

Immunizations by Pharmacists

Thank you for the opportunity to comment on the bill draft that would allow pharmacists to administer influenza vaccine to children over the age of five years and other immunizations to children above eleven years of age.

NDMA plans to thoroughly review the implications of the bill draft, particularly in the context of the young patient as this issue has not been discussed by pharmacists with NDMA or any state medical specialty society such as pediatricians or family medicine physicians. While the testimony on June 16 supporting the expansion of immunization administration by pharmacists was presented in terms of what might be advantageous for new pharmacists in getting into the “immunization business,” as was stated, or generally increasing immunization rates, it is important that the medical implications for children be fully considered.

In particular, NDMA suggests that a representative of the North Dakota Chapter of the American Academy of Pediatrics be invited to testify to discuss in detail the implications of the bill draft for children, particularly the impacts the legislation would have on ensuring that children see their primary care physician as recommended. Pediatricians in particular have strong concern about pharmacists giving immunizations to children because it is inconsistent with medical home principles, and would eliminate one good reason why kids come in for their much needed well-child visits in the critical pre-teen and teenage years.

In states surrounding North Dakota, it appears pharmacists are authorized to administer vaccines and flu shots to adults, with the exception that Minnesota authorizes qualified pharmacists to administer flu vaccine to children ten years of age or older under certain conditions.

The Minnesota statute (Minn. Stat. 151.01(5)) reads:

"Practice of pharmacy" means:

...

(5) participation in administration of influenza vaccines to all eligible individuals ten years of age and older and all other vaccines to patients 18 years of age and older under standing orders from a physician licensed under chapter 147 or by written protocol with a physician provided that:

(i) the pharmacist is trained in a program approved by the American Council of Pharmaceutical Education for the administration of immunizations or graduated from a college of pharmacy in 2001 or thereafter; and

- (ii) the pharmacist reports the administration of the immunization to the patient's primary physician or clinic;"

The Montana administrative rule (Mont. Admin R 24.174.503) reads:

ADMINISTRATION OF VACCINES BY PHARMACISTS

- (1) A pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs in order to administer and/or prescribe vaccinations.
- (2) A pharmacist may administer vaccines to persons 18 years of age or older provided that:
 - (a) the pharmacist has successfully completed an accredited course of training provided by the Centers for Disease Control and Prevention (CDC), the American Council on Pharmaceutical Education or other authority approved by the board;
 - (b) the pharmacist holds a current basic cardiopulmonary resuscitation certification issued by the American Heart Association, the American Red Cross or other recognized provider;
 - (c) the vaccines are administered in accordance with an established protocol that includes emergency measures; and
 - (d) the pharmacist has a current copy of or on-site access to the Centers for Disease Control and Prevention reference "Epidemiology and Prevention of Vaccine-Preventable Diseases."
- (3) The pharmacist must give the appropriate vaccine information statement to the patient or the patient's legal representative with each dose of vaccine covered by these forms and counsel the patient accordingly.
- (4) The pharmacist must maintain written policies and procedures for disposal of used or contaminated supplies.
- (5) The pharmacist must report any adverse events to the primary care provider identified by the patient and to the CDC.
- (6) A pharmacist administering any vaccine shall maintain the following information in the patient's medical records for a period of at least three years:
 - (a) the name, address, allergies, and date of birth of the patient;
 - (b) the date of administration;
 - (c) the name, manufacturer, dose, lot number, and expiration date of the vaccine;
 - (d) the vaccine information statement provided;
 - (e) the site and route of administration;
 - (f) the name and address of the patient's primary health care provider;
 - (g) the date on which the vaccination information was reported to the patient's primary health care provider under the provisions of the National Vaccine Injury Compensation Program;
 - (h) the name of the administering pharmacist; and
 - (i) any adverse events encountered.
- (7) The authority of a pharmacist to administer immunizations may not be delegated; however, an immunization-certified intern may immunize under the direct supervision of a pharmacist qualified under this chapter.
- (8) The pharmacist must provide a certified true copy of the immunization certificate and CPR certification to the board for initial endorsement on their pharmacist license.
- (9) In order to maintain the immunization endorsement on their pharmacist license, an immunization certified pharmacist must:
 - (a) maintain current CPR certification;
 - (b) participate in a minimum of two hours of continuing education on immunizations or vaccine-preventable diseases every year. The continuing education must be American Council on Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or Continuing Education Advisory Council (CEAC) approved; and
 - (c) maintain competency in vaccine administration technique by:
 - (i) professionally administering vaccinations to humans in the previous 12 months; or
 - (ii) having a Montana licensed health care provider authorized to prescribe or administer vaccines or an immunization-certified pharmacist witness and validate the pharmacist's vaccine administration technique every year.
- (10) The board shall randomly select renewal notice forms of immunization-certified pharmacists for audit and verification of the requirements listed in this rule.

The South Dakota administrative rule on influenza immunizations (ARSoDak 20:51:28:01) reads as follows, with additional rules on training requirements:

20:51:28:01. Authority to administer influenza immunizations. A pharmacist may administer influenza immunizations to eligible patients eighteen years of age and older if the pharmacist has met the qualifications set forth by this chapter and has been granted authorization by the board. The board may issue a certificate authorizing this function to the pharmacist who meets the qualifications established in § 20:51:28:02. The authority to administer influenza immunizations is valid only for the pharmacist meeting this requirement and may not be delegated to any other pharmacist or employee.

Clearly, our neighboring states and perhaps over thirty states in all recognize the collaborative role of pharmacists in administering immunizations to adults. Children present an entirely different set of considerations and challenges, and I encourage the Committee to involve pediatricians in discussing this important issue.

Thank you Chairman Weisz and Committee Members for the opportunity to provide testimony on the committee's study of unmet health care needs, and to provide our initial comments on the bill draft.