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December 10, 2015

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 Vaccine Information Materials for HPV (Human Papillomavirus) Gardasil®-9 Vaccine
[Docket No. CDC-2015-0089]

Dear Ms. Johnson-DeLeon:

On behalf of the American Nurses Association (ANA), we are pleased to comment on the matter referenced above. 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 vaccine information statement included in Docket No. CDC-2015-0089 identifies only "doctors" as providers. For example, section 3 (entitled "Some people should not get this vaccine"), advises the reader to "tell your doctor" if you have any severe allergies, while section 4 ("Risks of a vaccine reaction") advises the reader to "tell your doctor if you feel dizzy, or have vision changes or ringing in the ears." Similarly, sections 5 and 7 of the vaccine information statement refer only to "doctors." ANA recommends revising these sections of the form to include provider-neutral language throughout the statement.

The utilization of APRNs to provide primary care services is not a new practice. APRNs have delivered professional health services to patients for decades. In addition, in many states other health care providers assess the need for and administer certain immunizations. It is essential that information provided to the public, such as vaccine information statements, use provider neutral language to prevent confusion among health care consumers who receive immunizations from other health care providers and who use APRNs as their primary care provider.

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

Sincerely,

A handwritten signature in cursive script that reads "Debbie D. Hatmaker".

Debbie D. Hatmaker, PhD, RN, FAAN

Executive Director

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