

Report on Medicare Compliance Volume 28, Number 43. December 09, 2019

CMS: No Enforcement Actions Only on Guidance; Definition Is Fuzzy

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In a new memo,^[1] top CMS attorneys say the agency can't base enforcement actions on guidance, such as Medicare manual provisions, unless it's rooted in laws or regulations, but it's a little vague what they mean by enforcement actions.

The Oct. 31 CMS memo, which surfaced in late November, states that HHS's and CMS's ability to bring enforcement actions "predicated on violations" of payment policies "is restricted" to payment policies that were promulgated through notice and comment rulemaking in the wake of the Supreme Court's June 2019 decision in *Azar v. Allina Health Services, et al.*^[2] Enforcement actions can still be brought based on internet-only manuals (IOMs) and preambles in regulations if they are "closely tied to statutory or regulatory requirements," the memo stated. But "to the extent the IOMs and similar guidance set forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under *Allina*, it was not validly issued," according to the memo, which was written by CMS Chief Legal Officer Kelly Cleary and Deputy General Counsel Brenna Jenny. They noted, for example, that enforcement actions based exclusively on local coverage determinations (LCDs) "are generally unsupportable."

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