

Advisory Opinion on Sub-Regulatory Medicare Guidance

Insights

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On December 3, 2020, the HHS Office of the General Counsel (“OGC”) released an [advisory opinion](#) addressing the use of sub-regulatory guidance in enforcement actions in light of last year’s Supreme Court decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). In *Allina*, the Supreme Court held that the Medicare Act requires notice-and-comment rulemaking for any establishment of, or change to, a “substantive legal standard” concerning Medicare benefits or payment, including those that may be viewed as interpretive under the Administrative Procedure Act (our prior alert on the *Allina* decision is available [here](#)).

Definition of “Substantive Legal Standard.” In the Advisory Opinion, OGC defined “substantive legal standard” as “any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and 3) sets forth a requirement not otherwise mandated by statute or regulation.” For example, OGC stated that a unilaterally-issued statement of policy imposing discrete, binding criteria that purport to explain broad statutory or regulatory requirements would generally not be permissible under *Allina* because such a policy “will usually be viewed as creating a new norm,” as opposed to providing additional clarity.

Role of Sub-Regulatory Guidance in Enforcement Actions. OGC recognized in the Advisory Opinion that *Allina* generally precludes HHS from basing enforcement actions on sub-regulatory guidance that establish or change a substantive legal standard. But, OGC maintained that HHS may implicate sub-regulatory guidance in enforcement actions that are based on statute or regulation when the sub-regulatory guidance is “closely tied to statutory or regulatory requirements” and “aid[es] in demonstrating” whether the statutory or regulatory requirements are met. OGC identified “the critical question” as whether a Medicare violation could be shown without a sub-regulatory guidance document – if not, then the sub-regulatory guidance is invalid under *Allina* because it establishes “a norm” without notice-and-comment rulemaking. Similarly, OGC stated that enforcement actions based on sub-regulatory guidance codified in a retroactive regulation “may not always be appropriate,” though the guidance could be relevant for analyzing scienter or materiality in enforcement matters.

Role of LCDs in Enforcement Actions. Additionally, OGC noted that although it does not interpret *Allina* to require Local Coverage Determinations (“LCDs”) be

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promulgated by notice-and-comment rulemaking, “government enforcement actions based solely on LCDs are generally unsupported.” The Advisory Opinion does not address the federal district court decision on this issue in *Agendia v. Azar*, 420 F. Supp. 3d 985 (C.D. Cal. 2019), *appeal docketed*, No. 19-56516 (9th Cir. Dec. 27, 2019), a case our firm is handling. The district court in *Agendia* held that an LCD establishes or changes a substantive legal standard governing payment for services and thus must be adopted through notice-and-comment rulemaking to be enforceable. Oral argument in the case is set for January 15, 2021.

Weight of Preamble Text. Last, OGC discussed the appropriate use of preamble text for rulemaking. OGC indicated that HHS will rarely engage in notice-and-comment-rulemaking through preambles only. However, when HHS does so, it will clearly separate text containing binding legal obligations from nonbinding interpretive statements. HHS will show its intent to engage in notice-and-comment rulemaking through the preamble by either using language that shows intent to bind itself in the proposed and final rule preamble text (such as “HHS intends to bind itself” to the rule) or declaring that HHS would change the preamble policy by notice-and-comment rulemaking.

For further information, please contact [Bob Roth](#) in Washington D.C., [Katrina Pagonis](#) or [Erin Sclar](#) (*currently awaiting California Bar results*) in San Francisco, [Lloyd Bookman](#), [Pat Hooper](#) or [Paul Garcia](#) in Los Angeles, or your regular Hooper, Lundy & Bookman contact.

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