

New Guidance on Medicare Payment Rule Enforcement

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A few days before Thanksgiving, the news media published an internal memo by the Office of General Counsel (OGC) at the US Department of Health and Human Services (Department) to officials at the Centers for Medicare and Medicaid Services (CMS). The memo expressed OGC's views on the impact of the Supreme Court's *Azar v. Allina Health Services, et. al.*, No. 17-1484 decision earlier this year on the enforcement of various CMS guidance. Specifically, OGC states that [Medicare payment rules](#) that meet the Court's standard that did not go through notice-and-comment rulemaking cannot form the basis for an enforcement action, including an overpayment finding.

The issue, in this case, was whether the Department's determination that Medicare Part C patients should be included in the Medicare fraction represented a change in a "substantive legal standard" within the meaning of Section 1871(a)(2) of the Social Security Act (SSA). If the answer was yes, then notice-and-comment procedures were required under the title 18 of the SSA. In a 7-1 decision, the court held that the inclusion of Part C patients in the Medicare fraction was "substantive." The court explained that the "substantive legal standard" under Section 1871(a)(2) of the SSA means any legal standard or determination that creates rights and obligations, such as the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities or organizations to furnish services.

OGC concludes that, according to the Supreme Court, Congress imposed a notice-and-comment requirement for substantive Medicare rules in a broader range of circumstances than otherwise would be required under the Administrative Procedure Act. Therefore, CMS guidance documents, such as the Medicare Internet-Only Manuals, setting forth interpretive payment rules, are legally nonbinding and may not be used as the basis of an enforcement action. As an example, if a "broadly worded statute or regulation can be interpreted a variety of ways," sub-regulatory policy statements may be viewed as creating a new substantive rule, and thus cannot be enforced as binding rules under the Court's ruling. According to OGC's memo, CMS guidance documents that are "closely tied to a

statutory or regulatory requirement” may provide additional clarity through such guidance and enforcement actions implicating the guidance can still be brought. Further, even if the sub-regulatory guidance is not specifically enforceable as a substantive legal standard, it can be used for other purposes, such as scienter or materiality, as stated in the Department of Justice Brand Memo.

OGC indicates that it does not believe Local Coverage Decisions (LCDs) require notice-and-comment rulemaking because LCDs reflect payment determinations of the local Medicare Administrative Contractor (MAC) and are not binding on the Department. They accordingly do not create any substantive legal standards. In its memo, OGC concludes, that LCDs cannot be solely used as the basis for a “government enforcement action,” including an overpayment demand. OGC also notes that codifying guidance in a retroactive regulation could create other legal risks for enforceability.

The primary takeaway is that providers should examine carefully the basis for any enforcement action, including an overpayment determination, for whether the decision is based on sub-regulatory guidance that offends the Court’s standard. Providers should also be on the lookout for attempts by CMS to codify sub-regulatory guidance in notice-and-comment rulemaking in order to prospectively avoid this problem.

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