August 26, 2019

NASAL MIDAZOLAM

In May 2019, the FDA approved nasal midazolam as a seizure rescue medication in the treatment of patients with epilepsy aged 12 years and older. We have recently received numerous questions from school nurses regarding the administration of the medication in schools and whether the administration of said drug is delegable to trained staff.

Some of the questions around the drug are as follows:

1. Whether the first time administration of the drug can occur in a school setting?

A: While it is preferable that a student receive a dose of the subject medication for first time outside the school setting (in the event of side effects), there is nothing in the law that prevents a doctor from prescribing the rescue medicine and the school administering the medication pursuant to the student’s seizure action plan.

2. Because it is a benzodiazepine (Schedule IV controlled substance), whether trained staff (other than nurses/healthcare professionals) possess the skills to monitor the patient after administration?

A: KRS 158.838(1) permits the administration of prescribed FDA approved seizure rescue medications. KRS 158.838(11) exempts the administration of seizure rescue drugs by school employees trained pursuant to KRS 156.502 from any statutory or regulatory provisions restricting the activities that may be delegated to or performed by a person who is not a licensed health care professional. The administration of the medication should follow the student’s seizure action plan. (KRS 158.838 and 702 KAR 1:160).

3. If delegable, are trained staff competent to provide multiple doses of the drug?

A: Under KRS 158.838, as stated above, a school employee trained per KRS 156.502, can administer seizure rescue medications. The administration of the medication should follow the student’s seizure action plan. (KRS 158.838 and 702 KAR 1:160).

4. Whether the fact that it has to be drawn from a vial using a syringe impacts who can administer. A prepackaged prepared nasal spray administration of the drug, under the brand name Nayzilam, is not available until 2020. At this time, the drug is administered by drawing it from a vial with a syringe and then attaching an atomizer to the syringe and spraying it up the nose of a seizing patient?

A: KRS 158.838 only requires the seizure rescue medication be FDA approved and administered by a school employee who has met the requirements under KRS 156.502 to administer the medication.

Initially, the parents or guardians of students diagnosed with a seizure disorder are required to collaborate with school personnel to implement a seizure action plan. (KRS 158.838). All Kentucky school districts are required to adopt policies for the implementation of seizure action plans. (702 KAR 1:160). Further, each school district is required to have (at least one) staff at each school that can administer or assist with self-administration of certain medications including seizure rescue medication or medication to treat seizure disorder symptoms approved by the FDA. (KRS 158.838). If no school employee has been trained and delegated responsibility to perform a health service, the school district shall make any necessary arrangement for the provision of the health service to the student in order to prevent a loss of a health service from affecting the student's attendance or program participation. The school district shall continue with this arrangement until appropriate school personnel are delegated the responsibility for health care. (KRS 156.502).

Please note: Students with epilepsy are further protected from discrimination under federal law. See: Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and/or Title II of the Americans with Disabilities Act (ADA) and dependent on the needs of the particular student potentially the Individuals with Disabilities Education Act (IDEA).

[KRS 158.838](https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=48030) states, in relevant part, the following:

(1) (a) Beginning July 15, 2014, the board of each local public school district and the governing body of each private and parochial school or school district shall have at least one (1) school employee at each school who has met the requirements of KRS 156.502 on duty during the entire school day to administer or assist with the self-administration of the following medication:

. . . .

3. A seizure rescue medication or medication prescribed to treat seizure disorder symptoms approved by the United States Food and Drug Administration and any successor agency.

(b) For those assigned the duties under paragraph (a) of this subsection, the training provided under KRS 156.502 shall include instruction in administering:

. . . .

2. Seizure medications, as well as the recognition of the signs and symptoms of seizures and the appropriate steps to be taken to respond to these symptoms.

. . . .

(2) (a) Prior to administering any of the medications listed under subsection (1)(a) of this section to a student, the student's parent or guardian shall:

1.         Provide the school with a written authorization to administer the medication at school;

2.         Provide a written statement from the student's health care practitioner, which shall contain the following information:

            a. Student's name;

            b. The name and purpose of the medication;

            c. The prescribed dosage;

            d. The route of administration;

            e. The frequency that the medication may be administered; and

            f. The circumstances under which the medication may be administered; and

3. Provide the prescribed medication to the school in its unopened, sealed package with the label affixed by the dispensing pharmacy intact.

