

PUBLICATION

HHS Memorandum Clarifies CMS Obligations Following Supreme Court *Allina* Decision

Authors: Kathleen Rose Salsbury

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In response to the disruptive Supreme Court decision on the impact and effect of administrative guidance, HHS has issued a memorandum suggesting that CMS's ability to enforce some of its payment policies may be limited by the ruling.

A recently issued [internal memorandum](#) from the HHS Office of the General Counsel provides insight into the agency's interpretation of the Supreme Court's ruling in [Azar v. Allina Health Servs.](#), 139 S. Ct. 1804 (2019). The HHS Memorandum cautions CMS to ensure that guidance documents are issued in compliance with the notice-and-comment rulemaking obligations reflected in *Allina*.

The Court held in *Allina* that notice-and-comment rulemaking requirements applicable to Medicare under the Social Security Act apply more broadly than those found in the Administrative Procedure Act. The Court rejected the government's argument that notice-and-comment requirements only apply to substantive rules and instead held that interpretive rules and policy statements can also be subject to notice-and-comment requirements under the Medicare Act if they change a "substantive legal standard." While the Court stopped short of applying its ruling beyond the facts of the case at issue, the ruling suggests that any guidance issued without a notice-and-comment process that changes how payments are determined may not pass legal muster.

The HHS Memorandum takes the position that whether sub-regulatory guidance changes a substantive legal standard turns on how closely the guidance aligns with statutory or regulatory requirements. If an enforcement action could not be brought without the guidance document, the guidance document would need to be issued through notice-and-comment rulemaking. The Memorandum instructs CMS to avoid basing enforcement actions solely on sub-regulatory guidance documents even if they are consistent with *Allina*.

The Memorandum states that *Allina* does not govern the process for issuing Local Coverage Determinations (LCDs), noting that they are not binding on administrative law judges or HHS and therefore should not be viewed as creating a substantive legal standard. However, not all courts agree. See "[Azar v. Allina Health Services: Making Waves in Medicare Claim Appeals?](#)" in this publication of *Payment Matters*. The HHS Memorandum also asserts that the Physician Self-Referral Law advisory opinion process and the issuance of fraud and abuse waivers should not be altered by the ruling because they are authorized by statute.

It remains to be seen whether the government's interpretation of *Allina* will lead to any decrease in CMS's enforcement actions. Regardless, a surge in notice-and-comment rulemaking in 2020 seems likely.