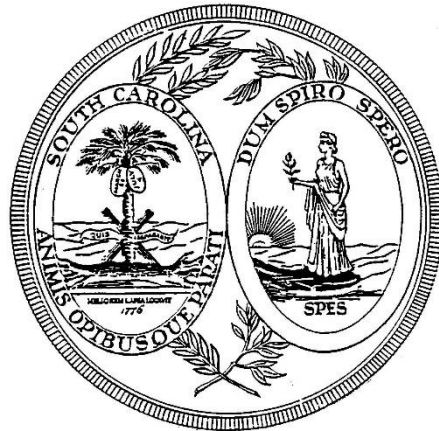


SEIZURE SAFETY IN SCHOOLS STUDY COMMITTEE

REPORT TO THE GENERAL ASSEMBLY



January 28, 2019

Seizure Safety in Schools Study Committee

Transmittal Memorandum from the Committee Chair

TO: The Honorable Jeffrey S. Gossett, Clerk of the South Carolina Senate
The Honorable Charles F. Reid, Clerk of the South Carolina House of Representatives

FROM: Dr. Carrie Tucker, Seizure Safety in Schools Study Committee Chair

DATE: January 28, 2019

RE: Report of the Study Committee to the General Assembly

On behalf of my fellow study committee members, I am pleased to enclose the final report containing the findings and recommendations of the Seizure Safety in Schools Study Committee.

We hope this report provides the first step toward adopting policies and legislation to ensure that every student who has a seizure disorder will have appropriate access while at school to the least restrictive rescue medication prescribed by the student's physician.

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Enabling Legislation

The Seizure Safety in Schools Study Committee was authorized by Act 125 of 2017. The deadline for its report to the General Assembly was extended by Act 290 of 2018.

Act 125, R.60, H.3587

A JOINT RESOLUTION TO CREATE THE "SEIZURE SAFETY IN SCHOOLS STUDY COMMITTEE" TO EXAMINE ISSUES RELATED TO EPILEPSY AND SEIZURE SAFETY AWARENESS IN PUBLIC SCHOOLS, TO PROVIDE FOR THE MEMBERSHIP, DUTIES, STAFFING, AND RESPONSIBILITIES OF THE STUDY COMMITTEE, AND TO PROVIDE ITS MEMBERS SHALL SERVE WITHOUT MILEAGE, PER DIEM, SUBSISTENCE, OR OTHER COMPENSATION.

Whereas, the South Carolina General Assembly finds that approximately 326,000 American children under the age of fifteen have epilepsy; and

Whereas, the South Carolina General Assembly finds thousands of South Carolina students, families, teachers, school administrators, and staff are impacted by students who have epilepsy; and

Whereas, the South Carolina General Assembly finds an understanding of epilepsy, seizures, seizure responses, and academic support is necessary to ensure the safety and educational achievement of students who have epilepsy. Now, therefore,

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. (A) There is created the "Seizure Safety in Schools Study Committee." The study committee shall review information concerning:

- (1) the state of epilepsy awareness among public school teachers, staff, and administrators;
 - (2) basic training in seizure response appropriate for public school teachers, staff, and administrators;
 - (3) existing laws, regulations, and policies affecting epilepsy and seizure safety in public schools; and
 - (4) other areas related to epilepsy and seizure safety in public schools that the committee considers necessary and relevant to its work.
- (B) The study committee must be composed of fourteen members, consisting of the following:
- (1) the Chairperson of the House of Representatives Committee on Education and Public Works or his designee;
 - (2) the Chairperson of the Senate Education Committee or his designee;
 - (3) the Chairperson of the House of Representatives Medical, Military, Public and Municipal Affairs Committee or his designee;
 - (4) the Chairperson of the Senate Medical Affairs Committee or his designee;

- (5) a member of the South Carolina Board of Nursing appointed by the board;
- (6) a public school nurse appointed by the South Carolina Board of Nursing;
- (7) a member of the South Carolina Board of Medical Examiners appointed by the board;
- (8) a physician who practices pediatric neurology appointed by the South Carolina Board of Medical Examiners;
- (9) a teacher appointed by the State Superintendent of Education;
- (10) the Director of the Department of Health and Environmental Control or his designee;
- (11) a public school administrator, appointed by the Governor, who shall serve as committee chair;
- (12) a director of a children's hospital appointed by the Governor;
- (13) a parent of a public school student with a seizure disorder appointed by the Governor; and
- (14) a representative from a statewide organization that supports families of children who have special medical needs appointed by the Governor.

