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Court Finds ACLA Claims Precluded, CMS PAMA Rules Stand

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The American Clinical Laboratory Association ("ACLA") challenged the final rules promulgated by the Department for Health and Human Services ("HHS") pertaining to how the Medicare Clinical Laboratory Fee Schedule ("CLFS") payment rates are established for laboratory services (*Am. Clinical Lab. Ass'n v. Azar*, No. 17-2645 ABJ, 2018 U.S. Dist. LEXIS 161639, 2018 WL 4539681 (D.D.C. Sept. 21, 2018)). The U.S. District Court of the District of Columbia granted HHS' motion for summary judgment to dismiss the complaint after concluding that the court lacked subject matter jurisdiction to hear the case. This is a significant setback for the laboratory industry that has been fighting against the reductions in Medicare reimbursement under the new payment methodology, but it is not the end of the road.

In accordance with Section 216 of Protecting Access to Medicare Act of 2014 ("PAMA"), beginning January 1, 2018 the Medicare CLFS payment rate was established using a volume-weighted median of private payor rates for laboratory services as reported by applicable laboratories. What laboratories met the definition of an "applicable laboratory" and whether HHS had the authority to redefine the term was at the center of the challenge by the ACLA.

In December 2017, ACLA filed a lawsuit arguing that in the final rule HHS redefined the term "applicable laboratory" from the plain text of the statute and in doing so excluded almost 90% of hospital laboratories which reduced private-payment data reported and in turn resulted in lower CLFS payment rates. HHS argued that the terms "laboratory" and "revenue" relevant to determining an "applicable laboratory" were ambiguous and regardless PAMA includes a statutory bar to judicial review.

While ACLA presented multiple claims and arguments, the court focused on the threshold question: whether PAMA bars judicial review of HHS' authority in "establishment of payment amounts under this section [of PAMA]." The court concluded that the statute did not permit judicial review; relying heavily on *Florida Health,* a D.C. Circuit case (*Fla. Health Scis., Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515 (D.C. Cir. 2016)). In *Florida Health,* the D.C. Circuit found that the statute gave HHS the power to make the choice as to what data should be used to calculate payment for hospitals' uncompensated patient care. The reasoning in *Florida Health* is sound as it relates to the statutory authority granted under at issue in that case. *Florida Health,* however, seems to be easily distinguishable from the case brought by ACLA because, as the court itself recognized, "*Florida Health* did not involve a rule about how the Secretary would obtain the data needed ... like this case does." That is, Congress already defined under PAMA what data to be reported and who should report that data. In doing so, we believe the court conflated the breadth of the judicial review bar under PAMA and failed to differentiate between challenging the validity of HSS' decisions made in the rulemaking process and contesting how and what data must be received and processed as per statutory procedure.

Here, ACLA argued that HHS overstepped its authority by redefining a clear statutory term; however, this was essentially ignored by the court by using the statutory judicial bar as a red-herring and conveniently limiting its analysis. Even though the court acknowledged that ACLA's arguments "raise important questions," the court refused to answer those very questions upon its determination that it could not hear the case. The court's failure to address these issues likely gives ACLA grounds for appeal.

ACLA's statement, released in response to the decision, reports that the association is exploring further legal options. The statement expresses concern that the decision "sets a harmful precedent that allows agencies to circumvent Congress' express directions at the expense of patient care." The association also urged Congress to take immediate action to resolve the issues raised in the lawsuit; specifically, the impact the reduction in Medicare CLFS payment rates will have on the laboratory industry. In the meantime, ACLA must seriously and carefully consider filing an appeal to request their central arguments be addressed and prepare to show the D.C. Circuit how this case can easily be distinguished from *Florida Health* and the underlying notion of judicial deference for an agency's implementation of a complex statute.

Of course, even if successful, the ACLA must still address the other jurisdictional issues raised by HHS, such as whether ACLA had standing to bring suit on behalf of its members and if injury to labs or impact on Medicare rates had been proven.

Sydney Reed, a Law Clerk (not admitted to the practice of law) in the firm's Houston office, contributed significantly to the preparation of this post.

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