AN ACT relating to psychotropic drugs.

WHEREAS, in 2023, Kentucky's Medicaid program statistics showed 89,200 children and adolescents under the age of 18 were prescribed psychotropic drugs, including 8,386 under the age of six; and

WHEREAS, the administration of nearly every psychotropic drug to children under the age of six is off-label, meaning the drug is prescribed for age groups not approved by the United States Food and Drug Administration (FDA); and

WHEREAS, psychotropic drugs, including stimulants, antidepressants, antipsychotics, and other behavioral drugs, are being prescribed to children using Medicaid funding and are documented by the FDA to have severe side effects, including but not limited to addiction, suicidal ideation, aggression, hallucinations, cardiovascular events, stunted growth, and developmental concerns; and

WHEREAS, parents and caregivers are frequently not informed of the FDA-documented risks associated with the psychotropics being prescribed, including the pediatric risks; and

WHEREAS, 21 C.F.R. sec. 208.20 establishes the requirements for an FDA Medication Guide to provide easily understandable information about the risks and side effects of prescription drugs for the average consumer, including parents and caregivers; and

WHEREAS, according to the 21 C.F.R. sec. 208.20, a Medications Guide must detail "the particular serious and significant public health concern that has created the need for the Medication Guide"; note any known "pediatric risk"; include the risk of "patients developing dependence on the drug products"; use a font size no smaller than ten-point; be written in "nontechnical, understandable language"; and "not be promotional in tone or content"; and

WHEREAS, to effectively monitor the effects of psychotropic drugs prescribed to children and adolescents, particularly the FDA-cited "pediatric effects," parents and

caregivers must be given a hard copy of the FDA Medication Guide for the psychotropic drug being prescribed; and

WHEREAS, because Medicaid is a state and federally funded program that provides essential healthcare services to vulnerable populations, including children and adolescents, it should be required to distribute the FDA Medication Guide to ensure recipients and their guardians are fully informed of the risks and potential adverse effects of psychotropic medications, thereby supporting informed consent and promoting patient safety; and

WHEREAS, a reliable system for parents and caregivers to report adverse drug reactions to psychotropic drugs is essential to help Medicaid agencies and legislators monitor and assess the frequency, severity, and impact of such reactions within the public sector; and

WHEREAS, the absence of an accessible, Medicaid-funded reporting mechanism for drug side-effects limits the ability to identify and address these risks effectively, thereby compromising the safety of children and adolescents; and

WHEREAS, Medicaid is the primary payer for psychotropic medications prescribed to children and adolescents in the public sector, including for off-label use in children under the age of six, making it directly responsible for ensuring the safety and monitoring of these prescriptions; and

WHEREAS, an adverse drug reaction (ADR) to psychotropic medications can have significant physical, psychological, and developmental impacts on children, requiring timely identification and response to mitigate harm; and

WHEREAS, the establishment of an online ADR reporting system would enable Medicaid to fulfill its duty of care by providing a mechanism to collect critical safety data, support evidence-based decision-making, and comply with its responsibility to protect public health; and

WHEREAS, funding this reporting system aligns with Medicaid's obligations under

federal law to monitor and improve the quality of care provided to its oversight and accountability for the use of public funds in prescribing psychotropic medications; and

WHEREAS, the provisions of this Act are established to address these findings and enhance oversight, informed consent, and accountability for children in the Medicaid program;

NOW, THEREFORE,

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 205 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Adverse drug reaction" or "ADR" means any unintended harmful reaction or side effect to a psychotropic drug;

(b) "Child" means an individual under eighteen (18) years of age;

(c) "Medicaid-enrolled provider" means any licensed health professional authorized to prescribe medication to Medicaid beneficiaries;

(d) "Medication Guide" means handouts accompanying certain prescription medications with significant safety concerns as required under 21 C.F.R. sec. 208.20;

(e) "Online reporting system" means a web-based platform through which Medicaid beneficiaries or their parents or guardians can report ADRs related to psychotropic drugs; and

(f) "Psychotropic drugs":

1. Means medications that affect the mind, emotions, or behavior of a person, including but not limited to stimulants, antidepressants, antipsychotics; and

2. Is limited to psychotropic drugs included on the Medicaid uniform preferred drug list.

(2) (a) A Medicaid-enrolled provider prescribing psychotropic drugs to a child covered by Medicaid shall provide a Medication Guide to the child's parents or legal guardians before issuing a prescription.

