

PUBLICATION

CMS Survey Guidance and Amendment to SOM Advance Copy of Revised F371; Interpretive Guidance and Procedures for Sanitary Conditions, Preparation of Eggs in Nursing Homes [Ober|Kaler]

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On May 20 the Centers for Medicare & Medicaid Services (CMS) issued S&C 14-34-NH devoted to the topic of egg preparation in skilled nursing facilities (SNFs). Lest one think that this is an odd or random topic, it is relevant to consider an earlier case in which an SNF was cited for "immediate jeopardy" (IJ) based on egg preparation.

Previously, Elgin Nursing and Rehabilitation Center found itself faced with a citation for immediate jeopardy, a \$5,000 civil money penalty, and the loss of any ability to offer a nurse aide training program for two years. The IJ citation and penalties were the result of the SNF honoring the request of five residents that they receive their eggs "over easy," "soft-cooked," or "soft fried." The citation was for failure to comply with the requirement under 42 C.F.R. § 483.35(i), requiring food to be served in a sanitary manner. The surveyors relied on State Operations Manual (SOM) guidance. It states:

Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking; - 145 degrees F for 15 seconds; until the white is completely set and the yolk is congealed.

The U.S. Court of Appeals for the Fifth Circuit in Case No. 12-60086 (May 17, 2013) rejected administrative appeal rulings in favor of CMS, holding that the underlying regulation was ambiguous and that this ambiguity was not resolved by the SOM (and other regional office guidance that are not regulations). The federal court held that the deference to which courts accord agency interpretations of their own regulations does not extend to agency interpretations of non-regulatory guidance, such as the SOM. The federal court went on to interpret the prior SOM provision according to its plain meaning, which resulted in a successful challenge to the deficiency and penalty.

On May 20 CMS developed guidance to resolve any ambiguity in its plain meaning in interpreting that applicable regulation. CMS states:

CMS recognizes the U.S. Food and Drug Administration's (FDA) Food Code and the Centers for Disease Control and Prevention's (CDC) food safety guidance as national standards to procure, store, prepare, distribute and serve food in a safe and sanitary manner.

CMS expressly rejects the use of release agreements with residents who wish to make a choice to have their eggs prepared in a manner inconsistent with FDA and CDC guidance, stating:

CMS is aware of facilities having secured signed health release agreements from residents (or the resident's representative) requesting to be served undercooked eggs. Health release agreements allowing soft-cooked, undercooked or sunny-side up unpasteurized eggs for resident preference are not acceptable.

Eggs that are *pasteurized* may be prepared in a soft-cooked, undercooked, or sunny-side up manner.

CMS also is clarifying SOM guidance that resulted in an IJ citation. According to CMS:

The surveyor interpretive guidance in Appendix PP at F371 will be revised in two ways to provide additional clarification: (1) unpasteurized eggs must be cooked until both the yolk and white are completely firm; and (2) deletion of the example of a negative outcome that could rise to the level of immediate jeopardy.

If the facility serves soft-cooked, undercooked, or sunny-side up unpasteurized eggs, surveyors are advised to determine the appropriate scope and severity "based upon the negative actual and potential outcomes and in accordance with instructions and guidance given at F371." This includes consideration of:

immediate risk of serious injury, harm, impairment or death, the number of residents affected, the surveyor's observations of egg availability, food preparation and meals and other system failures of the facility that could lead to food borne illness (i.e. whether undercooked, unpasteurized eggs are served widely to many residents, and the result of interviewing facility staff to identify additional system failures).

The Fifth Circuit ruling remains important and relevant in identifying when ambiguous SOM and other non-regulatory guidance may be challenged without deference to agency interpretations. This S&C guidance is important as an illustration of how the agency will develop clearer interpretive guidance in a way that sustains deference to its interpretation of the underlying regulation itself. It is also relevant as an example of when CMS will not permit release agreements to "trump" what it states to be clear health and safety standards.

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