(b) In addition to the statements required in paragraph (a) of this subsection, the parent or guardian of each student diagnosed with a seizure disorder shall collaborate with school personnel to implement the seizure action plan. The Kentucky Board of Education shall promulgate administrative regulations establishing procedures for the implementation of seizure action plans.

. . . .

(4) The school district or the governing body of each private and parochial school or school district shall inform the parent or guardian of the student that the school and its employees and agents shall not incur any liability as a result of any injury sustained by the student from any reaction to any medication listed under subsection (1)(a) of this section that a parent or guardian has authorized the school district to administer to a student to treat a hypoglycemic or hyperglycemic episode or a seizure or its administration, unless the injury is the result of negligence or misconduct on behalf of the school or its employees. The parent or guardian of the student shall sign a written statement acknowledging that the school shall incur no liability except as provided in this subsection, and the parent or guardian shall hold harmless the school and its employees against any claims made for any reaction to any medication listed under subsection (1)(a) of this section that a parent or guardian has authorized the school district to administer to a student to treat a hypoglycemic or hyperglycemic episode or a seizure or its administration if the reaction is not due to negligence or misconduct on behalf of the school or its employees.

(5) The permission for the administration of any of the medications listed under subsection (1)(a) of this section shall be effective for the school year in which it is granted and shall be renewed each following school year upon fulfilling the requirements of subsections (2) to (4) of this section

[KRS 156.502](https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=42933) states, in relevant part, the following:

(2)        Health services shall be provided, within the health care professional's current scope of practice, in a school setting by:

            (a) A physician who is licensed under the provisions of KRS Chapter 311;

            (b) An advanced practice registered nurse, registered nurse, or licensed practical nurse who is licensed under the provisions of KRS Chapter 314;

            (c) A nonlicensed health technician that has the administration of health services in his or her contract or job description as a job responsibility and who is delegated responsibility to perform the health service by a physician, advanced practice registered nurse, or registered nurse and has been trained and approved in writing by the delegating physician or delegating nurse for delegable health services; or

            (d) A school employee who is delegated responsibility to perform the health service by a physician, advanced practice registered nurse, or registered nurse; and

1. Has been trained by the delegating physician or delegating nurse for the specific health service, if that health service is one that could be delegated by the physician or nurse within his or her scope of practice; and

2. Has been approved in writing by the delegating physician or delegating nurse. The approval shall state that the school employee consents to perform the health service when the employee does not have the administration of health services in his or her contract or job description as a job responsibility, possesses sufficient training and skills, and has demonstrated competency to safely and effectively perform the health service. The school employee shall acknowledge receipt of training by signing the approval form. A copy of the approval form shall be maintained in the student's record and the personnel file of the school employee. A delegation to a school employee under this paragraph shall be valid only for the current school year.

(3) If no school employee has been trained and delegated responsibility to perform a health service, the school district shall make any necessary arrangement for the provision of the health service to the student in order to prevent a loss of a health service from affecting the student's attendance or program participation. The school district shall continue with this arrangement until appropriate school personnel are delegated the responsibility for health care in subsection (2) of this section.

[702 KAR 1:160](https://apps.legislature.ky.gov/law/kar/702/001/160.pdf) states, in relevant part, the following regarding Seizure Action Plans

(c) A requirement that, at all times when enrolled students, for whom documentation under KRS 158.838(2) or (7), including seizure action plans, has been provided to the school, are present during school hours or participating in school-related activities, there is a school employee who is trained to administer and can administer or assist with the self-administration of glucagon, insulin, or seizure medications approved by the United States Food and Drug Administration or successor agency and administered pursuant to a student’s seizure action plan. A student shall be permitted to conduct the actions and possess the supplies and equipment described in KRS 158.838(7) at school-related activities regardless of whether the student is a participant or mere observer of the school-related activity;

(d) A number at which parents can be reached; and

(e) The name of a family physician.