On August 15, 2005 the Centers for Medicare and Medicaid Services (CMS) published a proposed new regulation in the Federal Register which, if adopted, will increase immunization rates in Medicare and Medicaid participating long term care (LTC) facilities by requiring LTC facilities to offer each resident immunization against influenza annually, as well as lifetime immunization against pneumococcal disease.

The **proposed new regulation is not mandatory at this time.**

In general, and US Federal agency intending to adopt a new regulation must first publish the new regulation in the Federal Register and invite and consider public comments before adopting the regulation in final mandatory form.

The public comment period for this proposed regulation was set to expire August 30, 2005.

We will continue to monitor the Federal Register for new developments in this area after the public comment period has expired.

CMS’s announcement contains a lengthy discussion of the clinical rationale developed by CMS and by the CDC for requiring these immunizations in the long-term care population as well as the cost-benefit analysis.

PART 483--REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES
Sec. 483.25 Quality of care.

*(n) Influenza and pneumococcal immunizations--

(i) Influenza. The facility must ensure that--

(ii) The resident or the resident’s legal representative must be provided the opportunity to refuse immunization. If the resident or the resident’s legal representative refuses immunization, the facility must ensure the resident or the resident’s legal representative receives appropriate education and consultation regarding the benefits of influenza immunization.

(iii) The resident’s immunization status is documented in the resident’s medical record, including but not limited to; that the resident received influenza immunization, or immunization was medically contraindicated, or immunization was refused. If the immunization was refused, documentation must include that the resident or the resident’s legal representative received appropriate education and consultation regarding the benefits of influenza immunization.

(iv) Exception. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal shot may be given after 5 years following the first pneumococcal immunization if the vaccine was administered before age 65, unless medically contraindicated or the resident or the resident’s legal representative refuses the second shot.

(2) Pneumococcal disease. The facility must ensure that--

(i) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized; and

(ii) The resident or the resident’s legal representative must be provided the opportunity to refuse immunization. If the resident or the resident’s legal representative refuses immunization, the facility must ensure the resident or the resident’s legal representative receives appropriate education and consultation regarding the benefits of pneumococcal immunization.

(iii) The resident’s immunization status is documented in the resident’s medical record, including but not limited to; that the resident received pneumococcal immunization, or immunization was medically contraindicated, or immunization was refused. If the immunization was refused, documentation must include that the resident or the resident’s legal representative received appropriate education and consultation regarding the benefits of pneumococcal immunization.

(iv) Exception. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal shot may be given after 5 years following the first pneumococcal immunization if the vaccine was administered before age 65, unless medically contraindicated or the resident or the resident’s legal representative refuses the second shot.

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