

To: American Orthotic & Prosthetic Association

From: Tom Mills, Gordon Coffee, and Erica Stauffer

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Re: *Elgin Nursing and Rehabilitation Center v. U.S. Department of Health and Human Services*

In a May 2013 decision, *Elgin Nursing and Rehabilitation Center v. U.S. Department of Health and Human Services*, the U.S. Court of Appeals for the Fifth Circuit struck down a U.S. Department of Health and Human Services (“DHHS”) interpretation of a manual interpreting Medicare regulations. While the case bears some similarities to AOPA’s pending lawsuit against CMS, which challenges the documentation requirements set forth in a “Dear Physician” letter posted on CMS contractor websites, *Elgin* is not binding precedent for purposes of the AOPA case and the issues before the *Elgin* court differed significantly from those AOPA has raised in its case.

In connection with the regulation at issue in *Elgin*, which interpreted the governing law to require that long-term care facilities store, prepare, distribute, and serve food under “sanitary conditions,” CMS had issued an interpretive manual providing that unpasteurized eggs must be cooked to “145 degrees F for 15 seconds; until the white is completely set and the yolk is congealed.” After a state-level investigation determined that Elgin failed to comply with these provisions and placed residents in “immediate jeopardy” by serving them soft-cooked eggs, CMS adopted the state’s findings and imposed penalties that included a fine and termination of Elgin’s provider agreement. An ALJ affirmed the determination, which DHHS upheld. During the enforcement action, the agency interpreted its manual to mean that Elgin needed to meet *both* the temperature and congealment requirements to comply with the food sanitation regulation.

In declining to accept DHHS’ interpretation of the manual, the court reasoned that, while DHHS’ regulations and direct interpretations of regulations are entitled to some level of deference, “deferring to [DHHS’] interpretation of its manual interpreting its interpretive regulation” would be a step too far. The court explained that such “extraordinary deference” would give agencies the unchecked ability to issue vague regulations and interpretations that they could “later interpret as they see fit.” Not only would such deference protect agency action from review by the courts altogether, but it would permit agencies to punish regulated entities without providing fair notice of the relevant regulatory requirements in advance—a particularly important concern in an enforcement proceeding like the one underlying *Elgin*.

While the DHHS interpretation of its manual appears somewhat analogous to the “Dear Physician” letter, the *Elgin* decision is of limited use for purposes of AOPA’s case—and more generally for disputes on the issues of audits, physician documentation, exclusion of the prosthetist’s notes, and K-level criteria—for a number of reasons. First, it comes from a different court with no authority over this jurisdiction. Second, in addition to its non-binding

status and enforcement context, *Elgin* dealt with interpretation of an ambiguous regulation and manual provision. In the AOPA lawsuit, however, the government has not argued that it the “Dear Physician” letter was interpreting a statute or regulation. To the contrary, it said that the “Dear Physician” letter merely reaffirmed earlier standards. It similarly argued that later Local Coverage Determinations clarified that Medicare requires physician corroboration of prosthetist notes. CMS has not applied any of the concepts from *Elgin* to its actions related to prosthetics, nor to the pending issues of whether the court’s jurisdiction allows it to rule on the matters brought in the AOPA case. In short, the Fifth Circuit did not consider the question at issue in AOPA’s case—whether there was a change in relevant documentation standards and whether such a change requires notice and comment before implementation.

Finally, a provider wishing to rely on *Elgin* would have to undertake the expense of filing a federal lawsuit. Before a court would determine the applicability of *Elgin*, or the merits of any other issues raised by the provider, the provider would need to convince the court that it has jurisdiction in the first place, which often poses a significant hurdle in cases against CMS.