

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

December 1, 2015

The Honorable Governor Jay Inslee P.O. Box 40002 Olympia, Washington 98504

The Honorable Senator Randi Becker Senate Health Care Committee P.O. Box 40402 Olympia, Washington 98504

The Honorable Representative Eileen Cody, Chair House Health Care and Wellness Committee P.O. Box 40600 Olympia, Washington 98504

RE: Substitute House Bill 1625 - Concerning provisions of drugs to ambulance and aid services

Dear Governor Inslee, Representative Cody and Senator Becker:

Substitute House Bill 1625 relating to the administration of glucagon and hydrocortisone by emergency medical technicians (EMTs) requires the Washington State Emergency Medical Services and Trauma Care Steering Committee (steering committee) to submit a report to the legislature addressing:

- Adequacy of current training for EMTs to administer these medications;
- Feasibility of supplementing the training of EMTs either statewide or locally to administer these medications;
- Costs and likely use of stocking ambulances with these medications;
- Options for local solutions to specific community needs where only basic life support (BLS) is available, and in school settings;
- Data related to frequency of incidents requiring administration of glucagon and hydrocortisone sodium succinate (hydrocortisone); and
- Policy recommendations.

This letter serves as the steering committee's report.

Background:

The Department of Health (department) administers the state Emergency Medical Services (EMS) and Trauma System to ensure delivery of the right patient to the right facility in the right amount of time. It does this, in coordination with the steering committee and eight EMS and trauma care regions, by setting standards for regulation of EMS providers, providing training, developing patient care protocols, and many other responsibilities. The steering committee provides guidance and direction to the department through a secretary of health-appointed, 30-member committee with representatives of affected groups such as surgeons, hospitals, prehospital providers, firefighters, and consumers. In accordance with RCW 18.71.212, the secretary of health appoints and certifies county medical program directors (MPDs) who are physicians knowledgeable in their county's administration and management of prehospital emergency medical care and services. MPDs are responsible for both the supervision of training and medical control of EMS providers.

Geographical variation in the availability of emergency care resources affects provision of emergency medical care. EMS services that provide advanced life support (ALS) care must use paramedics¹, who are authorized to administer glucagon and hydrocortisone or other similar corticosteroids. Most people in Washington receive service from agencies with rapid ALS response times. Some communities have only basic life support (BLS) emergency services that use only emergency medical technicians (EMTs). EMTs are not authorized to administer glucagon and hydrocortisone. Some communities, such as some rural schools that rely on EMS for care when they do not have a school nurse on staff, have expressed concern regarding access to glucagon and hydrocortisone sodium succinate. These communities have asked that we explore options for local solutions to address their concerns. In addition, some urban and suburban communities that use EMTs as BLS first response, and that have a delay in ALS response because of geography and traffic patterns, may benefit from EMTs being able to administer these medications.

Hydrocortisone sodium succinate is used to treat adrenal insufficiency or Addison's disease. Most commonly, adrenal crises occur because of sudden withdrawal of prescribed steroid medications. This is a rare condition affecting about one in 10,000 people (0.001 percent). Treating an acute adrenal crisis generally requires hospitalization and is rarely treated by EMS. Adrenal crisis generally presents as shock. Even highly trained paramedics may be unable to recognize it as adrenal crisis unless the patient is wearing a Medic-Alert tag identifying the condition. Adrenal crisis treatment generally requires large doses of intravenous (IV) corticosteroids, and salt and fluid replacement, given over hours to days. Requiring EMTs to be trained to recognize patients with adrenal insufficiency and to administer the drug is beyond the current scope of practice of EMTs. There is also concern about the effectiveness of field treatment of adrenal insufficiency, especially if corticosteroids are given intramuscularly (IM).

¹ Paramedics are trained, through nationally accredited education programs that are generally two years long, to perform skills such as intubation, establishing intravenous access, and administering a wide variety of medications through invasive methods. EMT's are trained, through a 3-6 month program approved by the Department of Health, to perform skills such as basic CPR with use of an AED, splinting and bandaging wounds, and administering a few medications under certain conditions.