(C) The Speaker of the House of Representatives and the President Pro Tempore of the Senate shall provide staffing for the study committee.

(D) Members of the study committee shall serve without mileage, per diem, subsistence, or other compensation.

(E) Before January 31, 2018, the study committee shall make a report of the committee's recommendations to the General Assembly at which time the study committee must be dissolved.

SECTION 2. This joint resolution takes effect upon approval by the Governor.

Ratified the 9th day of May, 2017.

Approved the 10th day of May, 2017.

Act 290, R.150, H.4827

A JOINT RESOLUTION TO EXTEND THE DEADLINE FOR THE SEIZURE SAFETY IN SCHOOLS STUDY COMMITTEE TO SUBMIT ITS WRITTEN REPORT FROM JANUARY 31, 2018, TO JANUARY 31, 2019.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. The deadline for the Seizure Safety in Schools Study Committee to submit the written report required pursuant to Act 125 of 2017 is extended from January 31, 2018, to January 31, 2019.

SECTION 2. This joint resolution takes effect upon approval by the Governor.

Ratified the 15th day of March, 2018.

Approved the 20th day of March, 2018.

Study Committee Membership

- (1) Bonnie Loomis serving as the designee for the Chairperson of the House of Representatives Committee on Education and Public Works;
- (2) Senator Ross Turner serving as the designee for the Chairperson of the Senate Education Committee;
- (3) Representative Ivory T. Thigpen serving as the designee for the Chairperson of the House of Representatives Medical, Military, Public and Municipal Affairs Committee;
- (4) Senator Katrina F. Shealy serving as the designee for the Chairperson of the Senate Medical Affairs Committee;
- (5) Sallie Beth Todd, a member of the South Carolina Board of Nursing appointed by the board;
- (6) Dawn MacAdams, a public school nurse appointed by the South Carolina Board of Nursing;
- (7) Dr. Daniel Saad, a member of the South Carolina Board of Medical Examiners appointed by the board;
- (8) Dr. Addie Hunnicutt, a physician who practices pediatric neurology appointed by the South Carolina Board of Medical Examiners;
- (9) Timothy Stuhler, a teacher appointed by the State Superintendent of Education;
- (10) Victoria Ladd, serving as the designee for the Director of the Department of Health and Environmental Control;
- (11) Dr. Carrie Tucker, a public school administrator appointed by the Governor, to serve as committee chair;
- (12) Dr. William F. Schmidt, III, a director of a children's hospital appointed by the Governor;
- (13) Marcy Zimmerman, a parent of a public school student with a seizure disorder appointed by the Governor; and
- (14) Maggie Cash, a representative from a statewide organization that supports families of children who have special medical needs appointed by the Governor.

Findings

- At least one full-time Registered Nurse (RN) should be employed at each school in SC.
- Administration of nasal Midazolam has an efficacy and safety profile that is as good as, or better than rectal Diazepam which is the only rescue medication currently authorized for administration in the public school setting for students with refractory seizures in South Carolina.
- Every student who has a seizure disorder should have appropriate access to the least restrictive (buccal or nasal) rescue medication if it is prescribed by the student's physician or other healthcare provider.

