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IDSAs Headquarters

1300 Wilson Boulevard
Suite 300

Arlington, VA 22209

TEL: (703) 299-0200

FAX: (703) 299-0204

E-MAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

July 5, 2011

BY ELECTRONIC SUBMISSION: www.regulations.gov

Donald M. 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: Comments on Proposed Rule [Docket No. CMS-3213-P]: Influenza Vaccination Standard for Certain Participating Providers and Suppliers

Dear Dr. Berwick:

The Infectious Diseases Society of America (IDSAs) is pleased to have the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule requiring certain Medicare and Medicaid providers and suppliers to establish an influenza vaccination standard, including offering all patients an annual influenza vaccination, unless medically contraindicated or unless the patient or patient's representative/surrogate declined vaccination. IDSAs also appreciates the inclusion of a requirement that certain providers and suppliers develop policies and procedures that would allow them to offer vaccinations for pandemic influenza.

IDSAs represents more than 9,300 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education and research. Our members care for patients of all ages with serious infections, including influenza, meningitis, pneumonia, and tuberculosis; resistant infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* (*E. coli*), and *Salmonella*; cancer and transplant patients who have life-threatening infections caused by unusual microorganisms; foodborne disease; HIV/AIDS; and emerging infections like the 2009 H1N1 virus and severe acute respiratory syndrome (SARS).

IDSAs firmly supports doing all that is practical and necessary to protect patients against serious and life-threatening infectious diseases including influenza. IDSAs commends CMS for taking this step to improve influenza vaccination rates and to find ways to improve health disparities across the Medicare and Medicaid systems. IDSAs also appreciates CMS' acknowledgement of the critical need for vaccination during an influenza pandemic and the importance of health care providers and suppliers being prepared to offer those necessary vaccines.

Recommendations

CMS is correct in pointing out the lackluster results of current efforts to improve influenza vaccination rates. While the proposed rule is sure to improve influenza vaccination rates across specific facilities, IDSA supports going one step further and requiring policies for mandatory influenza vaccination of all health care personnel (HCP) unless valid medical contraindications exist. While IDSA certainly supports patients having improved access to influenza vaccines, a component of protection against influenza includes the immunization of personnel who are treating these patients.

The availability and uptake of influenza vaccination is especially important in the adult population, since there is no comprehensive mechanism for tracking adult vaccinations. IDSA strongly supports the utilization of patient and physician reminder systems as part of Electronic Medical Records and Immunization Information Systems (immunization registries). In IDSA's 2007 Policy Principles document, *Actions to Strengthen Adult and Adolescent Immunization Coverage in the United States*, we point out that not only are vaccine-preventable illnesses a financial burden-- \$10 billion per year in 2007-- they often result in avoidable deaths¹. Each year, influenza alone causes approximately 250,000 hospitalizations and 36,000 deaths². Of those deaths, 85 percent are in the over 65 population, an example of the importance of offering influenza vaccination to patients, but also ensuring that all HCP are appropriately vaccinated³.

Also of concern is pertussis, where in 2010 there were 9,477 cases reported in California alone, the highest number in 52 years⁴. IDSA urges CMS to consider adding pertussis vaccination to the proposed rule since vaccination protects adults and adolescents as well as those who are too young or too sick to be vaccinated. While some facilities have added pertussis vaccination to postpartum standing orders, the practice is not as comprehensive as it would be under a CMS final rule.

As recently as 2009, influenza vaccination rates for adults over 65 have ranged from over 55 percent to just over 70 percent, with the lowest rates belonging to African Americans, those identifying as multi-cultural, and Asian/Pacific Islanders⁵. These statistics alone demonstrate the need for CMS to carefully evaluate and correct disparities in influenza vaccination rates.

¹ Infectious Diseases Society of America. Actions to strengthen adult and adolescent immunization coverage in the United States: policy principles of the Infectious Diseases Society of America. *Clin Infect Dis*. 2007;44:e104-e108.

² Tilburt J, Mueller P, Ottenberg A, Poland G, Koenig B. Facing the challenges of influenza in healthcare settings: The ethical rationale for mandatory seasonal influenza vaccination and its implications for future pandemics. *Vaccine*. 2008;26(suppl 4):D27-30.

³ Centers for Disease Control and Prevention, Administration on Aging, Agency for Healthcare Research and Quality, and Centers for Medicare and Medicaid Services. Enhancing Use of Clinical Preventive Services Among Older Adults. Washington, DC: AARP, 2011.

⁴ CDC. Pertussis (Whooping Cough) – Recent Outbreak Activity. 2011. Available at: <http://www.cdc.gov/pertussis/outbreaks.html>.

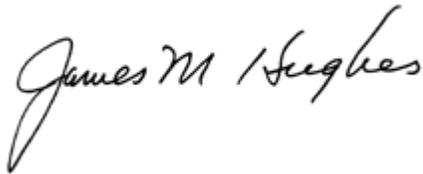
⁵ Centers for Disease Control and Prevention, Administration on Aging, Agency for Healthcare Research and Quality, and Centers for Medicare and Medicaid Services. Enhancing Use of Clinical Preventive Services Among Older Adults. Washington, DC: AARP, 2011.

In addition, while IDSA is aware of the potential burden additional record-keeping may place on the provider, we think it is important that CMS require facilities to track patients' reasons for refusal when they or their representative/surrogate refuse the influenza vaccine. If CMS chooses to add pertussis to the proposed rule, this documentation should also be collected for pertussis. These data will ultimately assist the federal government, health care providers, medical societies, etc., in constructing messages that better address barriers to vaccination.

IDSA's primary goal has been and continues to be the effective delivery of patient care, while protecting both patients and HCP from acquiring infections, like influenza, in health care settings. The best preventive measure against influenza is the use of a safe and effective influenza vaccine. IDSA strongly believes that CMS is taking an important step with this proposed rule, but we once again urge you to consider a rule that requires all HCP without a valid medical contraindication to receive an annual influenza vaccination as the best way to protect the health of both patients and HCP.

IDSA greatly appreciates the opportunity to comment and applauds this important step forward. Should you have any questions, please do not hesitate to contact Leslie McGorman, IDSA's Program Officer for Public Health at lmcgorman@idsociety.org or 703.299.0015.

Sincerely,

A handwritten signature in black ink that reads "James M. Hughes". The signature is written in a cursive, flowing style.

James M. Hughes, MD, FIDSA
President