FIRST REGULAR SESSION

HOUSE BILL NO. 364

101ST GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE GREGORY.

DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal section 208.227, RSMo, and to enact in lieu thereof two new sections relating to antipsychotic drugs.

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

Section A. Section 208.227, RSMo, is repealed and two new sections enacted in lieu 2 thereof, to be known as sections 208.226 and 208.227, to read as follows:

208.226. 1. For purposes of this section, the term "division" means the MO 2 HealthNet division of the department of social services.

3 2. The division shall not impose restrictions to access that preclude availability of
4 any individual antipsychotic medication.

5 **3.** The provisions of this section shall not prohibit the division from utilizing clinical 6 edits to ensure clinical best practices including, but not limited to:

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

8 (2) Compliance with nationally recognized and juried clinical guidelines from 9 national medical associations using medical evidence and emphasizing best practice 10 principles;

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

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

4. The division shall issue a provider update at least twice annually to enumerate
 treatment and utilization principles for MO HealthNet providers including, but not limited
 to:

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.

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

19 (2) Treatment with antipsychotic drugs should be as effective, safe, and 20 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; and

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

5. 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 use and on which they are stable or that they have successfully used previously. The division may recommend a reference list with no restrictions to access.

208.227. 1. [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.] For purposes of this section, the term "division" means the MO HealthNet division of the department of social services.

5 2. The division shall establish a pharmaceutical case management or polypharmacy 6 program for high risk MO HealthNet participants with numerous or multiple prescribed drugs. 7 The division shall also establish a behavioral health pharmacy and opioid surveillance program 8 to encourage the use of best medical evidence-supported prescription practices. The division 9 shall communicate with providers, as such term is defined in section 208.164, whose prescribing 10 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. 11 12 These programs shall be established and administered through processes established and 13 supported under a memorandum of understanding between the department of mental health and 14 the department of social services, or their successor entities.

- 15 [2.] **3.** The provisions of this section shall not prohibit the division from utilizing clinical 16 edits to ensure clinical best practices including, but not limited to:
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(1) Drug safety and avoidance of harmful drug interactions;

18 (2) Compliance with nationally recognized and juried clinical guidelines from national 19 medical associations using medical evidence and emphasizing best practice principles;

- 20 (3) Detection of patients receiving prescription drugs from multiple prescribers; and
- 21 (4) Detection, prevention, and treatment of substance use disorders.

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22 [3. The division shall issue a provider update no less than twice annually to enumerate
 23 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;

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

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

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

32 (5) Treatment choices should be informed by the best current medical evidence and
 33 should be updated consistent with evolving nationally recognized best practice guidelines; and
 34 (6) Cost considerations in the context of best practices, efficacy, and patient response
 35 to adverse drug reactions should guide antipsychotic medication policy and selection once the
 36 preceding principles have been maximally achieved.

37 4. If the division implements any new policy or clinical edit for an antipsychotic drug,

38 the division shall continue to allow MO HealthNet participants access to any antipsychotic drug

39 that they utilize and on which they are stable or that they have successfully utilized previously.

40 The division shall adhere to the following:

(1) If an antipsychotic drug listed as "nonpreferred" is considered elinically 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

44 be simple and flexible;

45 (2) If an antipsychotic drug listed as "nonpreferred" is known or found to be safe and
 46 effective for a given individual, the division shall not restrict the patient's access to that drug.
 47 Such nonpreferred drug shall, for that patient only and if that patient has been reasonably
 48 adherent to the prescribed therapy, be considered "preferred" in order to minimize the risk of
 49 relapse and to support continuity of care for the patient;
 50 (3) A patient shall not be required to change antipsychotic drugs due to changes in

51 medication management policy, prior authorization, or a change in the payor responsible for the

52 benefit; and

53 (4) Patients transferring from state psychiatric hospitals to community-based settings,

54 including patients previously found to be not guilty of a criminal offense by reason of insanity

55 or who have previously been found to be incompetent to stand trial, shall be permitted to

56 continue the medication regimen that aided the stability and recovery so that such patient was

57 able to successfully transition to the community-based setting.

58 5. The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug Administration-approved antipsychotic 59 60 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 61 with the Department of Health and Human Services. Clinical differences may include, but not 62 be limited to, weight gain, extrapyramidal side effects, sedation, susceptibility to metabolic 63 syndrome, other substantial adverse effects, the availability of long-acting formulations, and 64 proven efficacy in the treatment of psychosis. The available drugs for an individual patient shall 65 66 include, but not be limited to, the following categories: -(1) At least one relatively weight-neutral atypical antipsychotic medication; 67 (2) At least one long-acting injectable formulation of an atypical antipsychotic; 68 (3) Clozapine; 69 (4) At least one atypical antipsychotic medication with relatively potent sedative effects; 70 (5) At least one medium-potency typical antipsychotic medication; 71

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

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

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

76 <u>6. Nothing in subsection 5 of this section shall be construed to require any of the</u> 77 following:

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

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

81 (3) A trial of one of the eight categories of drugs listed in subsection 5 of this section

82 before having access to the other seven categories.

83 implement the provisions of this section. Any rule or portion of a rule, as that term is defined 84 in section 536.010, that is created under the authority delegated in this section shall become 85 86 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 87 88 powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective 89 date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of 90 rulemaking authority and any rule proposed or adopted after August 28, 2017, shall be invalid 91 and void.

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92 [8-] 5. The department shall submit such state plan amendments and waivers to the
93 Centers for Medicare and Medicaid Services of the federal Department of Health and Human
94 Services as the department determines are necessary to implement the provisions of this section.

- 95 [9. As used in this section, the following terms mean:
- 96 (1) "Division", the MO HealthNet division of the department of social services;
- 97 (2) "Reasonably adherent", a patient's adherence to taking medication on a prescribed
 98 schedule as measured by a medication position ratio of at least seventy-five percent;
- 99 (3) "Successfully utilized previously", a drug or drug regimen's provision of clinical
- 100 stability in treating a patient's symptoms.]