HB2512

LRB10410052KTG20123b

104TH GENERAL ASSEMBLY

State of Illinois

2025 and 2026

HB2512

Introduced 2/4/2025, by Rep. Jed Davis

SYNOPSIS AS INTRODUCED:

New Act
30 ILCS 105/5.1030 new

Creates the Accountability in Psychotropic Drug Prescriptions for Children Under Medicaid Act. Requires medical care providers prescribing psychotropic drugs to children under the State's Medicaid program to provide FDA Medication Guides to parents or legal guardians before issuing a prescription. Provides that the Medication Guides must be printed and reviewed with the parent or legal guardian, explaining (1) FDA-identified risks of the medication, including pediatric-specific warnings and (2) signs of potential side effects and adverse drug reactions detailed in the Medication Guide. Provides that written informed consent must be obtained from the parent or legal guardian before prescribing a psychotropic drug. Requires the Department of Healthcare and Family Services to, within 12 months after the effective date of the Act, develop and maintain a secure online reporting system for adverse drug reactions related to psychotropic drugs prescribed to children and adolescents. Contains provisions on adverse drug reaction reporting requirements; legislative oversight and reviews of adverse drug reaction reports related to psychotropic drugs; penalties for medical care providers who fail to comply with medication guide distribution; transparency and accountability reporting requirements for the Department of Healthcare and Family Services; and other matters. Amends the State Finance Act. Creates the Medicaid Oversight and Safety Measures Fund.

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A BILL FOR

AN ACT concerning health care.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Accountability in Psychotropic Drug Prescriptions for Children Under Medicaid Act.

Section 5. Legislative findings. The General Assembly finds the following:

(1) In 2023, Illinois' Medicaid program statistics showed 96,841 children and adolescents aged 0-17 being prescribed psychotropic drugs, including 7,227 children aged 0-5.

(2) The administration of nearly every psychotropic drug to children aged 0-5 is off-label, meaning the drugs are being prescribed for age groups not approved by the U.S. Food and Drug Administration (FDA).

(3) 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 include severe side effects, including, but not limited to, addiction, suicidal ideation, aggression, hallucinations, cardiovascular events, stunted growth, and developmental

concerns.

(4) Parents and caregivers are frequently not informed of the FDA-documented risks associated with the psychotropics being prescribed, including the pediatric risks.

(5) Section 208.20 of Title 21 of the United States Code of Federal Regulations (CFR) establishes the requirement for FDA Medication Guides to provide easily understandable information about the risks and side effects of prescription drugs for the average consumer, including parents and caregivers. According to federal regulations, Medication Guides must:

(A) Detail "the particular serious and significant public health concern that has created the need for the Medication Guide".

(B) Note any known "pediatric risks".

(C) Include the risk of "patients developing dependence on the drug product".

(D) Use a font size no smaller than 10-point.

(E) Be written in "nontechnical, understandable language".

(F) "Not be promotional in tone or content".

(6) 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.

(7) 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 Guides 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.

(8) 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.

(9) The absence of an accessible, Medicaid-funded reporting mechanism for drug side effects limits the ability to identify and address these risks effectively, compromising the safety of children and adolescents.

(10) Medicaid is the primary payer for psychotropic medications prescribed to children and adolescents in the public sector, including for off-label use in children as young as 0-5 years, making it directly responsible for ensuring the safety and monitoring of these prescriptions.

(11) Adverse drug reactions (ADRs) to psychotropic medications can have significant physical, psychological, and developmental impacts on children, requiring timely

identification and response to mitigate harm.

(12) The establishment of an online ADR reporting system would enable the State's Medicaid program 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.

(13) Funding this reporting system aligns with the State's Medicaid program's obligations under federal law to monitor and improve the quality of care provided to its beneficiaries, especially vulnerable pediatric populations, and would facilitate oversight and accountability for the use of public funds in prescribing psychotropic medications.

(14) The provisions of this Act are established to address these findings and enhance oversight, informed consent, and accountability in psychotropic drug prescriptions for children under the State's Medicaid program.

Section 10. Definitions. As used in this Act:

"Adverse drug reaction" or "ADR" means any unintended harmful reaction to a psychotropic drug.

"Department" means the Department of Healthcare and Family Services.

"FDA Medication Guides" means handouts accompanying

certain prescription medications with significant safety concerns, approved by the U.S. Food and Drug Administration (FDA), to inform patients and caregivers about risks, side effects, and proper usage.

"Medical care providers" means any licensed health professionals authorized to prescribe medication under the State's Medicaid program.

"Online Reporting System" means a web-based platform through which Medicaid beneficiaries or their guardians can report ADRs related to psychotropic drugs.

"Psychotropic drugs" means medications that affect the mind, emotions, or behavior, including, but not limited to, stimulants, antidepressants, antipsychotics, and other behavioral drugs, authorized or funded under the State's Medicaid program.

Section 15. Informed consent requirements.

(a) Distribution of FDA Medication Guides:

(1) Medical care providers prescribing psychotropic drugs to children under the State's Medicaid program must provide FDA Medication Guides to parents or legal guardians before issuing a prescription.

(2) The Medication Guides must be printed and reviewed with the parent or legal guardian, explaining:

(A) FDA-identified risks of the medication, including pediatric-specific warnings.

(B) Signs of potential side effects and adverse drug reactions detailed in the Medication Guide.

