



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-03 (rev)

DATE: November 17, 2005
TO: State Survey Agency Directors
FROM: Director
SUBJECT: Nursing Home Immunization Requirement

Letter Summary

A final rule published by the Centers for Medicare & Medicaid Services (CMS) on October 7, 2005 (70 FR 58834) requires Medicare & Medicaid participating nursing homes to provide residents with the opportunity to be immunized against influenza and pneumonia.

An advance copy of the new surveyor guidance for immunization requirements will be published in late spring of 2006.

Background/Facts:

Research has shown that vaccination programs in nursing homes have resulted in positive outcomes for residents. Nursing homes that have high rates of vaccinated residents have demonstrated not only fewer outbreaks of influenza than homes with lower vaccination rates but a significant decrease in the rate of hospitalization, pneumonia, and related mortalities as well. As part of CMS' continued commitment to enhance assessment of health status and delivery of preventive services to our beneficiaries, we collaborated with the Centers for Disease Control and Prevention to improve influenza and pneumococcal immunization coverage.

Discussion:

A final rule published by CMS on October 7, 2005 (70 FR 58834) requires Medicare & Medicaid participating nursing homes to provide residents with the opportunity to be immunized against influenza and pneumonia. The new regulation, which will be codified as 42 CFR 483.25(n) "Quality of Care," complements the existing federal requirement at 42 CFR §483.65(a), "Infection Control," that requires facilities to have an infection control program that is effective for investigating, controlling, and preventing infections.

The new regulation requires facilities to develop and implement specific policies and procedures for the provision of influenza and pneumococcal immunizations. In addition, the facility must ensure that:

- Residents or their legal representatives receive education regarding the benefits and potential side effects of the immunizations before they are offered the immunizations;
- As appropriate, residents will be offered the opportunity to receive the immunizations annually (1 Oct-30 Mar) for influenza;
- As appropriate, residents will be offered the opportunity to receive a one time dose of vaccine for pneumococcal pneumonia after the age of 65;
- Residents or their legal representatives have the right to refuse the immunizations; and
- The facility must provide documentation of the provision of education and the receipt, contraindication, and/or refusal for the immunizations in the resident's medical record.

CMS is developing survey guidance including interpretive guidelines and severity guidance for this new regulation. An advance copy of the guidance is expected to be released in the late spring of 2006 in a survey and certification memorandum that will also include an educational tool to be used for the implementation of the new rule. Additionally, in June 2006, CMS' Office of Clinical Standards and Quality will release a new immunization quality measure that will be incorporated into the survey guidance for this requirement.

In the interval prior to the release of the new guidance, surveyors should continue to survey for immunization according to the current survey process. Interpretive guidance for infection control concerns may be found at tag F-441 (42 CFR §483.65(a)). If the nursing home demonstrates it could not immunize residents due to a shortage or delay in vaccine availability, a deficiency is not to be cited. Surveyors should provide information regarding the new regulation to providers, including the need to develop the appropriate policies and procedures.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

Training: This clarification should be shared with all RO survey and certification staff, State agency surveyors, managers, and the RO training coordinator.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)