

D.C. CIRCUIT: CMS MANUALS ARE POLICY STATEMENTS, NOT BINDING AUTHORITY

Recently, the D.C. Court of Appeals held that CMS Manual instructions are general statements of policy, which have no binding effect. Although this case involved a procedural claim, the court's decision reminds providers that solely relying on CMS Manual instructions as guidance for Medicare coverage criteria could result in potential Medicare payment compliance issues.

BACKGROUND

In 2003, the Department of Health and Human Services ("HHS") promulgated a rule after notice and comment rulemaking, regarding the methodology of how hospital outlier payments were calculated. The 2003 rule also provided for reconciliation of outlier payments authorizing the Medicare Administrative Contractors ("MACs") to revisit outlier payments for a specific year. In 2010, HHS adopted a policy for the MACs to use when administering the reconciliation process that was published in the CMS Medicare Claims Processing Manual (the "Manual"). HHS did not engage in the notice and comment rulemaking process before issuing the instructions in the Manual.

A medical center in Indiana ("Medical Center") challenged the 2010 Manual instructions regarding reconciliation after being directed to repay \$2.4 million in outlier payments. The Medical Center argued that the 2010 instructions were procedurally invalid because they were not subject to notice and comment in contradiction of the Administrative Procedure Act ("APA") and Medicare Act.

The District Court concluded that under the Medicare Act, HHS was required to promulgate the 2010 instructions through notice and comment rulemaking and granted the Medical Center's motion for summary judgment. The government then filed an appeal with the D.C. Circuit.

D.C. COURT DECISION

On appeal, the government argued that the instructions do not alter a substantive legal standard for determining whether an outlier payment is warranted or the amount of an outlier payment. The Manual instructions do not compel the agency to order reconciliation in any particular case and, thus, are not binding on the agency. In turn, the Medical Center argued that the 2003 rule merely set forth the data that should be used in a reconciliation and failed to determine which outlier payments would be subject to a retroactive adjustment. In its view, only the 2010 instructions provide that determination and, therefore, establish a substantive legal standard.

The court held that the Manual instructions merely set forth enforcement policy and do not change the legal standards that govern hospitals nor do they change the legal standards that govern CMS. Rather, the Medicare Act and implementing regulations together establish the standard that governs hospitals' eligibility for outlier payments.

Further, the court rejected the Medical Center's arguments that the Manual instructions were procedurally invalid in contradiction with the APA and Medicare Act. The court re-emphasized that the instructions are general statements of policy that have no binding legal effect. Therefore, the instructions are exempt from the notice and comment rulemaking requirement.

Despite this procedural ruling, the court noted that a provider may still challenge Manual instructions on substantive grounds when such instructions are allegedly applied against the provider in a manner that is arbitrary or capricious and/or otherwise inconsistent with the implementing regulation(s).

PRACTICAL TAKEAWAYS

This decision is a reminder that Manual instructions may serve as a guide in determining Medicare coverage criteria and payment policy but have no binding effect on CMS. Accordingly, CMS is free to make coverage decisions in accordance with applicable rules and regulations regardless of whether the criteria in the Manual instructions are met. Additionally, this has significant import for False Claims Act cases, as it provides further support that a failure to comply with guidance documents should not be the basis for a FCA allegation. Providers are, therefore, encouraged to familiarize themselves not only with the Manual instructions but also with the implementing regulations that establish the standards for coverage under the Medicare program as such authority is binding on providers.

If you have questions or would like additional information about this topic, please contact:

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