Glucagon is used to treat severe hypoglycemia (low blood sugar) in patients with diabetes who have taken too much insulin, too much oral medication, or have not consumed enough food to counterbalance the insulin. They are in a coma or near coma, and cannot take forms of sugar such as glucose by mouth. This is an emergency and needs to be rapidly treated, preferably through IV glucose, but this can be given only by a paramedic or advanced EMT who can start the IV. If an IV cannot be started, in some cases an IM injection of glucagon will increase the patient's blood sugar level by releasing glucose stored in the liver as glycogen. It is not as effective as IV glucose, and it works only if the patient has adequate liver glycogen. This means it doesn't always work. Many diabetic patients carry their own glucagon kit for family or teachers to administer if a hypoglycemic episode occurs. Injecting IM glucagon is not within the current national or state scope of practice of the EMT. A few states allow EMTs to administer glucagon after determining that critical low blood glucose exists. These EMTs must complete special training on glucagon administration.

Adequacy of current training for EMTs to administer these medications:

These medications are not in the current scope of practice for EMTs. Therefore, EMTs are not trained in their administration.

The current national EMT education standards include training in the following pharmacological interventions:

- Assisting patients in taking their own prescribed medications: inhaled bronchodilators, epinephrine (Epipen), and nitroglycerine.
- Administering the following over-the-counter medications with appropriate medical oversight: oral glucose for suspected hypoglycemia, and aspirin for chest pain of suspected cardiac origin.

With special training and following medical program director (MPD) protocols, an EMT may perform finger-stick blood glucose determination (Glucoscan) and administer oral glucose, if the patient is conscious.

Current EMT educational content does not provide the necessary pharmacological knowledge of glucagon or hydrocortisone, and does not provide depth and breadth of knowledge necessary to determine or treat the conditions for which glucagon and hydrocortisone are used.

RCW 18.73.250 addresses the administration of epinephrine via single use, auto-injection device. With special MPD training and protocols, an EMT can draw epinephrine from a vial and administer the drug IM. Similarly, to implement RCW 69.50.315, the department has authorized EMTs to administer Narcan (naloxone), an opioid antagonist, to people in respiratory depression or apnea because of narcotic overdose. This is done by intranasal (IN) atomizer or IM injection, and requires MPD training and protocols. This statute may serve as a model for a statute related to administration of hydrocortisone sodium succinate or glucagon.

Feasibility of supplementing the training of EMTs either statewide or locally to administer these medications:

It is feasible to supplement training of EMTs to administer these medications; however, it is not costeffective or justifiable to require this statewide.

Washington certified EMTs, when approved by the county MPD to complete local specialized training (WAC 246-976-024), can perform the skills under MPD protocols and supervision. Specialized training for skills and medications is limited to routine, low risk skills that are minimally invasive and limited to conditions that are easily recognized.

The additional required education can supplement the national education standards in the use of these medications. A curriculum would need to be developed and implemented. The curriculum should include pertinent anatomy and physiology, assessment, signs and symptoms, pharmacological information such as indications and contraindications, as well as management of the medical conditions, and treatment provided. It is estimated that the training should take about one hour for each medication, assuming the EMT is already trained to draw up epinephrine from a vial and administer IM.

The costs and likely use of stocking ambulances with these medications:

Use of these medications is extremely low. For effective implementation, if mandated statewide, a minimum stock would have to be carried on each ambulance and aid vehicle. Medications typically expire annually so the costs in the following table are per year for the currently licensed 2,871 combined ambulances and aid vehicles.

Medicine Cost	Glucagon	Hydrocortisone	TOTAL
Per Vehicle	\$332	\$320	\$652
Statewide	\$953,172	\$918,720	\$1,871,892

This estimate does not include the costs of training, continuing education, implementation and compliance tracking, or the cost of curriculum development. Costs associated with proper disposal of unused medications may be substantial and should also be considered. If mandated statewide, this additional burden could result in loss of EMS service.