Recommendations

- The General Assembly should provide funding, or require local school districts to provide funding sufficient, to hire full-time nursing staff for every public school.
- The SC Board of Nursing (BON), SC Department of Health and Environmental Control (DHEC), the SC Department of Education (DOE), the SC School Nurses Association (SCSNA), and the SC School Boards Association (SCSBA) should work together to implement a standard state-wide training protocol for school nurse staff and designated voluntary unlicensed school personnel to administer seizure rescue medication prescribed by healthcare providers for school age children in SC. The National Association of School Nurses clinical guidelines for students with seizures and epilepsy, as well as existing protocols already in use in other states, offer proven strategies to accomplish this goal and should be the basis for this effort in our state. The training protocol should be developed and periodically reviewed in consultation with pediatric neurologists and the SC Children's Hospital Collaborative to ensure it reflects current best medical practice for seizure management in the school setting.
- The General Assembly should enact qualified immunity provisions for licensed nurses and trained unlicensed school personnel who act in good faith to administer prescribed seizure rescue medication to students experiencing refractory seizures.
- The BON, DHEC, DOE, SCSNA, and SCSBA should work with SC Children's Hospital Collaborative Telehealth Program to explore opportunities to improve the care for students with seizure disorders in the school setting.

Meeting Summaries

The Seizure Safety in Schools Study Committee met two times in the Gressette Building at the Capitol Complex.

November 27, 2018

The organizational meeting of the Study Committee was held on November 27, 2018.

The following members of the Study Committee were present: Carrie Tucker, Chair; Senator Katrina F. Shealy; Senator Ross Turner; Representative Ivory T. Thigpen; Maggie Cash; Addie Hunnicutt; Victoria Ladd; Bonnie Loomis; Dawn MacAdams; Daniel Saad; and William F. Schmidt, III. Carol Moody attended for Sallie Beth Todd.

The following House and Senate staff members were present: Ava Brumfield, Martha Casto, Mary Denis Cauthen, Gene Hogan, Pierce McNair, Julie Price, and Louise Spong.

Dr. Carrie Tucker called the meeting to order and noted that the purpose of the study committee is to review information concerning:

- (1) the state of epilepsy awareness among public school teachers, staff, and administrators;
- (2) basic training in seizure response appropriate for public school teachers, staff, and administrators;
- (3) existing laws, regulations, and policies affecting epilepsy and seizure safety in public schools; and
- (4) other areas related to epilepsy and seizure safety in public schools that the committee considers necessary and relevant to its work.

Dr. Tucker opened the floor for discussion. The study committee discussed the following items:

- There is no Epilepsy Foundation chapter in South Carolina or any other organization that is expressly focused on improving awareness of the condition and how to provide care and support for children with epilepsy in schools.
- There are many institutional and licensure organizations with overlapping authority regarding policies and procedures for care of these students.
- The 2005 Student Health and Fitness Act requires schools to develop individual healthcare plans and emergency action plans for students with chronic health conditions.
- Many schools in South Carolina do not have either a RN or a Licensed Practical Nurse (LPN).
- School nurses are guided by official BON opinion statements on the administration of over-the-counter medicines and legend drugs.
- Many schools have little or no emergency rescue equipment, and EMS arrival times vary depending on the school location.
- Until recently, premeasured rectal diazepam was the primary medication option for seizures in the school setting. Intranasal midazolam has a black box warning and is not yet available in a pre-measured unit dose except when compounded by a pharmacist.

Premeasured doses take the guess work out of drawing up a dose to administer while a student is having a seizure.

