FIRST REGULAR SESSION

SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 433

99TH GENERAL ASSEMBLY

Reported from the Committee on Seniors, Families and Children, March 16, 2017, with recommendation that the Senate Committee Substitute do pass.

ADRIANE D. CROUSE, Secretary.

1935S.04C

AN ACT

To repeal section 208.227, RSMo, and to enact in lieu thereof three 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Section A. Section 208.227, RSMo, is repealed and three new sections enacted in lieu thereof, to be known as sections 208.227, 208.229, and 208.231, to read as follows: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 division shall establish a pharmaceutical case management or polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs. The division shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-**

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

supported prescription practices. The division 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 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 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, 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 should be as effective, safe, and well-tolerated as supported by best medical evidence;

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

(4) Treatment with antipsychotic drugs 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 clinical edit for an antipsychotic drug, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they utilize and on which they are stable or that they have successfully utilized previously and have been reasonably adherent to the prescribed therapy. The division shall adhere to the following:

(1) If an antipsychotic drug listed as "non-preferred" is considered clinically-appropriate for an individual patient based on the patient's previous response to the drug 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 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. Such non-preferred drug 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 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 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 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 medication;

(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 before permitting a patient access to an atypical drug or antipsychotic medication;

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

(3) A trial of one of the eight categories of drugs 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.

9. As used in this section, the following terms mean:

(1) "Division", the MO HealthNet division of the department of social services;

(2) "Reasonably adherent", a patient's adherence to taking medication on a prescribed schedule as measured by a medication position ratio of at least seventy-five percent;

(3) "Successfully utilized previously", a drug or drug regimen's provision of clinical stability in treating a patient's symptoms.

208.229. 1. Pharmaceutical manufacturers shall pay to the state, in accordance with 42 U.S.C. Section 1396r-8, rebates on eligible utilization of covered outpatient drugs dispensed to MO HealthNet participants under the MO HealthNet pharmacy program as follows:

(1) For single source drugs and innovator multiple source drugs, rebates shall reflect the manufacturer's best price, as defined by 42 CFR 447.505, as updated and amended, and set forth in 42 CFR 447.509, as updated and amended; and

(2) For single source drugs and innovator and noninnovator multiple source drugs, any additional rebates necessary to account for certain price increases in excess of inflation, as set forth in 42 CFR 447.509, as updated and amended.

2. For purposes of this section, the terms "innovator multiple source drug", "noninnovator multiple source drug", and "single source drug" shall have the same meaning as defined in 42 CFR 447.502, as updated and amended.

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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