(b) The Medication Guide shall be printed and reviewed with the parent or legal guardian to inform them of:

1. FDA-identified side effects and cautionary monitoring citations of additional potential risks;

2. Any FDA black box warning detailing serious or life-threatening risks; and

3. Pediatric-specific side effects or warnings related to children and teens.

(3) A Medicaid-enrolled provider shall obtain written informed consent from the parent or legal guardian before prescribing a psychotropic drug to a child covered by Medicaid. The consent shall be:

(a) Signed by the parent or legal guardian, confirming that he or she:

1. Has received and reviewed the Medication Guide; and

2. Understands the associated risks and side effects of the psychotropic drug; and

(b) Kept on file by the Medicaid-enrolled provider, with a copy provided to the parent or legal guardian.

(4) (a) The cabinet shall, within twelve (12) months after the effective date of this Act, develop and maintain a secure online reporting system of ADRs related to psychotropic drugs prescribed to children and adolescents covered by Medicaid.

(b) The system required under paragraph (a) of this subsection shall include free text fields for the:

1. Name of patient;

2. Name of medication;

3. Name of the person reporting;

4. Email address of the person reporting; and

5. Phone number of the person reporting.

(b) The system required under paragraph (a) of this subsection shall include drop-down menus for the following:

1. Age of patient;

2. Class of psychotropic drug, including

a. Antidepressants;

b. Antipsychotics;

c. Mood stabilizers;

d. Stimulants;

e. Anti-anxiety drugs and sedatives;

f. Hypnotics; and

g. Unknown;

3. Type of adverse reaction experienced or observed, including:

a. Physical reaction, including:

i. Gastrointestinal issues, including nausea, vomiting, diarrhea, or constipation;

ii. Neurological symptoms, including dizziness, headaches, seizures, or tremors;

iii. Cardiovascular symptoms, including increased heart rate or blood pressure changes; and

iv. Allergic reactions, rash, hives, or anaphylaxis;

b. Psychological reaction experienced or observed, including:

i. Mood changes, including irritability, depression, or euphoria;

ii. Anxiety or panic attacks;

iii. Hallucinations or delusions;

iv. Agitation or restlessness; and

v. Suicidal thoughts or behaviors; and

c. Behavioral reaction experienced or observed, including:

i. Sleep disturbances, including insomnia or hypersomnia;

ii. Increased aggression or hostility;

iii. Manic behaviors;

iv. Cognitive impairments, including memory loss or confusion;

v. Self-harm; and

vi. Disassociation;

4. Severity level of reaction, including:

a. Mild;

b. Moderate; and

c. Severe; and

5. Relation of person reporting, including:

a. Parent;

b. Foster parent;

c. Relative;

d. Legal guardian;

e. Case worker;

f. Social worker; and

g. Direct care staff.

(5) (a) The cabinet shall compile and submit a report no later than November 1, 2027, and each November 1 thereafter, summarizing ADR data related to psychotropic drugs administered to children and adolescents covered by

Medicaid to the Legislative Research Commission for referral to the Interim Joint Committees on Health Services and Families and Children.

(b) The report shall include:

1. The number of ADRs reported, categorized by patient age;

2. The totals of various severity levels of ADRs reported; and

3. A breakdown of ADRs by type of adverse reactions detailing the number of incidents for each category.

(6) The cabinet shall submit a report no later than November 1, 2027, and each November 1 thereafter summarizing implementation efforts and compliance statistics of Medicaid-enrolled providers to the Legislative Research Commission for referral to the Interim Joint Committees on Health Services and Families and Children.

(7) Medicaid-enrolled providers failing to comply with subsections (2) and (3) of this section may incur penalties, including but not limited to termination of Medicaid enrollment.

(8) The cabinet shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement this section, including the establishment of enforcement mechanisms and appropriate penalties for violations.