AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

June 20, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS–3213–P
P.O. Box 8010
Baltimore, MD 21244–1850

Re: Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers, CMS 3213-P

Dear Dr. Berwick:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 100,300 family physicians and medical students nationwide, I am responding to the proposed *Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers* as published in the May 4, 2011, *Federal Register*.

This proposed rule discusses policies that, if finalized, would require certain Medicare and Medicaid providers and suppliers to offer all patients an annual influenza vaccination, unless the vaccination is medically contraindicated or the patient or patient's surrogate declined vaccination. This proposed rule also requires certain providers to develop policies and procedures that would allow them to offer vaccinations for pandemic influenza, in case of a future pandemic influenza event for which a vaccine may be developed.

Influenza is a serious disease and vaccination is the first and most important step that physicians, other healthcare workers, and patients can take to protect against the flu. The AAFP applauds the agency for releasing this proposed rule, since we share CMS' goal of increasing the number of patients receiving annual vaccinations against seasonal influenza and decreasing the morbidity and mortality rates from influenza.

The regulation proposed by CMS states, "While there is a large population that could benefit from pneumococcal vaccination, the vaccine should only be given once or twice, depending on the patient's age. Because it is not designed or recommended for regular administration, we believe it is best provided or prescribed by primary care physicians who maintain long-term records for patients." The AAFP concurs with the agency on this point, and it is the AAFP's policy that patients should receive all immunizations recommended by the AAFP in their patient centered medical home. Further, the AAFP believes that when recommended vaccines are provided outside of the medical home, all pertinent vaccine related information should be provided to the patient's medical home. As such, the AAFP strongly urges CMS to include in the final rule a requirement that immunizations made outside of the medical home (e.g. in a hospital setting) should be, to the greatest extent possible, electronically communicated back to the patient's primary care

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physician. Including this requirement would facilitate the continuity of healthcare for Medicare and Medicaid patients.

Though supportive of the overall intent of the proposed rule, the AAFP is concerned over potential unintended consequences it may have on rural health clinics (RHCs) and federally qualified health centers (FQHCs). Many RHCs and FQHCs are specially designated family medicine and primary care practices and as such will be subject to this rule. The proposed rule's regulatory impact analysis states that the typical covered entity will bear costs upwards of $5,000 annually to implement this provision. Many RHCs and FQHCs will struggle to afford and comply with the requirements. Though CMS states that, "Almost all of this [total annual costs to affected entities] would be reimbursed by insurance or charges to patients", the AAFP questions whether this statement is accurate. For example, Medicare will not reimburse an RHC for the time and training required to comply with these requirements. Also, current Medicare payment for vaccines and their administrations barely covers physicians' costs. Since CMS estimates that Medicare alone has the potential to save $380 million based on this rule, the AAFP encourages the agency to redirect at least some of these savings back into more appropriate payment to physicians, especially primary care physicians, for vaccines and their administration.

The AAFP believes that CMS may also be significantly underestimating the burden placed on covered entities. For example, CMS estimates that vaccine administration will take 6 minutes per patient on average. However, in the practice expense RVU methodology that CMS uses with its Medicare physician fee schedule, CMS allots 17 minutes for clinical staff time for vaccine administration (CPT code 90471) in non-facility settings, which is akin to the RHC or FQHC setting. The AAFP urges CMS to reconsider and recalculate the burden placed on covered entities.

AAFP will continue educating our members and the patients they treat about the prevention and control of seasonal influenza with vaccines using recommendations consistent with that of the Advisory Committee on Immunization Practices. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Lori J. Heim, MD, FAAFP
Board Chair