



Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3213-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

July 1, 2011

To Whom It May Concern:

As an organization dedicated to improving the health of all Americans through making disease prevention a national priority, Trust for America's Health is pleased to comment on the proposal to establish influenza vaccination standards for Medicare- and Medicaid-participating hospitals, critical access hospitals, rural health clinics, federally-qualified health centers, and end-stage renal disease facilities. We believe that this requirement will greatly improve rates of influenza immunization in the U.S. population and significantly reduce morbidity and mortality.

As the preamble notes, because of influenza's major threat to individual and population health, CDC recommends that influenza vaccines be given to all people ages 6 months and above.¹ However, in the 2008-2009 flu season, less than 40% of the population was vaccinated.²

We believe that the proposal to require Medicare-and Medicaid -participating hospitals to offer influenza vaccination to all patients will greatly improve immunization rates. The success of a similar requirement that CMS applied to long-term-care facilities in 2005 in raising vaccination rates to 90% clearly demonstrates the potential public health impact of this proposal. In addition, we support the proposal to require these facilities to establish plans for immunization in the case of pandemic influenza.

We would like to make the following recommendations to clarify and strengthen the proposed rule:

1. Clarify that vaccination must be offered to *all* patients, not only Medicare and Medicaid beneficiaries.

¹ CDC, "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2010; 59 (RR-8): 1-62.

² CDC, "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2009; 58(RR-8): 1-56



As the preamble notes, Medicare and Medicaid beneficiaries would compose roughly half of the population that stands to be immunized as a result of this step. It is vital that facilities understand that they are required to offer immunization to *all* patients, not only those who are in Medicare or Medicaid.

2. Include healthcare personnel in the scope of the requirement.

HHS's Healthcare Infection Control Practices Advisory Committee (HICPAC), in conjunction with the CDC's Advisory Committee on Immunization Practices (ACIP) recommends influenza vaccination of all healthcare workers.³ Furthermore, in its 2010 updated position paper on Influenza Vaccination of Healthcare Personnel, the Society for Healthcare Epidemiology of America noted that multiple studies have demonstrated an association between increased vaccination of healthcare workers and decreased morbidity and mortality among patients in hospitals and long-term care facilities.⁴

Despite the importance of influenza vaccination for healthcare workers, rates remain low. CDC reports that the 2009-2010 flu season was the first year since 1989 that seasonal vaccination rates exceeded 49 percent of health care personnel (HCPs).⁵ However, even in that pandemic year, when education and awareness were at a peak, H1N1 vaccination of HCPs was estimated to be only about 37 percent.⁶ These rates are even lower in non-hospital settings. Studies have identified a number of reasons for this low rate, including provider perceptions that they "did not need it," concern about vaccine side effects, or the perception of belonging to a low-risk group.⁷

TFAH agrees that there is a compelling and urgent need to increase influenza vaccination rates among healthcare workers in a broad set of healthcare settings.⁸ Therefore, we

³ Pearson ML, Bridges CB, Harper SA. Influenza vaccination of health-care personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2006 Feb 24;55(RR-2):1-16 (online at <http://www.guideline.gov/content.aspx?id=8697>).

⁴ Thomas R. Talbot, MD, MPH, Hilary Babcock, MD, MPH, Arthur L. Caplan, PhD, Deborah Cotton, MD, MPH, Lisa L. Maragakis, MD, MPH, Gregory A. Poland, MD, Edward J. Septimus, MD, Michael L. Tapper, MD and David J. Weber, MD, MPH, "Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel," *Infection Control and Hospital Epidemiology*, Vol. 31, No. 10 (October 2010) (pp. 987-995) (online at <http://www.jstor.org/stable/full/10.1086/656558>)

⁵ CDC, *MMWR Weekly*, "Interim Results: Influenza A (H1N1) 2009 Monovalent and Seasonal Influenza Vaccination Coverage Among Health-Care Personnel --- United States, August 2009--January 2010." April 2, 2010 / 59(12);357-362.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm>

⁶ Ibid.

⁷ "Adult Immunizations: Shots to Save Lives," *supra* note 1, p. 10.

⁸ The definition of healthcare personnel should include all paid and unpaid workers within a healthcare setting, as defined by the HHS Healthcare Infection Control Practices Advisory Committee and the Advisory Committee on Immunization Practices.

recommend that the proposed rule be expanded to include healthcare personnel in its scope. Covered facilities should be required to offer seasonal and, as appropriate, pandemic influenza vaccination to all paid and unpaid workers within a healthcare setting, in a manner consistent with the recommendations of HICPAC and ACIP.

3. Ensure clear guidance and rigorous enforcement.

Meaningful implementation of these new standards will require robust guidance for facilities and surveyors. In developing guidance, we urge CMS to provide clear detail on the requirements that each type of facility covered by the rule must meet to achieve compliance. The existing operating manual for long-term care facilities' implementation of an analogous requirement offers a useful template.⁹

In addition, we urge that enforcement mechanisms reflect the crucial importance of influenza vaccination. In assessing the severity level of violations, CMS should consider both the risk to individuals who do not receive proper vaccination, and the increased risk at a population level when immunization rates are low in a facility or community. Further, CMS should consider the risk to patients and others when healthcare personnel do not receive appropriate influenza vaccination.

Conclusion

Thank you very much for the opportunity to comment on this important proposed rule. We are happy to see CMS addressing this key preventive health issue in such a fundamental way. If you would like any additional information, please contact our Director of Government Relations, Becky Salay, at (202) 223-9870 ext. 15, or via email at bsalay@tfah.org.

Sincerely,



Jeffrey Levi, Ph.D.
Executive Director

⁹ State Operations Manual, Guidance to Surveyors for Long Term Care Facilities Appendix PP - §483.25(n) Influenza and pneumococcal immunizations (online at http://www.cms.gov/CFCsAndCoPs/Downloads/som107ap_pp_guidelines_ltcf.pdf).