

HOUSE BILL No. 2695

By Representative Howe

2-4

1 AN ACT concerning health and healthcare; relating to children receiving
2 medical assistance; enacting the enhanced oversight and accountability
3 for the prescription of psychotropic drug act; enhancing oversight of
4 psychotropic drug prescriptions for children receiving medical
5 assistance; requiring the department of health and environment to
6 establish an adverse drug reaction online reporting system.

7
8 WHEREAS, In 2023, KanCare statistics showed that 37,372 children
9 and adolescents from ages 0-17 were prescribed psychotropic drugs,
10 including 2,784 aged 0-5; and

11 WHEREAS, The administration of most psychotropic drugs to children
12 aged 0-5 is prescribed off-label, meaning that the drugs are being
13 prescribed for an age group that is not approved by the United States food
14 and drug administration (FDA); and

15 WHEREAS, Psychotropic drugs, including stimulants, antidepressants,
16 antipsychotics and other behavioral drugs, are being prescribed to children
17 receiving medical assistance and are documented by the FDA to include
18 severe side effects, including but not limited to, addiction, suicidal
19 ideation, aggression, hallucinations, cardiovascular events, stunted growth
20 and developmental concerns; and

21 WHEREAS, Parents and caregivers are frequently not informed of the
22 risks posed by the off-label prescription of psychotropic drugs documented
23 by the FDA, including the pediatric risks; and

24 WHEREAS, 21 C.F.R. § 208.20 establishes a requirement for FDA
25 medication guides to provide nontechnical, understandable information
26 about the potential risks and side effects of prescription drugs to the
27 average consumer, including parents and caregivers. According to 21
28 C.F.R. § 208.20, medication guides must detail the particular and
29 significant public health concern that created the need for a medication
30 guide, note any pediatric risks, include the risk of patients developing a
31 dependence on the drug, use a font no smaller than 10-point and not be
32 promotional in tone or content; and

33 WHEREAS, To effectively monitor the effects of psychotropic drugs
34 prescribed to children and adolescents, particularly those drugs cited by
35 the FDA for having pediatric risks, parents and caregivers must be given a
36 hard copy of the FDA medication guide for the psychotropic drug

1 prescribed; and

2 WHEREAS, The state's medical assistance program is a state and
3 federally funded program that provides essential healthcare services to
4 vulnerable populations, including children and adolescents. It should be
5 required to distribute the FDA medication guides to ensure patients and
6 their guardians are fully informed of the risks and potential side effects of
7 psychotropic drugs, thereby supporting informed consent and promoting
8 patient safety; and

9 WHEREAS, A reliable system for parents and caregivers to report
10 adverse drug reactions to psychotropic drugs is essential to help state
11 medical assistance program agencies and legislators monitor and assess the
12 frequency, severity and impact of such reactions within the public sector;
13 and

14 WHEREAS, The absence of an accessible reporting mechanism for
15 psychotropic drug side effects funded by a medical assistance program
16 limits the ability to identify and address these risks effectively,
17 compromising the safety of children and adolescents; and

18 WHEREAS, The state's medical assistance program is the primary
19 payer for psychotropic drugs prescribed to children and adolescents in the
20 public sector, including for off-label use in children, making it directly
21 responsible for ensuring the safety and monitoring of these prescriptions;
22 and

23 WHEREAS, Adverse drug reactions to psychotropic drugs can have
24 significant physical, psychological and developmental impacts on children,
25 requiring timely identification and response to mitigate harm; and

26 WHEREAS, The establishment of an online adverse drug reactions
27 reporting system would enable the state medical assistance program to
28 fulfill its duty of care by providing a mechanism to collect critical safety
29 data, support evidence-based decision making and comply with its
30 responsibility to protect public health; and

31 WHEREAS, Funding this reporting system aligns with the state
32 medical assistance program's obligations under federal law to monitor and
33 improve the quality of care to its beneficiaries, especially vulnerable
34 pediatric patients, and would facilitate oversight and accountability for the
35 use of public funds in prescribing psychotropic drugs; and

36 WHEREAS, The Kansas legislature establishes the following
37 provisions to enhance oversight, informed consent and accountability for
38 the prescription of psychotropic drugs to children receiving medical
39 assistance.

40 Now, therefore:

41 *Be it enacted by the Legislature of the State of Kansas:*

42 Section 1. Sections 1 through 6, and amendments thereto, shall be
43 known and may be cited as the enhanced oversight and accountability for

1 the prescription of psychotropic drug act.

2 Sec. 2. As used in this act:

3 (a) "Adverse drug reaction" means any unintended harmful reaction
4 of a psychotropic drug.

5 (b) "Child" means an individual under 18 years of age.

6 (c) "Medication guide" means a handout produced by the United
7 States food and drug administration that accompanies certain prescription
8 medications with significant safety concerns and are used to inform
9 patients and caregivers about risks, side effects and proper usage.

10 (d) "Medical assistance" means the same as defined in K.S.A. 39-702,
11 and amendments thereto.

