

April 6, 2016

Suzanne Johnson-DeLeon
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mailstop A–19
1600 Clifton Road NE
Atlanta, GA 30329

Submitted electronically to www.regulations.gov

Re: Proposed updated vaccine information statements for hepatitis A and hepatitis B vaccines

Dear Ms. Johnson-DeLeon:

On behalf of the American Nurses Association (ANA), we are pleased to comment on the proposed updated vaccine information statements for hepatitis A and hepatitis B vaccines. As the only full-service professional organization representing the interests of the nation's 3.4 million registered nurses (RNs), ANA is privileged to speak on behalf of its state and constituent member associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions, and provide advice and emotional support to patients and their family members. ANA members also include the four advanced practice registered nurse (APRN) roles: nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists. ¹

The Centers for Disease Control and Prevention (CDC) develops vaccine information materials that all health care providers must give to patients/parents prior to administration of specific vaccines. CDC requests written comments on the proposed updated vaccine information statements for hepatitis A and hepatitis B vaccines. While ANA generally supports the proposed changes to the vaccine statements, we recommend revising these documents to include provider-neutral language throughout the statements.

Specifically, the vaccine information statements include references to both "health care providers" and to "doctors." For example, the vaccine information statement for hepatitis A, paragraph 2 (captioned *Hepatitis A vaccine*) and paragraph 7 (captioned *How can I learn more?*) advise the

¹The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.

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reader to "ask your healthcare provider" for more information on certain topics. Paragraph 4 (captioned *Risks of a vaccine reaction*) advises the reader that "your doctor" can provide more information about reactions, and to tell your doctor if you feel dizzy, or have vision changes or ringing in the ears. Paragraph 5 (captioned *What if there is a serious problem?*) describes circumstances when the reader should "call your doctor."

With regard to the vaccine information statements for hepatitis B, paragraph 4 (captioned *Risks of a vaccine reaction*) states that "your doctor" can provide more information about reactions, and to "tell your doctor" about certain symptoms listed on the statement, while paragraph 5 (captioned *What if there is a serious problem?*) advises when the reader should call the doctor. Paragraph 7 (captioned *How can I learn more?*) advises the reader to "ask your healthcare provider" for additional information.

It is essential that information provided to the public, such as these vaccine information statements, use provider neutral language to prevent confusion among health care consumers who use APRNs as their primary care provider. The use of APRNs to provide primary care services is not a new practice. APRNs have delivered professional health services to patients for decades. Rather than include some references to doctors and others to healthcare providers, ANA recommends revising the statements to consistently refer to "healthcare providers."

We appreciate the opportunity to share our views on this matter. If you have questions, please contact Mary Jo Assi, Director, Nursing Practice and Work Environment (maryjo.assi@ana.org).

Sincerely,

Debbie D. Hatmaker, PhD, RN, FAAN

Debbie Harmaku

Executive Director

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President Marla Weston, PhD, RN, FAAN, ANA Chief Executive Officer