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Hospitals Have Hope As Justices Mull Medicare Case

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On Tuesday, Jan. 15, the U.S. Supreme Court heard arguments in Azar v. Allina Health Services, a case with a nearly 10-year history that has been long-awaited by the nations' hospitals. And for good reason. The financial stakes in Allina are high: Both the Centers for Medicare & Medicaid Services and respondents — several Medicare-participating hospitals — agree that a favorable outcome for the hospitals could lead to billions of dollars in additional Medicare payments to thousands of hospitals. By many reports, the argument went well for the Allina hospitals, so things look bright.

But the case is about more than money. It could significantly affect how CMS operates the Medicare program and how other agencies, such as the U.S. Department of Justice, enforce violations of Medicare rules. A basic tenet of the Administrative Procedure Act is that agencies are not required to undertake notice-and-comment rule-making to adopt interpretive rules. Agencies, including CMS, have been able to adopt policies that have significant impact on regulated industries without taking their comments under the interpretive-rule exception. But the central question in Allina is whether a special provision of the Medicare statute reverses this principle and requires CMS to use notice and comment to adopt interpretive rules.

The significance is that CMS has issued thousands of interpretive rules and guidance in the form of Medicare manuals and other such instructions that govern the far corners of a vast and intricate program. A ruling for the hospitals could mean that many of these rules would be subject to challenge, particularly in a False Claims Act enforcement action. Further, CMS argues that if it were forced to adopt all its interpretive rules through notice and comment, it would disrupt the administration of the program and mire the agency in inaction.

Allina History and the Part C Question

Allina sprouts from a highly technical area of Medicare hospital reimbursement. Hospitals that serve a "disproportionate share" of low-income individuals receive an upward adjustment to their Medicare rates, otherwise known as disproportionate share hospital, or DSH, payments. Under the Medicare statute, each hospital's adjustment is unique and depends on the percentage of its patients "entitled to

benefits under Part A" of Medicare who are also entitled to "supplementary security income," or SSI, cash benefits, a proxy for low-income patients. CMS determines each hospital's so-called SSI ratio on a yearly basis, gives that number to its administrative contractors who then make final payment determinations for the year for each hospital using its unique percentage. DSH payments can measure in the tens of millions of dollars per year for many qualifying hospitals.

Another part of Medicare — Part C — allows beneficiaries to enroll in private managed care plans to receive their benefits. But the Medicare statute requires a beneficiary to be "entitled to benefits under Part A" to enroll in Part C, the same language used in the DSH statute. Should Part C enrollees, then, be counted in the SSI ratio used to determine DSH payments? The answer matters a lot. If they are, it tends to lower the SSI ratio and hospital reimbursement. In fact, the Allina parties generally agree that this dispute at the center of their case is worth billions of dollars.

CMS' history on the Part C question is troubled. Until 2004, CMS had no specific policy and its practice was to calculate hospital SSI ratios without including Part C patients. In 2003, CMS proposed in rule-making to exclude them, reasoning that once enrolled in Part C, beneficiaries were no longer "entitled to benefits under Part A." In 2004, however, CMS reversed course and adopted the opposite policy in a final rule, concluding that Part C enrollees remained "entitled to benefits under Part A" even after enrollment. In 2014, the United States Court of Appeals for the D.C. Circuit vacated CMS' 2004 rule, agreeing with the Allina hospitals that it was not a "logical outgrowth" of its 2003 proposal and violated the notice requirements of the Administrative Procedure Act.

CMS adopted the policy anyway by instructing its contractors to included Part C patients in final DSH payment determinations for fiscal year 2012 hospital cost reports, claiming that it was an interpretive, nonbinding policy that did not require notice-and-comment rule-making and that hospitals could challenge in administrative appeals. The Allina hospitals sued again. When then-Judge Brett Kavanaugh of the D.C. Circuit ruled in their favor, the government sought certiorari leading to Allina II now before the Supreme Court.

Azar v. Allina Health Services (Allina II)

The Allina hospitals claim that CMS' attempt to end-run around the vacated 2004 Part C rule violated an overlooked provision of the Medicare statute. Adopted in 1986 and amended in 1987, § 1395hh(a)(2) states that "[n]o rule, requirement or other statement of policy … that establishes or changes a substantive legal standard governing … payment for [Medicare] services … shall take effect unless it is promulgated … by regulation …"

Because the D.C. Circuit vacated the 2004 rule, according to the Allina hospitals, the preexisting baseline policy was to exclude Part C patients. CMS' decision to use SSI ratios that included these patients for 2012 payment determinations, therefore, constituted a "statement of policy" which "changed" a "substantive legal standard" without notice-and-comment rule-making. The policy was "substantive" because it created, defined and regulated the hospitals' rights and its substantive impact was to lower Medicare reimbursement.

In that sense, the Allina hospitals argue that Congress intended to distinguish the term "substantive legal standard" from a "procedural" rule that agencies use to organize and direct their operations. Even interpretive rules can have substantive effect in this way, and Congress required those type of Medicare rules to be issued by regulation.