Options for localized solutions to specific community needs where only BLS services are available, including schools:

If a need was identified for glucagon administration in a community or school district, and there were no paramedics, advanced EMTs or other persons willing and able, a county MPD could request approval from the department to train a select group of EMTs to "assist" in administering the patient's own glucagon. The patient's medication would be kept at the school or day care center, similar to Epipens and other medications. This option would require the department to carefully monitor the outcomes. Additionally, if a county MPD determines that the medications permitted for special circumstances were of critical need for the county, these could be "stocked" in the responding vehicles if the agency has the budget to stock and maintain them. This scenario would most likely occur in rural communities without ALS personnel. The same approach could be considered for administration of hydrocortisone.

For schools, the department and the Office of Superintendent of Public Instruction (OSPI) would need to collaborate to identify where gaps in school nurse resources exist. These gaps could be bridged using localized EMS training in administering these medications. Alternatively, school personnel could be trained and authorized to do this administration using a patient's own glucagon or hydrocortisone kept at

the school. This solution would also work when ALS response is available but takes longer than 10 minutes to get to the patient.

Policy recommendations

The steering committee finds that a statewide mandate regarding use of hydrocortisone sodium succinate and glucagon by EMTs would not provide a meaningful benefit to patient care and would constitute an undue burden on EMS agencies. The committee supports localized solutions where the county MPD can work with the community or patient and the EMS agency to ensure that the appropriate EMS training and medications are available. This can be accomplished through existing rules that allow for specialized training. Statutory requirements would not be necessary.

Sincerely,

All

Sam Arbabi, MD Chair, EMS and Trauma Care Steering Committee

cc: Representative Joe Schmick Representative Sharon Wylie



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Appendix A

Frequency of incidents requiring hydrocortisone sodium succinate administration:

Addison disease is very rare. Lancet estimates the prevalence in Europe as 40-70 million cases; the vast majority are between 30 and 50 years of age. There are estimates of 4-6 million new cases per year, mostly of the autoimmune etiology. Extrapolating from European prevalence suggests that in Washington State, there are about 70 to 490 people with primary Addison disease. Most will not present in crisis because they are being appropriately medicated. The initial treatment of Addison Crisis, presenting as shock, is baseline laboratory data, fluids and salt replacement, glucose IV if indicated, and intravenous steroids. This is out of the scope of all but the paramedic. Congenital adrenal hyperplasia (usually a result of 21-hydroxylase deficiency) is even rarer, occurring in one of 15,000 to 18,000 live births, meaning that Washington State has about four new cases per year (86,566 births in 2013). These children get into difficulty when they become ill with vomiting, fever or other symptoms, or for one reason or another cannot take the oral steroid replacement. They will then deteriorate into a shock state or Addison Crisis. Parents are usually taught by their pediatrician to give IM hydrocortisone to children if they cannot take the oral medication, to prevent a crisis. These children should have Medic Alert identification on their persons, and the schools should know about the medical problems. Treatment of a child is same as for an adult, e.g., labs, IV fluids and salt, glucose as indicated, and IV steroid replacement.

- In Washington State 17 counties use a corticosteroid. The most common is Solu-Medrol. None use hydrocortisone. Source: Statewide medication comparison done in 2008.
- Hydrocortisone and ethylprednisolone are both listed in the NEMSIS suggested list of medications for advanced life support (ALS). Source: National EMS Information System (NEMSIS) TAC Whitepaper; NEMSIS V3 Suggested Medications, updated January 10, 2014.
- EMS agencies allow only ALS use of hydrocortisone.

