



August 30, 2018

WSRMP RISK ALERT- EpiPen Supply Disruption

Dear Members,

In response to the nationwide supply interruption of EpiPens (Epinephrine auto-injectors) and the impact it is having on districts with students that rely on these life-saving devices, WSRMP is issuing this Risk Alert.

The Washington Schools Risk Management Pool has received an influx of questions regarding students with life-threatening health conditions that require them to rely on an epinephrine auto injector for immediate medical treatment. With the nationwide supply interruption, many students have been unable to fill their prescription, thus relying on expired EpiPens. This is placing a heavy burden on districts as they prepare for the new school year, balancing the need to comply with state law, while educating students with life-threatening health conditions.

Washington State law explicitly states that schools must meet certain requirements for students with life-threatening medical conditions in allowing the student to attend school. If a student is unable to meet the requirements of RCW 28A.210.320, schools are required to prohibit the student from attending school and must provide written notice to the parent or guardian of the student before the student is excluded. Allowing students to attend school in violation of RCW 28A.210.320 increases the potential liability of the district and is not recommended.

RCW 28A.210.320

Children with life-threatening health conditions—Medication or treatment orders—Rules.

(1) The attendance of every child at every public school in the state shall be conditioned upon the presentation before or on each child's first day of attendance at a particular school of a medication or treatment order addressing any life-threatening health condition that the child has that may require medical services to be performed at the school. Once such an order has been presented, the child shall be allowed to attend school.

(2) The chief administrator of every public school shall prohibit the further presence at the school for any and all purposes of each child for whom a medication or treatment order has not been provided in accordance with this section if the child has a life-threatening health condition that may require medical services to be performed at the school and shall continue to prohibit

the child's presence until such order has been provided. The exclusion of a child from a school shall be accomplished in accordance with rules of the state board of education. Before excluding a child, each school shall provide written notice to the parents or legal guardians of each child or to the adults in loco parentis to each child, who is not in compliance with the requirements of this section. The notice shall include, but not be limited to, the following: (a) The requirements established by this section; (b) the fact that the child will be prohibited from further attendance at the school unless this section is complied with; and (c) such procedural due process rights as are established pursuant to this section.

(3) The superintendent of public instruction in consultation with the state board of health shall adopt rules under chapter [34.05](#) RCW that establish the procedural and substantive due process requirements governing the exclusion of children from public schools under this section. The rules shall include any requirements under applicable federal laws.

(4) As used in this section, "life-threatening condition" means a health condition that will put the child in danger of death during the school day if a medication or treatment order and a nursing plan are not in place.

(5) As used in this section, "medication or treatment order" means the authority a registered nurse obtains under RCW [18.79.260\(2\)](#)

WSRMP recommends that districts comply with RCW 28A.210.320 & WAC 392-380-045 for those students that are unable to provide a medication or treatment order in accordance to these sections if the student has a life-threatening medical condition that may require medical services to be performed.

On August 21, 2018, the Food and Drug Administration (FDA) approved the use of EpiPens, and the authorized generic version manufactured by Meridian Medical Technologies, A Pfizer company, beyond the manufacturer's labeled expiration date. A listing of FDA approved EpiPens with the extended expiration dates can be located at <https://www.fda.gov/Drugs/DrugSafety/DrugShortages>.

WSRMP recommends that districts only accept medication (EpiPen) that fall within the expiration date or has been FDA approved with an extended expiration date. Districts should not accept expired medication that does not have FDA approval.

According to the latest press release below, it is unclear how long the disruption will continue. WSRMP is continuously monitoring the supply disruption and will provide additional information as it becomes available.

Pfizer -Important Notice Regarding EpiPen Auto-Injector U.S. Supply

Meridian, a subsidiary of Pfizer that manufactures EpiPen® (epinephrine injection, USP) 0.3 mg and EpiPen Jr® (epinephrine injection, USP) 0.15 mg Auto-Injectors, continues to experience manufacturing constraints affecting U.S. supply. Pfizer takes very seriously the importance of EpiPen to everyone who needs it, and we are working tirelessly to increase production and expedite shipments as rapidly as possible. Currently, supplies will vary from pharmacy to pharmacy, and we cannot guarantee that product will be available at all pharmacies.

We are actively exploring several options that would help stabilize supply. We will continue to provide updates, including timing for resolution, as we have them.

We understand the challenges this situation continues to pose to patients. Ensuring continuity of the supply of our medicines is paramount.

Because EpiPen is distributed and sold by Mylan Specialty L.P. in the U.S., medical professionals should direct questions about EpiPen usage to Mylan at 800-796-9526.

If you have any questions or concerns, please contact Gerald Martens, Director of Risk Management at 206-394-9735 or gmartens@wsrmp.com.