The government contends that § 1395hh(a)(2) simply incorporates the basic requirements of the Administrative Procedure Act. Legislative rules, which have the "force of law," must undergo notice and comment. Interpretive rules, which are nonbinding on parties, do not. The decision to include Part C patients in the SSI formula, while it may have a material impact on the hospitals' Medicare reimbursement, is not a "substantive legal standard" because it is an interpretation of the Medicare statute that is not binding on the hospitals, administrative adjudicators or the courts, the government argued to the court.

What Are the Implications of Allina?

Because reports suggest the Allina hospitals may preserve their lower court victory, it is interesting to speculate what a post-Allina world would look like. In the short term, a pro-hospital decision would mean more money — lots of it — for hospitals. There are thousands of DSH hospitals in the country, and it is likely that nearly all of them have preserved a Part C challenge to years of DSH payments.

But a loss for the government in Allina is likely to have implications beyond refunding billions of dollars. The Medicare program — particularly the rules regarding reimbursement — is infamously dense and complex. Judge Royce Lamberth of the U.S. District Court for the District of Columbia once described Medicare as "a law written by James Joyce and edited by E.E. Cummings." This nearly impenetrable text is administered in hundreds of pages of regulations and, more important, thousands of pages of subregulatory guidance including more than a dozen manuals setting forth rules that were never adopted through notice-and-comment rule-making.

If the court agrees that Congress intended in § 1395hh(a)(2) to require CMS adopt even interpretive rules by regulation so long as they have a "substantive" or material impact on the rights of hospitals, then many of the rules set forth in thousands of pages of subregulatory guidance could be challenged. And that could have profound impact in the following areas.

Medicare Reimbursement

The parties at argument disputed the volume of Medicare subregulatory rules that are substantive as opposed to procedural, such as the thousands of pages of instructions that direct hospitals how to complete cost reports, or instructions to CMS contractors for conducting conduct audits or processing claims. The government argued that it would be nearly impossible to adopt this volume of rules through notice and comment, plus their many changes year after year, without disrupting the program. The Allina hospitals argued that, by their estimate, only 35 or so pages of these manuals constituted substantive rules, with the vast majority being merely procedural. Plus, CMS issues thousands of pages of rule-making each year when it annually updates the major payment rules for hospitals, physicians, skilled nursing facilities and other providers.

Whoever is correct, it is certain that some percentage of these subregulatory rules do affect the rights of health care providers for Medicare reimbursement. There are likely to be additional reimbursement opportunities — and legal challenges — for hospitals and other Medicare providers that flow from an Allina loss for CMS.

Just to take but one example, the Medicare program reimburses hospitals for the unpaid deductibles and co-payments of its beneficiaries. Most of CMS' rules reimbursing "bad debt" are set forth in the Provider Reimbursement Manual, which is not promulgated by regulation. They are unquestionably "substantive" and many of them disfavor providers, such as CMS' purported policy that providers must

gather information and assess the resources of patients before seeking reimbursement regardless of income level. It is not hard to see hospitals challenging these rules as void or ineffective — and therefore, not applicable to their bad debt claims.

Health Care Fraud Enforcement

A loss for the government in Allina could prove to be a further stumbling block in False Claims Act enforcement actions where the government's theory of liability turns on compliance with a subregulatory rule. It was only a year ago that the Department of Justice made headlines with the Brand memorandum which stated that DOJ litigators may no longer use noncompliance with agency guidance documents as a basis for proving violations of applicable law in False Claims Act cases. The DOJ will not treat a party's noncompliance with agency guidance as establishing that the party violated an applicable statute or regulation.

To the extent that there was any daylight left after the Brand Memo for pursuing False Claims Act violations based on violations of agency subregulatory guidance, a loss for the government in Allina could shut the door in Medicare cases. Presumably any such enforcement action would allege that the agency guidance document created a "substantive legal standard" in that the Medicare provider was required to follow it. In this hypothetical version of a post-Allina world, however, this guidance could not "take effect" unless it was promulgated by regulation even if it was a long-standing interpretation of a regulation. If not "in effect," then it would appear to not meet the False Claims Act requirement that the rule be material to Medicare's decision to pay the claim for payment.

To provide an example, it was not until 2014 when Medicare adopted the "two midnight" rule that CMS defined by regulation the standards by which it would pay for medical services on an inpatient basis versus an outpatient basis which is generally cheaper.

Prior to that, CMS' standards were only set forth in the Medicare Benefits Policy Manual. But CMS contractors denied thousands of claims relying on these standards; the U.S. Department of Health and Human Services' Office of Inspector General has audited and sought to recover millions of dollars relying upon these standards; and, most significantly, the Department of Justice continues to pursue hospitals under the False Claims Act in so-called short-stay cases for allegedly violating these standards.

In this hypothetical post-Allina world, CMS, HHS OIG and the DOJ may no longer be able to pursue these matters because the standards in the Benefit Policy Manual were not issued by regulation and, pursuant to § 1395hh(a)(2), are not in effect and therefore unenforceable.

We can expect a decision in Azar v Allina Health Services sometime this spring or summer. If victorious, the Allina hospitals and others may see a big payday. But the broader implications of Allina may continue to spin out for several more years.

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Disclosure: King & Spalding represents several hospitals in pending claims challenging CMS' Part C policy.