- There is evidence that midazolam is as safe, if not safer, than diazepam.
- Intranasal Midazolam routinely is prescribed as a rescue medication for seizures that occur in non-healthcare settings. Practitioners train parents on standard dosage and medication administration.
- BON Advisory Opinion #50 prohibits anyone other than a RN from administering insulin, eye drops, ear drops, vaginal or rectal medication other than diazepam. Students who are capable may self-administer insulin.
- Other states, including Michigan, Texas, Utah, Washington, Oregon, and Colorado, have policies that govern training and procedures for designated unlicensed assistive personnel who respond to seizure emergencies in the school setting.
- The National Association of School Nurses has a toolkit document for seizure management in the school setting.
- It would be optimal for there to be one statewide plan so that RNs, LPNs and designated unlicensed assistive personnel all could be trained to respond to seizures. The plan should include procedures for how to handle a student who has been diagnosed with a seizure disorder and has a healthcare provider's prescribed protocol in place as well as procedures for a student whose first seizure occurs at school. The plan should also include appropriate immunity from liability provisions.
- There should be regular periodic review by a group comprised of DHEC, Board of Medical Examiners (BME), BON, school boards, school nurses, and parents to holistically evaluate administration of seizure medications in the school setting. The Children's Hospital Collaborative, working with DHEC and the SC Department of Labor, Licensure, and Regulation (LLR), could convene such a group to meet regularly and provide a forum for dialog and recommendations for improvements in seizure management in the school setting.
- Currently, medication management decisions are made on a district-by-district basis. There is no statewide protocol for ensuring Schedule II and III medications are kept securely on school premises to ensure safety and to prevent diversion.
- Some parents use essential oils, CBD oil, and other non-legend substances for children with seizure disorders. There is not good information about interactions between these substances and other medications a student may be taking.
- Telemedicine can play an important role in connecting school nurses and trained unlicensed assistive personnel with healthcare professionals. Members of the SC Children's Hospital Collaborative are working together and in partnership with the SC Telehealth Alliance to implement pediatric telehealth services in SC, including school-based telehealth services.
- The LLR Healthcare Collaborative Committee meets quarterly with the BME, BON, Board of Pharmacy, and DHEC. The next meeting is on January 11, 2019. Dr. Saad offered to get the seizure safety in schools topic on the agenda to provide a venue for all stakeholders to work together to bring recommendations to this study committee and the House and Senate Medical Affairs Committees. He invited all members of the Seizure Safety in Schools Study Committee to attend.

Dr. Tucker noted the deadline for the study committee to report its finding to the General Assembly is January 31, 2019. There was a brief discussion about whether to seek a legislative extension to the deadline. She suggested that the committee think about making broad, big-picture recommendations to address the primary issues that have been identified. Dr. Tucker urged the study committee members to attend the January 11 LLR Healthcare Collaborative Committee meeting.

January 15, 2019

The second Study Committee meeting was held to receive an update from the January 11, 2019 LLR Healthcare Collaborative Committee meeting and to formulate recommendations for the Study Committee report to the General Assembly.

The following members of the Study Committee were present: Carrie Tucker, Chair; Senator Katrina F. Shealy; Senator Ross Turner; Representative Ivory T. Thigpen; Maggie Cash; Addie Hunnicutt (by telephone); Victoria Ladd; Dawn MacAdams; and Daniel Saad (by telephone). Neil Lipsitz attended for Sallie Beth Todd.

The following House and Senate staff members were present: Ava Brumfield, Mary Denis Cauthen, Gene Hogan, Pierce McNair, and Louise Spong.

Dr. Carrie Tucker called the meeting to order and provided the following summary of the portion of the January 11, 2019 LLR Healthcare Collaborative Committee (HCC) meeting that focused on seizure safety in schools.

The HCC discussed the following topics:

- The administration of intranasal Midazolam has a better efficacy and safety profile than rectal Diazepam which is the only rescue medication currently authorized for administration in the public school setting for students with refractory seizures.
- Legislation will be needed to provide qualified immunity for RNs, LPNs, and unlicensed school personnel who provide intranasal Midazolam to students in good faith efforts to treat refractory seizures.
- There should be one standard training protocol for the administration of intranasal Midazolam in the public school setting. Existing protocols already in use in other states can be the basis for this effort in South Carolina.
- School nurses annually report to the SC Department of Education the number of students diagnosed with seizure disorders and the number of doses of emergency/rescue medications administered in the school setting.
- The UCB Pharmaceutical Company, a global biopharmaceutical company, has Fast Track, Orphan Drug status approval by the US Food and Drug Administration

(FDA) for a proprietary intranasal Midazolam product to be used for refractory seizures in children. However, new medications can be very costly. Cost effective, individual intranasal Midazolam subunits that are prepared by local pharmacists can be made available for rapid deployment by school staff as well as trained family members. It is estimated that locally compounded alternatives would cost approximately \$35 with the medication lasting at least 30 days before the potency cannot be guaranteed. The General Assembly may wish to conduct a biokinetics study, which have a one-time cost of \$8,000 to \$10,000 to determine how long these compound medications actually are effective.