(b) Written and signed informed consent. Before prescribing a psychotropic drug, written informed consent must be obtained from the parent or legal guardian. The consent must:

(1) Be signed by the parent or legal guardian, confirming that they:

(A) Have received and reviewed the FDA Medication Guide.

(B) Understand the associated risks and side effects.

(2) Be kept on file by the medical care provider, with a copy provided to the parent or legal guardian.

Section 20. Medicaid establishment of an Adverse Drug Reaction (ADR) Online Reporting System.

(a) Adverse drug reaction online reporting system. The Department of Healthcare and Family Services shall, within 12 months after the effective date of this Act, develop and maintain a secure online reporting system for adverse drug reactions related to psychotropic drugs prescribed to children and adolescents. The system shall include the below free-text fields and drop-down menus for categorizing the type of drug, the nature of the adverse reaction, and the severity level. These features shall streamline the reporting process by

simplifying user input, ensuring faster processing, and reducing errors for a secure online system, which will allow the Department of Healthcare and Family Services to provide legislators with summaries of the adverse reactions being reported.

(1) Name of Patient (free-text field)

(required)

(2) Age of Patient (drop-down menu)

(required)

(3) Class of Psychotropic Drug (drop-down menu)

(optional to skip if the reporter doesn't know the category)

(A) Antidepressants.

(B) Antipsychotics.

(C) Mood Stabilizers.

(D) Stimulants.

(E) Anti-anxiety drugs and Sedatives.

(F) Hypnotics.

(4) Name of Drug (free-text field)

(required)

(5) Adverse Reaction Category (drop-down menu)

(required)

(A) Physical Reaction:

(i) Gastrointestinal issues (nausea, vomiting, diarrhea, constipation).

(ii) Neurological symptoms (dizziness,

headaches, seizures, tremors).

(iii) Cardiovascular symptoms (increased heart rate, blood pressure changes).

(iv) Endocrine/metabolic effects (weight changes, hormonal imbalances).

(v) Allergic reactions (rash, hives, anaphylaxis).

(B) Psychological Reaction:

(i) Mood changes (irritability, depression, euphoria).

(ii) Anxiety or panic attacks.

(iii) Hallucinations or delusions.

(iv) Agitation or restlessness.

(v) Suicidal thoughts or behaviors.

(C) Behavioral Reaction:

(i) Sleep disturbances (insomnia, hypersomnia).

(ii) Increased aggression or hostility.

(iii) Manic behaviors.

(iv) Cognitive impairments (memory loss, confusion).

(v) Self-harm.

(vi) Disassociation.

(D) Other (free-text field)

(6) Severity level (drop-down menu) (required)

(A) Mild.

(B) Moderate.

(C) Severe.

(7) Name of Person Reporting (free-text field)

(required)

(8) Relation of Person Reporting (drop-down menu)

(required)

(A) Parent.

(B) Foster Parent.

(C) Relative.

(D) Legal Guardian.

(E) Case Worker.

(F) Social Worker.

(G) Direct Care Staff.

(H) Other (free-text field).

(9) Email Address of Person Reporting (free-text field)

(optional, to facilitate any needed follow-up)

(10) Phone Number of Person Reporting (free-text field)

(optional, to facilitate any needed follow-up)

(b) Adverse drug reaction reporting requirements. The Department shall compile and submit quarterly reports summarizing ADR data related to psychotropic drugs administered to children and adolescents to the legislative committees overseeing Medicaid funding. These reports shall

include:

(1) The number of ADRs reported broken down by age group.

(2) The severity level of ADRs reported.

(3) A breakdown of ADRs by Adverse Reaction Category and severity of reactions detailing the number of incidents for each category of reaction and severity.

(c) Legislative oversight. Legislative committees shall review ADR reports related to psychotropic drugs during Medicaid budget hearings and program reviews and may recommend actions to improve medication safety.

(d) Implementation. The Department shall allocate funds to establish and maintain the ADR online reporting system specifically for psychotropic drugs and may seek additional funding as needed.

Section 25. Penalties for medical care provider noncompliance with medication guide distribution. Suspension of Medicaid reimbursement. Medical care providers failing to comply with the signed informed consent form on the Medication Guide may face penalties, including suspension of Medicaid reimbursements.

Section 30. Penalty for Department noncompliance. If the Department fails to submit the required quarterly ADR reports to the appropriate legislative committees within the specified

timeframe, the following penalties shall apply:

(1) Monetary penalty. The Department shall incur a monetary fine for each quarter of noncompliance, with the fine amount increasing for subsequent violations. The fine shall be deposited into the Medicaid Oversight and Safety Measures Fund, a special fund created in the State treasury for the sole purpose of improving Medicaid oversight and safety measures.

(2) Reduction in Medicaid funding. The State's Medicaid program shall face a reduction in its funding allocation for the following fiscal quarter until full compliance is demonstrated, including the timely submission of all required ADR reports.

(3) Oversight review. The Governor or relevant State oversight body shall initiate a formal review of the Department's operations and reporting procedures, which may result in further corrective actions, including the appointment of an external auditor to ensure the accurate and timely reporting of ADR data.

Section 35. Transparency and accountability reports. The Department must submit annual reports to the General Assembly summarizing implementation efforts, compliance statistics, and the impact of this Act, including fiscal analysis and health outcomes.

Section 45. The State Finance Act is amended by adding Section 5.1030 as follows:

(30 ILCS 105/5.1030 new)

Sec. 5.1030. The Medicaid Oversight and Safety Measures Fund.