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U.S. Supreme Court ruling expands scope of Medicare notice-and-comment requirement

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On June 3, 2019, the U.S. Supreme Court held in *Azar v. Allina Health Services* that Medicare interpretive guidance must go through notice-and-comment if it establishes or changes a substantive legal standard governing payment, coverage, or eligibility.[1] The 7-1 decision affirmed a ruling by the D.C. Circuit vacating a Centers for Medicare & Medicaid Services (CMS) policy used to calculate disproportionate share hospital (DSH) payments for hospitals serving a disproportionate share of low-income patients in fiscal year (FY) 2012.[2] The majority opinion, authored by Justice Gorsuch, may have ramifications well beyond the Medicare DSH payment formula: it may expand the number and types of Medicare policies that are required to be promulgated through notice-and-comment.

The Supreme Court's decision

The Medicare Act has its own notice-and-comment provisions, which are distinct from the notice-and-comment provisions applicable to most non-Medicare programs under the Administrative Procedure Act (APA). In the *Allina Health Services* decision, the Court answered the long-standing question whether the Medicare Act's notice-and-comment provisions are coterminous with those in the APA, which, among other things, exempt interpretive rules (i.e., guidance interpreting statutory or regulatory provisions) from the requirements of notice-and-comment. The answer is no.

The Court's ruling is a victory for a group of hospitals that sued CMS over the agency's interpretation of the Medicare DSH payment formula for FY 2012. CMS had originally adopted that interpretation through notice-and-comment. That rule was challenged and vacated due to procedural defects. CMS then engaged in another round of notice-and-comment and adopted the same interpretation, but only for FY 2013 and later years. The agency did not apply the new rule to FY 2012, presumably because that would have been impermissibly retroactive. Rather, for FY 2012, CMS readopted the interpretation in an interpretive rule (i.e., interpretive guidance, which, here, took the form of a website notice) that CMS viewed as exempt from the requirements of notice-and-comment.

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1 See *Azar v. Allina Health Servs.*, No, 17-1484, slip. op., at 7–10, 12 (S. Ct. June 3, 2019).

2 See *id.* at 17. Justice Kavanaugh, who authored the appellate court decision below, took no part in the Supreme Court's consideration or decision.

In taking this approach, CMS assumed that the Medicare Act parallels the APA in exempting interpretive rules from the requirements of notice-and-comment. Under the APA, notice-and-comment are typically required when an agency adopts "substantive" rules (i.e., rules that have the force and effect of law). But "interpretive" rules (i.e., interpretive guidance that does not carry the force and effect of law) are expressly exempted from the notice-and-comment requirement. Manual provisions, transmittals, and other guidance are therefore often issued by agencies as interpretive rules to avoid the time and expense of notice-and-comment.

The Supreme Court, however, rejected CMS's view that, like the APA, the Medicare Act incorporates an interpretive rule exception to notice-and-comment.

The text of the Medicare Act requires notice-and-comment for any rule (other than a national coverage determination) that establishes or changes a "substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]."[3] Unlike the APA, the Medicare Act does not expressly exempt interpretive rules from its notice-and-comment requirement.

The Supreme Court reasoned that the Medicare Act's omission of an express interpretive rule exception is by design. The Court conducted a comparison of the text and structure of the Medicare Act and those of the APA, and concluded that the language of the Medicare Act makes clear that Congress did not intend interpretive Medicare rules to be categorically excluded from the notice-and-comment requirement. The Court observed that a rational Congress could have determined that the benefits of public notice-and-comment are "especially valuable when it comes to a program where even minor changes to the agency's approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate."[4]

Implications for the Medicare program

The most immediate question is how CMS will respond to the Supreme Court's ruling. CMS appears likely to seek to narrow the impact of the ruling on its administration of the Medicare program by concluding, to the extent reasonably possible, that existing and future guidance does not in fact constitute a statement of policy that establishes or changes a substantive legal standard governing payment, coverage, or eligibility. In support of any such conclusion, CMS might point to the *Allina Health Services* Court's express skepticism of the government's suggestion that a significant number of manual provisions would need to be readopted through notice-and-comment rulemaking.[5] Thus, there may be limited change in Medicare program administration, at least to start.

That said, because the *Allina Health Services* decision could be read expansively to mean that notice-and-comment is required any time CMS interprets an ambiguous Medicare statutory or regulatory provision to establish a new or modified substantive legal standard governing payment, coverage, or eligibility, CMS could be more inclined to engage in notice-and-comment than it otherwise would be, at least going forward, with respect to more controversial or aggressive interpretations, which the agency could view as potentially more vulnerable to an *Allina Health Services*-based challenge.

Stakeholders dissatisfied with an interpretive guidance that CMS may issue without notice-and-comment may wish to consider whether it would appropriate to invoke the *Allina Health Services* decision to argue procedural infirmity. One strategic potential consideration is that a broader

3 Social Security Act § 1871(a)(2).
4 Slip op. at 16.
5 *Id.* at 15.

understanding of the *Allina Health Services* decision could inhibit CMS from quickly issuing interpretive guidance in instances where stakeholders would welcome such guidance.

Ultimately, the full ramifications of the Supreme Court's decision are likely to take years to become clear, after substantial additional litigation. Like CMS, lower courts will have to wrestle with whether to give the *Allina Health Services* decision broad or narrow effect. If lower courts endorse an expansive understanding of the decision, it could dramatically alter the landscape of Medicare regulation, as CMS currently implements large swathes of the Medicare program through manuals, transmittals, and other guidance that do not go through notice-and-comment. But lower courts may instead ultimately apply the *Allina Health Services* decision much more narrowly: as noted above, the decision itself appears to imply that the Supreme Court did not think that its holding would dramatically expand notice-and-comment[6], and courts may be reluctant to construe the decision's reasoning in a way that would practically impede the operation of the Medicare program.

If you have any questions about the Supreme Court's *Allina Health Services* decision and its implications, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

6 *See id.*

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