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The Impact of Allina — Potential  
Limitation on CMS's Ability to  
Recoup Overpayments

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## THE *ALLINA* MEMO

- October 31, 2019 memorandum in which CMS's legal counsel outlined the implications Supreme Court decision in *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019).
- From the Office of the General Counsel to the Deputy Administrator & Director of the Center for Medicare.

## HOLDING IN *ALLINA*

- The Allina Memo succinctly summarizes the Supreme Court's holding:
  - “[A]ny Medicare issuance that establishes or changes a ‘substantive legal standard’ governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, must go through notice-and-comment rulemaking.”

## CONSEQUENCES OF CMS'S NON-COMPLIANCE

- “Where the Department of Health and Human Services (“HHS” or “the Department”) . . . or [CMS] issued guidance that, under *Allina*, should have been promulgated through notice-and-comment rulemaking, the Department’s ability to bring enforcement actions predicated on violations of those payment policies is restricted.”

## APPLICATION OF *ALLINA*

- Guidance that is “closely tied to statutory or regulatory requirements” generally do not create or establish a substantive legal standard.
  - Because these types of guidance do not require notice-and-comment rulemaking, enforcement actions implicating these guidance material may still be brought.
  - “The sub-regulatory guidance in these circumstances . . . is ‘aid[ing] in demonstrating that the standards in the relevant statutory and regulatory requirements have been or have not been satisfied.’”

## APPLICATION OF *ALLINA*

- Guidance that is not closely tied to statutory or regulatory standards, issued without the requisite notice-and-comment period, cannot be relied upon in enforcement actions.
- “The critical questions is whether the enforcement action could be brought absent the guidance document. If the answer is no, then the guidance document establishes a norm and, under *Allina*, is invalid unless issued through notice-and-comment rulemaking.”

## EXAMPLE OF APPLICATION

- *Amjad Butt, M.D. and Cardiovascular Institute of Selma, LLC, DAB CR5491 (2019).*
  - Statutory requirement for locum tenens physician to include NPI.
  - Medicare Claims Processing Manual (“MCPM”) requirement to include Q6 modifier.
  - “In light of the Supreme Court's recent decision in *Azar v. Allina Health Services* . . . it is unclear what effect, if any, I should give to the MCPM’s requirement to use the Q6 modifier.”

# Today's Presenter



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