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Azar v. Allina: Supreme Court Decides Important Case on When CMS Must Use Formal Rulemaking when Instructing Medicare Contractors

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On June 3, 2019, the U.S. Supreme Court issued a decision in **Azar v. Allina Health Services**. The case involved a challenge by hospitals over whether the Department of Health and Human Services ("HHS") was required to proceed through notice-and-comment rulemaking before promulgating a retroactive Medicare rate calculation methodology for Disproportionate Share (DSH) payments to hospitals. In a 7-1 decision by Justice Gorsuch, the Court ruled in favor of the hospitals, holding that the new rate calculation established a substantive legal standard, and therefore notice-and-comment was required under the Medicare Act.

Strikingly, the Court flatly rejected the government's legal argument that under the Medicare Act CMS's guidance to its contractors is nonbinding interpretative guidance that does not have the force of law, and thus legally cannot be "substantive rules" within the meaning of the Administrative Procedures Act. The Court also addressed the policy arguments that a notice-and-comment requirement under the circumstances at issue would be unduly burdensome, would take many years to complete, and could become a major roadblock to the implementation of Medicare. The Court was skeptical of these arguments and recognized that there might be benefits to notice-and-comment in a program "where even minor changes … can impact millions of people and billions of dollars in way that are not always easy for regulators to anticipate." Ultimately, the Court did not let these policy arguments impact its view that the hospitals' legal reading of the text is "obvious" and the government's reading as "most unlikely," and thus that any thorny policy or implementation problems, if any, are left for Congress.

Background

As discussed in our **prior post**, the Court reviewed the U.S. Court of Appeals for the D.C. Circuit's decision that threw out a Medicare rate calculation methodology for DSH payments adopted by HHS for its failure to undergo notice-and-comment rulemaking.

Under Medicare Part A, hospitals that serve a disproportionate number of low-income patients receive DSH payments. DSH payments are calculated using the so-called "Medicare fraction." The fraction's denominator is the days of care hospitals provide to patients "eligible to benefits under" Part A. The numerator is the days providing care to Part A eligible patients who are also eligible for income support payments under the Social Security Act. A larger fraction creates a larger DSH payment to a hospital

The dispute before the Court arose in 2014 when HHS published on its website the 2012 Medicare fractions. The 2012 fractions included Medicare Part C patients in the denominator, resulting in smaller Medicare fractions, and reduced DSH payments to hospitals of approximately $4 billion. A group of hospitals sued HHS in federal court, arguing that HHS violated the Medicare Act by skipping its notice-and-comment obligations when publishing a new Medicare fraction methodology that included Part C patients. HHS disagreed on the basis that its decision to include Part C patients in the DSH calculation, was a "statement of policy" but did not create "a substantive legal standard" and therefore was exempt from notice-and-comment rulemaking. The district court sided with HHS, and granted summary judgment to the government on the basis that the reimbursement adjustment formula constituted an "interpretive rule" which, in its view of the Medicare Act, did not require notice-and-comment.

On appeal from district court, the U.S. Court of Appeals for the D.C. Circuit, in an opinion authored by then Judge Kavanaugh, held that HHS violated the Medicare Act when it changed its reimbursement

adjustment formula without providing notice and opportunity for comment, and reversed the decision below. The panel held the 2012 Medicare formula that included Part C days established a "substantive legal standard" and therefore was not interpretative. The Circuit Court also held that the Medicare Act does not exempt interpretive rules, but instead broadly requires notice and comment for every rule, requirement, or other statement of policy that establishes or changes a substantive legal standard. The government sought *certiorari*, and the Supreme Court granted it.

Analysis of The Supreme Court's Decision

Azar v. Allina Health Services has drawn considerable attention because it appeared to provide an opportunity for the Court to address a long-open and disputed question in administrative law: what is the distinction between an interpretative and substantive rule? The Court expressly declined to take up this question. Instead the Court ruled narrowly on the plain language of the Medicare Act. The Court in a 7-1 decision authorized by Justice Gorsuch, in which Justice Kavanaugh did not participate, held that the Medicare Act does not exempt interpretative rules from its notice-and-comment requirements. Under the Medicare Act, HHS is explicitly required to undergo notice-comment-rulemaking prior to establishing "substantive legal standards" as that term is specifically defined in the Medicare Act. The Court applied this construction and held that by including Part C days in the 2012 Medicare fraction, HHS established a "substantive legal standard," and was therefore required to undergo notice-and-comment.

