PUBLICATION

Court Upholds Procedural Validity of HHS's Outlier Reconciliation Instructions

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On December 26, 2017, the United States Court of Appeals for the District of Columbia Circuit upheld the procedural validity of 2010 manual instructions setting out the criteria by which Medicare outlier payments might be subject to reconciliation. *Clarian Health West, LLC v. Hargan, Case No. 16-5307* Rejecting a contrary decision from the District Court in 2016, the Court of Appeals ruled that neither the Medicare Act nor the Administrative Procedure Act (APA) required HHS to go through notice-and-comment rulemaking before promulgating criteria for selecting those hospitals that might be subject to reconciliation.

Under Medicare Part A, hospitals may qualify for supplemental or "outlier" payments for extraordinarily costly cases when the charges associated with those cases, adjusted to cost, exceed certain thresholds set by the Secretary. Under the regulation at 42 C.F.R. § 412.84, MACs calculate a cost-to-charge ratio for each hospital, multiply the total amount billed for each case by this ratio, and then compare this amount to a fixed-loss threshold to determine if an outlier payment is warranted. In the late 1990s and early 2000s, however, the cost-to-charge ratio employed in this formula was subject to manipulation, with some hospitals engaging in a practice called "turbocharging." Therefore, in 2003, after going through notice-and-comment rulemaking, the Secretary promulgated a regulation providing for a recalculation (or, in CMS's parlance, a "reconciliation") of the outlier payments in certain situations in which data from the hospital's finalized cost report did not support the cost-to-charge ratio initially employed. 42 C.F.R. § 412.84(i)(4).

The 2003 regulation, however, did not specify how hospitals would be selected for this reconciliation process, and it was not until 2010 that HHS issued instructions addressing this point. Medicare Claims Processing Manual (Manual), Ch. 3, § 20.1.2.5(A) (Dec. 3, 2010). Plaintiff hospital challenged the 2010 Manual instructions, maintaining that they were invalid under the APA and the Medicare Act by failing to go through notice-and-comment rulemaking. The District Court agreed with this argument, but the Court of Appeals has now reversed that earlier decision.

The Court of Appeals ruled that the 2010 Manual instructions do not establish or change a substantive legal standard governing payment and thus are not subject to the Medicare Act's notice-and-comment requirements. The Court agreed with HHS that, while reconciliation of outlier payments alters providers' legal rights, this change results from the Medicare Act and its implementing regulations, and not from the 2010 instructions. Moreover, the instructions bind neither HHS nor the PRRB in adjudications. Indeed, as stated in the 2010 instructions, reconciliation may be initiated in any situation in which CMS deems reconciliation to be appropriate even if the criteria of the Manual instructions are not met. Thus, the instructions, by themselves, did not alter or establish a substantive legal standard governing payment that the Medicare Act might require be promulgated by regulation.

The Court of Appeals further held that, under the APA, the Manual instructions are not legislative rules but instead are general statements of policy. Acknowledging that the line between the two principles is difficult to distinguish, the court nevertheless ruled that the 2010 Manual instructions have no binding legal effect and, as such, are a statement of policy. The court noted that HHS has characterized the instructions as simple guidance that merely explains how the agency will enforce its statute and regulations. The court observed that

the APA leaves it up to agencies on how to establish policies and that agencies may forego notice-and-comment procedures and announce through a policy statement their intentions for future adjudications.

The provider has 90 days in which to seek Supreme Court review.