12 (e) "Parent" includes a parent or guardian and every person who is by
13 law liable to maintain, care for or support the child.

14 (f) "Prescriber" means the same as defined in K.S.A. 65-1626, and
15 amendments thereto.

16 (g) "Psychotropic drugs" mean medications that affect the mind,
17 emotions or behavior, including, but not limited to, stimulants,
18 antidepressants, antipsychotics or other behavioral drugs authorized or
19 funded under the state medical assistance program.

20 (h) "Online reporting system" means a web-based platform through
21 which a child receiving medical assistance or such child's parent can report
22 an adverse drug reaction related to psychotropic drug use.

23 Sec. 3. (a) Before prescribing or administering a psychotropic drug to
24 a child receiving medical assistance, a prescriber shall provide any
25 medication guide for such drug to such child's parent.

26 (b) Medication guides shall be provided to a parent in writing and
27 reviewed with the parent to make them aware of:

28 (1) Potential side effects identified by the United States food and drug
29 administration, as well as cautionary monitoring citations;

30 (2) any United States food and drug administration black box
31 warning that details serious or life-threatening risks; and

32 (3) pediatric-specific side effects or warnings relating to children and
33 adolescents.

34 (c) Before prescribing or administering a psychotropic drug, written
35 informed consent shall be obtained from a parent. Such written informed
36 consent shall be:

37 (1) Signed by a parent, confirming that they have received and
38 reviewed the medication guide and understand the associated risks of the
39 medication that is being prescribed; and

40 (2) kept on file by the prescriber, with a copy provided to the parent
41 or legal guardian.

42 Sec. 4. (a) The secretary of health and environment shall develop and
43 maintain a secure online reporting system for adverse drug reactions

1 related to psychotropic drugs prescribed to children. The reporting system
2 shall include, at minimum, the following fields:
3 (1) Name of the patient;
4 (2) age of the patient;
5 (3) class of the prescribed psychotropic drug;
6 (4) name of the prescribed psychotropic drug;
7 (5) type of adverse reaction, including, but not limited to:
8 (A) Physical reactions, such as gastrointestinal issues, neurological
9 issues, cardiovascular symptoms, endocrine or metabolic effects or allergic
10 reactions;
11 (B) physiological reactions, such as mood changes, increased anxiety,
12 hallucinations or delusions, agitation or restlessness or suicidal thoughts;
13 and
14 (C) behavioral reactions, such as sleep disturbances, increased
15 aggression, mania, cognitive impairments, self-harm or disassociation;
16 (6) severity level of such reaction, to be measured as either mild,
17 moderate or severe; and
18 (7) name of the person reporting the reaction, such person's relation
19 to the patient and the phone number and email address of the person
20 reporting the reaction.
21 (b) (1) Documents or other information reported or maintained by the
22 secretary pursuant to subsection (a) shall be confidential and privileged
23 and shall not be subject to disclosure under the open records act, K.S.A.
24 45-215, et seq., and amendments thereto.
25 (2) The provisions of this subsection shall expire on July 1, 2031,
26 unless the legislature reviews and reenacts this provision pursuant to
27 K.S.A. 45-229, and amendments thereto, prior to July 1, 2031.
28 (c) On and after the first day of the legislative session of 2027, the
29 secretary of health and environment shall compile and submit quarterly
30 reports that summarize the adverse drug reaction data related to
31 psychotropic drugs prescribed to children and adolescents and submit such
32 reports to the senate standing committee on ways and means, the house of
33 representatives standing committee on appropriations, the house of
34 representatives standing committee on social services budget and the
35 Robert G. Bethell joint committee on home and community-based services
36 and KanCare oversight. Such reports shall include:
37 (1) The overall number of adverse drug reactions reported and
38 categorized by age;
39 (2) the total number of adverse reactions categorized by severity
40 level; and
41 (3) a breakdown of adverse drug reactions by adverse drug reaction
42 category, detailing the number of incidents for each category.
43 (d) Any information submitted to committees shall be disaggregated

1 by age, gender and race and shall not include any personally identifiable
2 information. Such legislative committees shall review such reports and
3 may recommend actions to improve the safety of prescribing psychotropic
4 drugs.

5 (e) The secretary of health and environment shall allocate moneys to
6 establish and maintain the adverse drug reaction online reporting system
7 and may seek additional moneys as needed.

8 Sec. 5. On and after the first day of the legislative session of 2027,
9 the secretary of health and environment shall submit annual reports to the
10 senate standing committee on ways and means, the house of
11 representatives standing committee on appropriations, the house of
12 representatives standing committee on social services budget and the
13 Robert G. Bethell joint committee on home and community-based services
14 and KanCare oversight summarizing implementation efforts, compliance
15 statistics and the impact of sections 1 through 4, and amendments thereto,
16 including fiscal analysis and health outcomes.

17 Sec. 6. This act shall take effect and be in force from and after its
18 publication in the statute book.