In reaching its conclusion, and contrary to HHS's position, the Court found that in drafting the Medicare Act, Congress adopted a different standard for notice-and-comment rulemaking than in the Administrative Procedures Act (APA). The APA distinguishes between "substantive rules," which have the force of law, and "interpretative rules," which advise the public of an agency's understanding of the statutes it administers. Under the APA, substantive rules require notice-and-comment, whereas interpretative rules do not.

The Court delved deeply into a textual and structural analysis, and concluded that the Medicare Act does not track the APA's distinction between substantive and interpretative. Applying this conclusion, the Court found that where, as here, HHS seeks to establish a "substantive legal standard," regardless of whether it is labelled an interpretive rule or statement of policy, the Medicare act demands notice-and-comment rulemaking. The Court further held that HHS failed to provide "a lawful excuse" for failing to comply with such rulemaking procedures.

In his dissent, one page longer than the majority opinion, Judge Breyer attempted to harmonize the differing Medicare and APA language, arguing they were essentially the same and that the standard should be that notice-and-comment rulemaking is required for "all substantive rules, irrespective of the labels the agency affixed." Notably, Justice Breyer was troubled that the majority de-linked the interpretation of the Medicare's procedural rules from the APA – or in his words "leaves the APA behind."

More broadly, the implications of the *Allina* decision need to be weighed in the context of the extensive efforts by the conservative legal community, and led by Justice Thomas and deceased Justice Scalia, to cut back on the level of deference courts are to give to agency interpretations of statutes it administers. We discussed this trend in a previous blog post: **Developments in Judicial Deference of Administrative Agency Actions**. The most well-known deference standard is from ***Chevron U.S.A. Inc. v. Natural Resources Defense Council*** , which holds that, where Congress has "not directly spoken to the precise question at issue," i.e., where a statute is ambiguous (the so-called first prong), courts are to uphold an agency's reasonable or "permissible constructions of [a] statute" (the so-called second prong). A long-standing stalwart supporter of agency deference has been Justice Breyer, a former Harvard Law School professor specializing in administrative law. He is known in the health care bar, going back as early as the 2000 Supreme Court decision in ***Shalala v. Illinois Council on Long Term Care, Inc.***, for his consistent support of HHS decisions. Notably here, nowhere does the Court speak in terms of deference, we suggest possibly because of the Allina majority's distaste of the concept and possibly as well to garner the support of so many Justices, with the result that Justice Breyer was the lone dissenter. But unmistakably, the conservative Justices took a meaningful chip out of Medicare deference jurisprudence by dislodging Medicare procedural interpretation from the APA's jurisprudence.

Takeaways and Potential Impact on the Medicare Program

The Supreme Court's decision will result in the distribution of up to $4 billion to health systems in withheld DSH payments to hospitals. There is a significant dispute as to whether the decision may also hamper HHS's ability to efficiently administer the Medicare program. Because of the scope and complexity of the Medicare program, the agency relies extensively on interpretative guidance published in policy manuals to administer the program. The hospitals argued that a decision in its favor would not be a major disruption to the administration of the Medicare program. The Solicitor General vigorously argued that a Court's decision in favor of the hospitals could "substantially undermine . . . the administration of the Medicare scheme." The majority stuck to its strongly held legal view, and concluded that concluded "if notice and comment really does threaten to become a major roadblock to the implementation of Medicare . . . the agency can seek relief from Congress." Notwithstanding the arguments and speculation by the parties and the Court, we do not know whether the decision when implemented actually will be enormously disruptive of the agency's ability to administer the Medicare program.

The decision raises some very significant issues going forward. First, to what extent will CMS promulgate through notice and comment any of the existing guidance, through manual provisions and otherwise, that creates a "substantive legal standard" or arguably does so, how will it make these decisions, and will it apply this ruling narrowly – and minimize the burden – or more expansively, to support its argument that Congress must act?

Second, prospectively, what will be CMS's approach to issuing rules, policy, guidance, or other notices that potentially constitute substantive legal standards?

Third, in both ongoing litigation and future litigation, there likely will be a plethora of issues relating to whether CMS was required to follow notice and comment with respect to any sub-regulatory guidance and failed to do so.

Fourth, recall that the Department of Justice (DOJ) policy is to prohibit the use of agency guidance documents as the basis for proving legal violations in actions brought under the False Claims Act (FCA). This policy now is a valuable tool in defending FCA actions that attempt to use alleged noncompliance with agency sub-regulatory guidance as support for an FCA theory. The decision in *Azar v. Allina* provides another powerful litigation tool to challenge the use of sub-regulatory guidance in FCA cases.

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