the MO HealthNet division, shall provide a report to the general assembly on or before December thirty-first of each year based on the information received from manufacturers under this section. The attorney general shall also post the report on the attorney general's website. The drug utilization review board shall advise the division as to suggested remediations for the drug price increases, including the use of a more restrictive prior authorization process, as such term is defined in section 208.164.

4. Information provided to the attorney general under this section shall be confidential and not subject to public disclosure under chapter 610. The report released by the attorney general under subsection 3 of this section shall be released in a manner that does not allow for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information.

5. The attorney general may bring a civil action for injunctive relief, costs, and attorney fees, and to impose upon a manufacturer that fails to provide the information required under this section a civil penalty of no more than ten thousand dollars per violation. Each unlawful failure to provide information shall constitute a separate violation.

6. The department of social services shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department determines are necessary to implement a program within the MO HealthNet pharmacy program to remove a drug from the state's pharmacy formulary if the cost of such drug exceeds five percent of the percent increase in the medical care component for prescription drugs of the Consumer Price Index for All Urban Consumers, as reported by the Bureau of Labor Statistics, or its successor index, from September to September of the preceding calendar year, and if such increase is not found to be justified.

208.229. 1. Under the MO HealthNet pharmacy program, any covered outpatient drug that is newly prescribed to a MO HealthNet participant who has not previously been prescribed such drug shall by subject to prior authorization, as such term is defined in section

208.164, as well as be limited to not more than a fifteen-day trial supply for the first dispensation of the drug.

2. The number of prescriptions of a covered outpatient drug for a MO HealthNet participant that may be filled or refilled shall be limited to five per participant during any one period of eligibility that does not exceed the normal monthly eligibility span for that participant's assistance category. The only allowable exception to the five-prescription limitation shall be for certain specified drugs as listed in 13 CSR 70-20.040 that are commonly prescribed for long-term chronic medical conditions, and for prior authorized drugs.

208.231. 1. The MO HealthNet division shall, subject to the approval of the Centers for Medicare and Medicaid Services and to the extent provided under 42 CFR 447.53, require MO HealthNet participants to pay a nominal co-payment for covered outpatient drugs as follows:

(1) Four dollars for drugs on the preferred drug list (PDL), as defined in 13 CSR 70-20.200; and

(2) Eight dollars for drugs that are not on the PDL.

2. MO HealthNet participants who are exempt under 42 CFR 447.56(a)(1) shall not be subject to a co-payment for a covered outpatient drug.

3. The division shall not impose a co-payment for any covered services described in 42 CFR 447.56(a)(2).

4. The co-payments established in this section shall be considered separate from any shared dispensing fee for which the MO HealthNet participant may be liable.

5. The department may promulgate any rules and regulations necessary 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, 2017, shall be invalid and void.

6. The department shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department determines are necessary to implement the provisions of this section.

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