Policy for Vaccine Administration by Emergency Medical Services Providers in Virginia

Purpose
This policy is designed to provide guidance to Virginia Emergency Medical Services (EMS) Operational Medical Directors (OMD), EMS agencies, and EMS providers in the development of a program for the administration of vaccines by appropriately certified, authorized, and supervised EMS providers.

Background
Previously, EMS providers have not been recognized by the Code of Virginia as having the ability to administer vaccines under routine circumstances. EMS providers could be authorized to administer vaccines in the event of a declared emergency by the Governor and under the direction and authorization of the Commissioner of Health.

Amendments to the Code of Virginia, effective March 29, 2010 recognized certain EMS providers among those identified as able to administer vaccinations to minors. Amendments to the Code of Virginia, effective March 29, 2010 recognized certain EMS providers as being authorized to administer vaccinations under the authority of their operational medical director (OMD)/EMS Physician without the physical presence of the medical director.

Personnel and Responsibilities
An Operational Medical Director (OMD)/EMS Physician serves as the “prescriber” identified in the Code of Virginia, and as the supervising physician for the EMS providers administering vaccines. They are responsible for the following:

- A prescriber is a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance
- They must hold a current endorsement as an EMS physician in Virginia and be affiliated with the EMS agency developing the vaccination program
- The OMD is ultimately responsible for the supervision of the vaccination program
- Provides authorization for purchase of vaccine and other necessary supplies for vaccine administration
- Ensuring appropriate physical management and handling of vaccine
- Ensuring that the vaccine program is registered with the Virginia Immunization Information System (VIIS)
- Developing/approving protocols for approval and training of vaccinators, provision of specific vaccine information/education and informed consent to recipients of vaccine
- Developing/approving specific procedures for administration of vaccine and management of any vaccination related complications, development and approval of appropriate record keeping, reporting of vaccination information and any adverse events or complications, and implementation of an ongoing quality management program for the vaccination program.
The Board of Nursing has developed a model protocol for the administration of vaccines by pharmacists in Virginia. It provides a concise outline of requirements for a vaccination program, as well as vaccine specific information on patient screening and provision of consent, administration of specific vaccines, and record keeping including sample documents and record forms: http://www.virginiapharmacists.org/associations/7940/files/updated%202006%20Immunization%20Protocol.doc

EMS providers participating in a vaccination program must:
- Hold a valid, unrestricted Virginia ALS certification
  - Flu vaccine administration to minors is limited to EMT-Intermediate and EMT-Paramedic only
- Approved by the OMD/EMS Physician to practice at the appropriate certification level
- Must be affiliated with the Virginia EMS agency developing the vaccination program
- Must be individually approved by their agency OMD as a vaccinator
- Must follow protocols approved by their OMD for vaccine administration

Procedures

The OMD must direct the development of a plan for purchase/acquisition of vaccine, including proper storage and handling of each type of vaccine according to recommendations by the Centers for Disease Control (CDC) and the vaccine’s manufacturer.

- Specific information regarding vaccine management in general as well as information for specific vaccines is available from the CDC: http://www.cdc.gov/vaccines/recs/storage/default.htm
- The OMD must ensure they approve each provider who will administer vaccine has been individually and that the provider has received training in the necessary areas. These include handling of the vaccine, screening and provision of information and informed consent to vaccine recipients, specific administration protocols for each vaccine administered, observation of vaccine recipients and management of complications of vaccine administration (including severe allergic reaction) and the maintenance of appropriate records regarding vaccine administration.
- The OMD/Agency will keep a written record of those providers approved to administer vaccine: an example is provided in Appendix B
- The OMD must assure that before administering any vaccine, a copy of the most recent Vaccine Information Statements (VIS) is provided to the recipient or their legal guardian. Provision of the appropriate VIS is required by Federal law for many vaccines. Such information must be reviewed with the adult recipient, or if a minor by their parent, legal guardian or person standing in loco parentis to confirm their understanding of the benefits and risks of the intended vaccine. Non-English speaking individuals seeking vaccination for themselves or their child/children should be provided a copy of the VIS in their native language. VIS are available for specific vaccines in a variety of languages: http://www.cdc.gov/vaccines/pubs/vis/default.htm
- General information regarding vaccine administration as well as vaccine-specific information is available from the CDC: http://www.cdc.gov/vaccines/default.htm

- The Operational Medical Director must assure that every provider screens every recipient for indications and contraindications prior to administering the vaccine. Screening tools shall at a minimum follow CDC and manufacturer’s recommendations. Examples are available for children and teens: http://www.immunize.org/catg.d/p4060.pdf, and for adults: http://www.immunize.org/catg.d/p4065.pdf

- A record of vaccine administration must be kept in the recipient’s vaccination record and a second copy kept at the administering location documenting the date that the vaccine was administered, the route, dose, site, manufacturer and lot number, the publication date of the Vaccine Information Statements (VIS), along with the name and title of the person administering the vaccine. Sample vaccination recording materials are available through the CDC: http://www.cdc.gov/vaccines/recs/immuniz-records.htm#recording

- Vaccine record keeping should conform to guidelines of the Virginia Immunization Information System (VIIS), and each vaccination program should be registered with the VIIS. Information regarding registration and record keeping is available: http://www.vdh.virginia.gov/epidemiology/immunization/viis/index.htm

- The OMD must also develop a protocol for the care and observation of vaccine recipients, and for management of adverse events related to vaccine administration. These protocols would be expected to dovetail with existing agency patient care protocols for the management of serious allergic reactions and anaphylaxis

- The OMD must ensure that the vaccination program is prepared to identify and report adverse reactions to vaccine administration, and be familiar with the Vaccine Adverse Event Reporting System (VAERS). Information regarding adverse events associated with vaccination is available generally through the CDC: http://www.cdc.gov/vaccines/vac-gen/safety/default.htm, and specifically about the VAERS: http://vaers.hhs.gov/about/index
Appendix A

§ 32.1-46.02. Administration of influenza vaccine to minors.
The Board shall, together with the Board of Nursing and by August 31, 2009, develop and issue guidelines for the administration of influenza vaccine to minors by licensed pharmacists, registered nurses, or licensed practical nurses, certified emergency medical technicians-intermediate, or emergency medical technicians-paramedic pursuant to § 54.1-3408. Such guidelines shall require the consent of the minor's parent, guardian, or person standing in loco parentis, and shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention.

§ 54.1-3408. Professional use by practitioners.
I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.
I, ____________________________, MD/DO licensed in the Commonwealth of Virginia do hereby authorize, ____________________________,

NAME OF VIRGINIA LICENSED EMS AGENCY

a Virginia licensed Emergency Medical Services agency for whom I serve as an Operational Medical Director (OMD)/EMS Physician as recognized by the Virginia Office of EMS and those affiliated and certified Advanced Life Support providers listed below to administer vaccines to patients in accordance with the laws and regulations of the Commonwealth of Virginia. In exercising this authority, the participants shall comply with the protocol for administration of vaccines. This medical directive also covers emergency care if it is necessary.

The participants must agree to any significant changes in the protocol.

Signatures:

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