



---

7272 Wisconsin Avenue  
Bethesda, Maryland 20814  
301-657-3000  
Fax: 301-664-8877  
[www.ashp.org](http://www.ashp.org)

July 1, 2011

Department of Health and Human Services  
Centers for Medicare and Medicaid Services  
Attention: CMS-3213-P  
P.O. Box 8010  
Baltimore, MD 21244-1850

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

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments in response to the Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers; Proposed Rule (Proposed Rule) establishing a new condition of participation (CoP) as published in the Federal Register on May 4, 2011.<sup>1</sup> For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

As noted in the Federal Register, CMS is proposing to require certain Medicare and Medicaid providers and suppliers to offer all patients an annual influenza vaccination, unless medically contraindicated or unless the patient or their representative declines the vaccination. While we applaud the agency for their desire to increase the number of patients receiving annual vaccination against seasonal influenza and to decrease the morbidity and mortality rates from the disease, we believe there are significant implementation issues with the Proposed Rule.

---

<sup>1</sup> Federal Register Volume 76, Number 86

### **Background**

ASHP has long recognized the importance of vaccinating against influenza. Of relevance to the Proposed Rule, ASHP has the following two policies of note:

#### *UNIVERSAL INFLUENZA VACCINATION*

*Source: ASHP Commission on Therapeutics*

*To advocate universal administration of influenza vaccinations to the United States population.*

#### *INFLUENZA VACCINATION REQUIREMENTS TO ADVANCE PATIENT SAFETY AND PUBLIC HEALTH*

*Source: ASHP Council on Professional Affairs*

*To advocate that hospitals and health systems require health care workers to receive an annual influenza vaccination except when (1) it is contraindicated, or (2) the worker has religious objections, or (3) the worker signs an informed declination; further,*

- *To encourage all hospital and health-system pharmacy personnel to be vaccinated against influenza; further,*
- *To encourage hospital and health-system pharmacists to take a lead role in developing and implementing policies and procedures for vaccinating health care workers and in providing education on the patient safety benefits of annual influenza vaccination; further,*
- *To work with the federal government and others to improve the vaccine development and supply system in order to ensure a consistent and adequate supply of influenza virus vaccine.*

As noted in the above policies, ASHP supports the goals of the Proposed Rule in concept; however, we believe that settings such as primary care physician offices, public health departments, employer health clinics, and community pharmacies are most appropriate as primary providers of the influenza vaccine with hospitals playing a secondary role. We believe that it would be difficult and a significant unfunded cost burden to implement the Agency's CMS' proposed requirement that hospitals offer vaccinations to all patients, especially those in the outpatient setting. Many outpatient departments do not employ individuals who are trained to provide immunizations, nor do they currently maintain the adequate storage capabilities. We do not believe that emergency departments, which are staffed by individuals properly trained to administer a vaccine, are the appropriate setting for this service. We are concerned that should CMS finalize the Proposed Rule as written, hospitals would have to hire additional pharmacy and nursing staff to remain compliant.

Further support for the provision of influenza vaccination by primary care physicians is found in CMS' requirement to verify a patient's account of whether he or she has contraindications to the vaccine or has already been vaccinated for the current season. Safe immunization practices mandate verification and primary care providers maintain the patient's medical record which

would include the type of information that CMS would require. Conversely, documenting compliance in a hospital-based setting would be challenging at best and impossible at worst. In general, hospital outpatient departments do not have access to complete patient information like a primary care provider would, and there would be no simple way to verify contraindications or record of prior vaccination during the current influenza season. Of strong concern to the Society is the problematic timeframe that the Agency has set forth to implement this regulation. For a number of reasons, this schedule is unrealistic.

First, health care professionals generally order influenza vaccine anywhere from six to ten months in advance of the anticipated influenza season. Since the proposed rule was issued after most hospitals would have pre-ordered vaccine, hospitals would invariably face inadequate supply on hand should CMS finalize this Proposed Rule by the 2011 to 2012 influenza season. Further, on the manufacturer side, since industry has not factored CMS' Proposed Rule into their predicted demand, finalizing the Agency's proposal could lead to a shortage of influenza vaccine. It also would create a greater number of competitors for limited vaccine supplies than has historically been the case.

While CMS does state that providers would not be required to offer vaccination in the event of a shortage, the details on how CMS would enforce this provision are crucial. Consistent with the ASHP policy cited above, we believe that in the event of shortage or pandemic, limited supplies of vaccine should be used to protect health care professionals in the hospital setting first rather than the general population who would likely not fall under the guidelines for priority immunization given limited availability. This approach provides some assurance for hospital workers to continue to provide health care services. We believe CMS should address in the Final Rule whether or not prioritizing health care worker vaccination over patients would fall under its discretionary authority. It is also unclear how CMS would inform hospitals that the CoP would be suspended during periods of shortage or pandemic. Additionally, regional or hospital level shortages may occur and the Agency should address how it would handle these types of circumstances.

We are also concerned that the Proposed Rule may unintentionally threaten the traditional channels of vaccination (e.g., primary care physicians, community pharmacies, and employer sponsored sites). If hospitals are required to offer vaccination, the Society is concerned that insurers may reconsider separate coverage at sites other than hospitals.

In terms of adapting information technology (IT) systems to facilitate documentation, it would be difficult, if not impossible, to demonstrate compliance with this Condition of Participation (CoP) with manual chart reviews. Even with documentation, without good Electronic Health Records (EHRs), duplicate vaccinations would be not uncommon. The Agency should address

how CMS plans on assessing compliance with the CoP prior to availability of IT documentation should the Agency move forward with a Final Rule.

Finally, CMS should address the following issues that the Proposed Rule raises, but does not answer:

- While influenza vaccination is recommended for everyone, some patients are more at risk for complications of the disease (e.g., elderly, pregnant women, those with concomitant disease states). The Centers for Disease Control and Prevention recommendations can be found at [http://www.cdc.gov/flu/about/disease/high\\_risk.htm](http://www.cdc.gov/flu/about/disease/high_risk.htm), and the agency should directly address the recommendations of the CDC in their Final Rule.
- From a national perspective, the CDC has defined influenza season as October through March, not September through February as noted by CMS. On a regional level, the influenza season starts and stops within that broader time frame. That is, it doesn't necessarily last a uniform five months nationwide. To conserve resources, facilities should be allowed to establish programs that match those shorter time frames specific to their region.
- The Agency should clarify what is meant by "counseling." Direct health care provider to patient counseling would be a significant barrier in the inpatient setting and an even greater burden for outpatient visits.
- CMS should clearly define what an "outpatient" is for the purposes of the CoP. For example, would patients who are receiving laboratory, physical therapy, chemotherapy, or commercial pharmacy services be considered outpatients and therefore subject to the Proposed Rule? It is essential that this question be addressed in the Final Rule.

The Society appreciates this opportunity to comment to the Agency and strongly recommends that CMS reconsider this Propose Rule in light of the issues we raise. Should you have additional questions, I can be reached by telephone at 301-664-8806, or by e-mail at [ctopoleski@ashp.org](mailto:ctopoleski@ashp.org).

Sincerely,



Christopher J. Topoleski  
Director, Federal Regulatory Affairs