- The SC Children's Hospital's Telemedicine Initiative could assist schools with patient evaluations and treatment instructions especially in rural settings where no school nursing staff are present.

Dr. Tucker then opened the floor for discussion. The study committee discussed the following items:

- Many public schools in SC do not employ a full-time RN.
- The children's hospitals in SC are actively engaged in the development of pediatric telehealth services in this state. Further discussion is needed between schools and the children's hospitals to determine what opportunities exist for the use of telehealth services to provide care to students with seizure disorders and for providing education to school personnel about seizure disorders and the administration of seizure rescue medications, including intranasal Midazolam.
- BON Opinion #52, in part, states that in schools where there is a RN or LPN on staff full-time at the school to provide health services for students, the RN assigned to the school or the RN supervising the clinical practice of the LPN assigned to the school may select, train, determine the competency of, and evaluate unlicensed school personnel for assisting students with medications in situations where the RN or LPN on staff at the school is absent or not available. Unlicensed school personnel may be trained to assist students with regularly scheduled medications only if there is a RN or LPN employed at the school full-time to provide health services for students.
- BON Opinion #50, in part, states that
 1. The RN assigned to the school or the RN supervising the clinical practice of the LPN assigned to the school shall determine if the nursing services required for meeting the needs of a student may be provided safely by unlicensed school personnel.
 2. To determine if training of unlicensed school personnel is appropriate the RN shall consider the following:
 - whether the nursing service is delegable according to the laws governing nursing practice;
 - the outcome for the student if the nursing service is not provided promptly;
 - whether the student's condition is stable and predictable;
 - the nature and complexity of the nursing service;

- the risk to the student if the nursing service is provided inappropriately or incorrectly;
- the necessary knowledge, skills and abilities needed to perform the nursing service;
- the competency and availability of unlicensed school personnel;
- whether the outcome anticipated is stable and predictable; and
- the number of unlicensed school personnel that can safely be evaluated by the licensed nurse.

3. The RN shall consult with the student's healthcare practitioner, as appropriate, to determine if complicated emergency treatments or potent emergency medications may be provided safely by unlicensed school personnel.

4. An RN or LPN cannot legally be required by school officials to delegate the practice of nursing, nor to delegate nursing tasks to unlicensed school personnel where, in the nurse's judgment, the safety of the student would be jeopardized. A school principal/administrator cannot by law require a school nurse to delegate the practice of nursing in any way that is contrary to the requirements of the laws and regulations governing nursing practice, nor can a school principal/administrator who is not licensed to practice nursing legally delegate nursing tasks.

- Medication administration and training is currently determined on a district-by-district basis in public schools, but should instead be uniform across the state.
- The General Assembly can enact legislation to authorize the administration of a medication by properly trained LPNs and unlicensed school personnel.
- In 2018, the FDA granted Midazolam nasal spray orphan drug designation for the rescue treatment of seizures in patients who require control of intermittent bouts of seizure clusters or acute repetitive seizures. Midazolam nasal spray has also been granted Fast Track designation by the FDA and could be approved in 2019. The product is formulated in a premeasured dose, and is intended to be delivered intranasally without active inhalation by the patient.
- Individual nasal Midazolam subunits that are prepared by local pharmacists can be made available for rapid deployment without having to draw the medication from a vial and prepared for intranasal use. Many medications lose potency more quickly after being drawn from a vial into a syringe. A study to evaluate the efficacy time-line for pre-drawn Midazolam could be conducted by a testing laboratory.