Azar v. Allina Health Services, 139 S.Ct. 1804 (2019)

Topics Covered: Regulatory Burdens

Outcome: Very Favorable

Issue

The issue in this case was whether the Centers for Medicare & Medicaid Services (CMS) must employ notice-and-comment rulemaking to establish the criteria used in making payments under Medicare.

AMA Interest

The AMA supports greater advance notice and opportunity to comment on proposed federal regulations.

Case Summary

Under the Medicare Act, CMS pays special adjustments to qualified hospitals based on their care for low-income patients. These are known as disproportionate share hospital (DSH) adjustments.

The DSH payment formula is complicated, and for many years CMS has struggled with the question of whether and how to include Medicare Part C beneficiaries in the calculation. Medicare Part C patients tend to be somewhat wealthier than non-Part C patients, and so the decision of whether to include them affects the amount of the DSH payments. When Part C patients are included in the formula, the DSH payments are lower. In some years, CMS has considered Part C patients in its calculations, and in some years it has not. CMS has employed an interpretive rule-making process rather than a "notice-and-comment" procedure in determining how to account for Part C patients. Most recently, CMS calculated its DSH payments with the inclusion of Part C patients.

Several hospitals, including Allina Health Services, challenged the CMS formula for calculating their 2012 DSH payments. The hospitals asserted that CMS had improperly included Part C patients in the calculations, but CMS rejected their argument. After exhausting their administrative remedies, the hospitals sued CMS in the United States District Court for the District of Columbia.

The hospitals argued that the Medicare Act has special requirements for adoption of regulations, different from other statutes that incorporate the Administrative Procedure Act (APA). While the APA might, in certain circumstances, allow adoption of interpretive rules, without notice-and-comment, this loophole does not apply to Medicare rules. All Medicare rules that govern payment for services, the hospitals claimed, must follow notice-and-comment to be

effective. Thus, CMS had no right to change the formula without following the notice-and-comment mechanism – and accordingly the CMS DSH calculation (with inclusion of the Part C patients) was invalid.

CMS countered that the hospitals were misinterpreting the Medicare Act and that, in fact, the Medicare Act incorporates the APA exceptions that allow, in certain circumstances, promulgation of administrative rules without notice-and-comment. CMS argued that, under the APA (and therefore under the Medicare Act), CMS should be allowed to adopt interpretive rules without notice-and-comment.

On cross-motions for summary judgment, the district court found that the Medicare Act did incorporate the APA provisions regarding promulgation of interpretative rules without notice-and-comment. The court found that the calculation of the DSH payments depended on an interpretive rule, and thus the CMS instructions to the MACs for these calculations had been proper. It entered judgment for CMS.

The hospitals appealed to the United States Court of Appeals. Based on what it characterized as the "fairly straightforward language" of 42 U.S.C. § 1395hh(a)(2), the Court of Appeals found that the Medicare Act requires notice-and-comment for the adoption of any "rule, requirement, or other statement of policy" that governs "payment for services." These requirements were "readily met here." It specifically held that the Medicare Act does not incorporate the APA interpretive-rule exception to the notice-and-comment requirement.

The Court of Appeals also gave an alternative rationale, based on 42 U.S.C. § 1395hh(a)(4), which requires notice-and-comment for a narrower class of regulations, viz., "a final regulation … that is not a logical outgrowth of a previously published notice of … rulemaking." The specific regulation here was not deemed such a "logical outgrowth" and therefore required notice-and-comment (which it did not have). The Court of Appeals reversed the trial court and ordered judgment to be entered for the hospitals.

Pursuant to a petition of CMS, the United States Supreme Court granted review. On June 3, 2019 the Supreme Court, in a 7-1 decision, determined that CMS was required to go through notice and comment rulemaking in order to change the DSH payment formula. It affirmed the Court of Appeals.

Litigation Center Involvement

The Litigation Center filed an *amicus* brief on behalf of the hospitals and in support of affirmance. It argued that notice-and-comment leads to clearer rules, and this clarity benefits physicians, patients, and the general public.

United States Supreme Court brief