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## CMS Proposes Rule Advancing Universal Access to Influenza Immunization

By: [John S. Linehan](#)

CMS recently issued a [proposed rule \[PDF\]](#) requiring certain Medicare and Medicaid certified entities to offer all patients annual influenza vaccinations and to develop policies and procedures addressing the threat of pandemic influenza. Through these measures, CMS seeks to boost the overall seasonal vaccination rate from approximately 40 percent to 60 percent and to enhance medical preparedness in the event of a pandemic outbreak. Comments must be received **no later than July 5, 2011**. CMS plans to issue final rules in the early Fall of 2011, which would go into effect in time for the 2011-2012 influenza season.

As proposed, the rule updates the conditions of participation and coverage for the following Medicare and Medicaid providers and suppliers:

- Hospitals (all types that participate in Medicare)
- Critical Access Hospitals (CAHs)
- Rural Health Clinics (RHCs)
- Federally Qualified Health Centers (FQHCs) and
- End-Stage Renal Disease (ESRD) Facilities

These provider types are targeted for coverage under the rule because they have the licensed staff and capacity necessary to control and administer influenza vaccine.

The proposed vaccination standard requires covered providers to develop policies and procedures concerning the administration of annual and pandemic influenza vaccinations. Such measures must ensure that influenza vaccination is offered to

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all patients, except when medically contraindicated or when the patient (or the patient's representative or surrogate) declines vaccination. Additionally, each patient or representative must be informed of the benefits and risks of vaccination, and patient medical records must document information pertaining to the offered vaccine administration. Seasonal influenza procedures will need to be implemented on an annual basis, during the period spanning September 1 through February; pandemic procedures shall be designed for activation in the event that a pandemic is announced by the Secretary.

By conscripting front-line providers to promote vaccinations during routine physician-patient interactions, the proposed rule signifies CMS's adoption of a direct and comprehensive approach to combating influenza. The rule is largely based upon a narrower regulation, passed in 2005, that requires participating nursing homes to offer annual influenza vaccinations to their residents. See 42 C.F.R. § 483.25(n). The success of this earlier measure — which is credited with expanding the vaccination rate in the long term care population to approximately 91 percent — has reinforced CMS's view that vaccination is best promoted through person-to-person counseling rather than merely through generalized public awareness campaigns or increased insurance coverage.

### **Ober|Kaler's Comments**

As drafted, the proposed rule affords providers significant flexibility in designing influenza policies and procedures. Beyond meeting the requirements noted above, such measures need only reflect "the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated)." However, in the rule's preamble, CMS placed special emphasis upon the following issues: (1) recurrent shortages in vaccine supply; (2) large and persistent health disparities among different racial and ethnic groups; and (3) the importance of minimizing delays when responding to pandemic influenza events. Covered providers should accordingly heed these concerns when drafting new influenza policies and procedures.