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Azar v. Allina Health Services: Making Waves in Medicare Claim Appeals?

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When ruling that notice-and-comment procedures may be required for Medicare guidance, the Supreme Court may not have foreseen the potential disruptive impact on Medicare coverage rules.

A recent order by a federal district court in California suggests that we have not yet seen the extent to which the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804, 204 L. Ed. 2d 139 (2019) may permeate into the intricate web of CMS Medicare coverage policies or other CMS determinations. See Tom Coons' *Payment Matters* article addressing the *Allina* decision. In *Allina*, the Court determined that the Secretary of Health and Human Services ("Secretary") must first afford the public notice and a chance to comment when the Secretary "wishes to establish or change a 'substantive legal standard.'" *Allina*, 139 S. Ct. at 1808 (quoting 42 U.S.C. § 1395hh(a)(2)). The Court concluded that because a 2004 policy that "dramatically – and retroactively – reduced payments to hospitals serving low-income patients" was not provided to the public in advance for notice and comment and the government did not identify "a lawful excuse for neglecting its statutory notice-and-comment obligations," that the policy must be vacated. *Id*.

The Central District of California in *Agendia, Inc. v. Azar*, No. 8:19-cv-00074 (C.D. Cal. Oct. 29, 2019) recently relied on *Allina* to conclude that a Medicare Administrative Contractor's ("MAC's") local coverage determination ("LCD") and corresponding policy article were "unlawfully promulgated without notice and comment" consistent with the policies that cannot "evade notice-and-comment obligations under § 1395hh(a)(2)." *Agendia* at 17 (citing *Allina*, 139 S. Ct. at 1817).

The plaintiff in *Agendia* was a certified Medicare laboratory supplier that furnished molecular diagnostic tests for the treatment of breast cancer patients between June 2012 and January 2013. *Id*. at 4. Based on the MAC's decision that the tests did not comply with its policy concerning molecular diagnostic tests and the criteria set forth in its LCD L32288, claims were denied by the contractor and the denials were upheld through the redetermination and reconsideration levels of appeal. *Id*. At the third level of appeal, an Administrative Law Judge ("ALJ") found that the testing was medically reasonable and necessary, but the Medicare Appeals Council subsequently reversed that decision on the basis the tests did not meet coverage criteria set out in the LCD. The laboratory appealed the Department of Health & Human Services' ("HHS'") final decision in federal district court. *Id*.

In its complaint, the laboratory argued that the coverage criteria set forth in the LCD failed to meet due process requirements, in violation of the Administrative Procedure Act ("APA") and Medicare Act. *Id*. at 7. HHS, on the other hand, argued that an LCD does not establish or change a substantive legal standard and instead "simply determines coverage 'in accordance with' the reasonable and necessary standard." *Id*. at 12 (quoting 42 U.S.C. § 1395ff(f)(1)(B)). The government also asserted that because there is a special process for establishing LCDs separate from § 1395hh, that neither the APA nor § 1395hh apply to LCDs. *Id*.

The court found merit in the laboratory's assertions, agreeing that the Medicare Act does not allow the government to establish or change a substantive legal standard unless it is through regulation. *Id*. (citing 42 U.S.C.§ 1395hh). The court compared the decision by Congress to create a separate notice and comment process for National Coverage Determinations ("NCDs") with its choice not to do so for LCDs. *Id*. at 15-16. In analyzing whether the LCD should be considered a rule that establishes or changes a substantive legal

standard, the court noted that an LCD is initially binding on contractors and is later entitled to substantial deference in the administrative appeals process. *Id*. at 16-17 (citing 42 U.S.C. § 1395hh). Thus, the court concluded that the LCD "establishes a standard that defines [the laboratory's] right to payment" and this standard is "substantive during the entire process, whether it is binding or entitled to substantial deference." *Id*. at 17. The court therefore found that since policies in an LCD are interpretations of the Social Security Act, this is the "kind of 'gap-filling policy' that cannot 'evade notice and comment obligations under [the Medicare Act].'" *Id*. (quoting *Allina* at 139 S. Ct. at 1817). The court remanded the case to the Medicare Appeals Council for further hearing in accordance with its decision. *Id*.

Baker Donelson Comments

Agendia represents a striking interpretation of the notice and comment standard set forth in *Allina*. While a *recent internal HHS memorandum* suggests that HHS may not agree that an LCD must be promulgated through notice and comment, top officials at HHS nevertheless appear to believe (according to this memorandum) that certain enforcement actions based on LCDs will not be supportable post-*Allina*. *See* "HHS Memorandum Clarifies CMS Obligations Following Supreme Court *Allina* Decision." Regardless of whether HHS will appeal the *Agendia* decision, the fact that a district court took this action is not insignificant since LCDs and policy articles are used to impose specific and detailed Medicare coverage and reimbursement requirements for numerous services and items.

There are approximately 2,200 LCDs currently in effect as of this article's publication date; archived LCDs and policies may still be applicable in older cases. Thus, the combined effects of the Medicare claim appeals backlog and decisions like *Agendia* remain unknown. Yet the sheer volume of these types of policies demonstrates immediate far-reaching implications if these are indeed "unlawfully promulgated." Providers should review adverse determinations to determine whether they are based on the clear language of a statute or regulation or whether they are based on policies that include additional requirements. The post-*Allina* space may indeed change the landscape for Medicare claim appeals as well as other related regulatory schemes.