



## Arizona Hospital and Healthcare Association

*Submitted electronically*

July 5, 2011

Donald M. Berwick, M.D., M.P.P.  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS-3213-P, Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers; Proposed Rule (Vol. 76, No. 86), May 4, 2011.***

Dear Dr. Berwick:

On behalf of our 102 member hospitals, the Arizona Hospital and Healthcare Association (AzHHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on influenza vaccination for certain participating providers and suppliers.

AzHHA acknowledges that increasing the number of individuals who receive the annual influenza vaccination is a key factor in decreasing the morbidity and mortality rates from influenza, and is key to community health promotion. However, using hospital-based settings (including short-term acute care, critical access, long-term acute care, psychiatric, rehabilitation, children's and cancer hospitals) as a primary method of offering and administering immunization would be very complex and burdensome to implement, and not a cost-effective way to accomplish the agency's goal. We believe that collaboration with public health departments is a better approach to achieving these goals.

AzHHA is also concerned that CMS has grossly underestimated the cost and burden of implementing this rule, and that the proposal essentially translates into another unfunded mandate for hospitals in the midst of an already difficult economic climate. **We fully support the detailed comments made on this proposed rule by the American Hospital Association (AHA) in their recent comment letter to you dated July 1, 2011,** and strongly urge you to rescind this proposed rule. While we concur that increasing immunization rates is a desirable goal, mandating immunization provision through the hospital Conditions of Participation (CoP) is inappropriate.

According to CMS, the CoPs are “minimum standards for patient health and safety, and CoPs focus on creating a foundation to ensure quality and safe care for beneficiaries throughout a given facility.”<sup>1</sup> In other words, the CoPs are intended to articulate the minimum processes and structures hospitals should have in place to ensure safe and effective delivery of the services they have chosen to provide. Offering patients influenza vaccination, while important to individual wellness and reducing the societal burden of influenza, does not rise to the level of a “minimum standard for patient health and safety” in the same way that the fire safety or anesthesia care CoPs do. Imposing the proposed requirement via the CoPs may result in terminating hospitals from the Medicare and Medicaid programs for violations that pose no threat to the health and safety of a hospitalized patient.

There are also many good locations at which individuals can, and do, commonly receive influenza vaccinations including primary care physicians’ offices, clinics run by state and local public health departments and convenient sites such as local pharmacies and employer health clinics. These organizations currently offer vaccinations to all individuals during the influenza season at a minimal price, and at optimum convenience to the individual. Furthermore, given the acuity of patients receiving inpatient services, for most, offering flu vaccinations during an inpatient stay would not be medically prudent anyway.

- **AzHHA urges CMS to use existing quality reporting systems to promote hospital accountability for a public health issue.**

CMS has other options that it can use to increase vaccination rates. We think that public reporting of certain quality measures has driven improvement and is an appropriate way to hold hospitals accountable for the patients they serve. CMS recently finalized a global influenza immunization measure that will be implemented for the fiscal year 2014 in its inpatient quality reporting program. Inpatient acute hospitals are required to begin submitting data to CMS during the first quarter of calendar year 2012. Incorporating immunization measures into existing quality improvement systems makes sense, and avoids addition of burdensome mandates to offer immunization to everyone in inpatient and outpatient settings as a Condition of Participation.

- **AzHHA urges CMS to recalculate the estimated economic impact of implementing the proposed rule.**

CMS uses burden estimates contained in its regulatory impact analysis to conclude that the benefits expected in terms of decreased medical care costs and savings in patient time would outweigh the costs associated with the proposed rule. CMS also concludes that the

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<sup>1</sup> 75 *Federal Register* 72001 (November 24, 2010)

proposed rule would have little consequential adverse impact on provider costs, net of insurance reimbursement. We disagree with these conclusions and believe, in concert with AHA's detailed analysis, that CMS' estimates of burden and overall impact analysis vastly underestimate the cost and burden hospitals would face in the following areas:

- Developing implementing policies and procedures
- Tracking of patient immunization history
- Implementing necessary changes to medical and electronic record systems
- Training hospital staff
- Educating and counseling patients
- Verifying patient immunization status
- Securing of immunization inventory and storage
- Administering immunizations
- Documenting immunizations for inpatient AND outpatient services in a patient medical record; and
- Securing reimbursement for immunization services

Hospitals do voluntarily offer certain patients flu vaccinations, when medically appropriate for the patient, but the global mandate to offer influenza vaccination to all patients a Medicare Condition of Participation is not appropriate. We also question the legal implications for our hospitals in circumstances where over-immunization or adverse reactions might occur for immunizations administered to persons admitted for conditions where immunization would be contraindicated during the time period surrounding the hospitalization.

Thank you again for the opportunity to comment on this proposed rule. If you have any questions, please feel free to contact Tanie Sherman, Director of Regulatory Advocacy, at (602) 549-9022 or [tsherman@azhha.org](mailto:tsherman@azhha.org).

Sincerely,



Laurie Liles  
President and Chief Executive Officer