FIRST REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 139

99TH GENERAL ASSEMBLY

0471H.04C D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 208.227, 208.790, and 208.798, RSMo, and to enact in lieu thereof eight new sections relating to controlled substances, with a delayed effective date for certain sections.

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

Section A. Sections 208.227, 208.790, and 208.798, RSMo, are repealed and eight new sections enacted in lieu thereof, to be known as sections 195.430, 195.435, 208.227, 208.229, 208.790, 208.798, 338.700, and 338.710, to read as follows:

195.430. 1. There is hereby established in the state treasury the "Controlled Substance Abuse Prevention Fund", which shall consist of moneys appropriated by the general assembly, not to exceed the amount of fees collected by the department of health and senior services for the issuance of registrations to manufacture, distribute, or dispense controlled substances. The state treasurer shall be custodian of the fund. In accordance with sections 30.170 and 30.180, the state treasurer may approve disbursements. The fund shall be a dedicated fund and moneys in the fund shall be used solely for the operation, regulation, enforcement, and educational activities of the bureau of narcotics and dangerous drugs. The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

2. All fees authorized to be charged by the department shall be transmitted to the department of revenue for deposit in the state treasury for credit to the fund, to be disbursed solely for the payment of operating expenses of the bureau of narcotics and dangerous drugs to conduct inspections, enforce controlled substances laws and

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.

regulations, provide education to health care professionals and the public, and prevent abuse of controlled substances.

3. Any moneys appropriated or made available by gift, grant, bequest, contribution, or otherwise to carry out the purposes of this section shall be paid to and deposited in the controlled substances abuse prevention fund.

195.435. The bureau of narcotics and dangerous drugs shall employ investigators as needed based on the number of controlled substance registrants.

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.~~**]** **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. **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-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 practice 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. The division shall adhere to the following:

(1) If an antipsychotic drug listed as "nonpreferred" 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 "nonpreferred" 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 nonpreferred 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;

(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 meanings as defined in 42 CFR 447.502, as updated and amended.

208.790. 1. The applicant shall have or intend to have a fixed place of residence in Missouri, with the present intent of maintaining a permanent home in Missouri for the indefinite future. The burden of establishing proof of residence within this state is on the applicant. The requirement also applies to persons residing in long-term care facilities located in the state of Missouri.

2. The department shall promulgate rules outlining standards for documenting proof of residence in Missouri. Documents used to show proof of residence shall include the applicant's name and address in the state of Missouri.

3. Applicant household income limits for eligibility shall be subject to appropriations, but in no event shall applicants have household income that is greater than one hundred eighty-five percent of the federal poverty level for the applicable family size for the applicable year as converted to the MAGI equivalent net income standard. **The provisions of this subsection shall only apply to Medicaid dual eligible individuals.**

4. The department shall promulgate rules outlining standards for documenting proof of household income.

208.798. The provisions of sections 208.780 to 208.798 shall terminate on August 28, **[**~~2017~~**] 2022**.

338.700. As used in sections 338.700 to 338.710, the following terms shall mean:

(1) "Board", the Missouri board of pharmacy;

(2) "Department", the Missouri department of health and senior services;

(3) "Program", the RX cares for Missouri program.

338.710. 1. There is hereby created in the Missouri board of pharmacy the "RX Cares for Missouri Program". The goal of the program shall be to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri.

2. The board, in consultation with the department, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop or provide programs or education to promote medication safety or to suppress or prevent prescription drug abuse, misuse, and diversion in the state of Missouri. In no case shall the authorization include, nor the funds be expended for, any state prescription drug monitoring program including, but not limited to, such as are defined in 38 CFR 1.515. Funds disbursed to a state agency under this section may enhance, but shall not supplant, funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for implementing the program in consultation with the department. The board and the department may enter into interagency agreements between themselves to allow the department to assist in the management or operation of the program. The board may award funds directly to the department to implement, manage, develop, or provide programs or education pursuant to the program.

4. After a full year of program operation, the board shall prepare and submit an evaluation report to the governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall expire on August 28, 2019.

Section B. The enactment of sections 195.430 and 195.435 of this act shall become effective on August 28, 2019.

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