Frequency of incidents requiring glucagon:

- Glucagon: IV glucose is the treatment of choice; Clark County uses five to 10 units per year on diabetics, and then only if there is a problem starting an IV. Of interest, of the two most recent uses in Clark County, the patient had no response from the glucagon and required glucose IV.
- Glucagon is in the medication formulary of every ALS county in Washington. Source: Washington Emergency Medical Service Information System (WEMSIS).
- Principle use is for treatment of diabetic emergency hypoglycemia. Source: <u>Kedia, N. (2011).</u> <u>Treatment of severe diabetic hypoglycemia with glucagon: an underutilized therapeutic</u> <u>approach. Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy, 4, 337–346.</u> <u>http://doi.org/10.2147/DMSO.S20633</u>
- Must be mixed: Glucagon is supplied in a kit containing one vial of lyophilized powder, one vial of 1 mL sterile water for reconstitution. Reconstituted medication must be used immediately. Source: Web Page Drugs.com, FDA prescribing information, side effects and uses. <u>http://www.drugs.com/pro/glucagon.html</u>

- Glucagon requires storage in a controlled environment: Glucagon has a shelf life of 24 months if stored at 68 to 77 degrees F. Source: Web page, Drugs.com, FDA prescribing information, side effects and uses <u>http://www.drugs.com/drug-interactions/glucagon.html</u>
- Onset of action is about 10 minutes. Source: Drugs.com FDA prescribing information http://www.drugs.com/pro/glucagon.html
- Glucagon may have adverse effect such as tachycardia (rapid heart rate) or hypertension. Source: Web Page Drugs.com, FDA prescribing information, side effects and uses <u>http://www.drugs.com/pro/glucagon.html</u>
- A few companies manufacture a glucagon kit that does not have to be mixed. This medication is still in clinical trials, and is expected to be submitted to FDA for approval in 2015-2016. Source: Web Page: diatribe, Research and Product News for People with Diabetes http://diatribe.org/classdevice-typetopic-area/glucagon
- Of the 27 responses to the glucagon study questionnaire, about one third of the basic life support agencies were reluctant to use glucagon. Cost, time to train and lack of use were the most prevalent reasons for reluctance. Source: 2008 Department of Health glucagon report

Oregon Legislation: In 2015 the Oregon Legislature passed Senate Bill 875, which allows school personnel to administer medication to treat adrenal insufficiency in students experiencing adrenal crisis.

Comments on Report: This report was presented to the EMS and Trauma Care Steering Committee on September 16, 2015. On October 1, 2015, Department of Health held an open public meeting to present the report. The following is a summary of the comments:

- The Washington State medical program directors support allowing localized solutions to specific community needs. This means that if there were an identified need for glucagon administration in a community or school district, and there were no paramedic, advanced EMTs or any other people willing and able, a medical program director could request to train a select group of EMTs to assist in administering the patient's own glucagon. The patient's medication would be kept at the school or day care center.
- The EMS and Trauma Care Steering Committee supports the policy recommendation of the report to allow localized solutions to meet specific community needs and not have a statewide mandate regarding the use of glucagon and hydrocortisone.
- One representative from the Washington Ambulance Association expressed concerns about the cost of purchasing the medications if it is legislatively mandated.
- One public member expressed the following concerns:
 - The report was deficient in including the benefits of the use of glucagon. He indicated seeing data showing two deaths per year because of hypoglycemia and that the number of hypoglycemic-related deaths may be under-reported if the patient experiences cardiac arrest, stroke, or other conditions where hypoglycemia may have been a co-morbid or primary factor leading to the critical condition causing death.
 - The cost of caring for a person requiring long-term complex care because of conditions such as coma and brain injury caused by hypoglycemic events that may have been prevented with early intervention. He suggested that because people who would benefit from the availability of glucagon tend to be younger and more in the prime of life, that their loss from an economic standpoint would likely exceed the cost to the state.
 - He was also concerned about the availability of someone present to administer glucagon.

• He indicated that basic life support crews providing glucagon to a patient while waiting for ALS services to arrive may prevent brain damage and patient conditions from worsening and as such, glucagon should be mandated in areas where EMS advanced life support response is greater than 10 minutes.