Health Law Daily

Wolters Kluwer

July 10, 2019

STRATEGIC PERSPECTIVES: U.S. Supreme Court decides *Allina* and analysis, predictions follow

The U.S. Supreme Court decision in *Allina* is a win for hospitals, but what do experts think it will mean going forward?

By Cathleen Calhoun, J.D.

The U.S. Supreme Court handed hospitals a victory, finding that the government could not create a "self-serving label" to avoid its notice and comment requirements, in its decision in *Azar v. Allina Health Services* on June 3, 2019. But how did the court reach its decision, and what do professional groups and experts in the field say about its meaning? This Strategic Perspective provides an overview of the court's decision and the perspective of several legal experts as to what it means for providers.

U.S. Supreme Court Ruling

In a 7–1 decision, (see Supreme Court sides with hospitals, ending interpretive battle, June 3, 2019), the high court affirmed the D.C. Court of Appeal's ruling under §1395hh(a)(2), finding that notice-and-comment obligations were required before changes were implemented to include Medicare Part C beneficiaries in a hospital's Medicare fraction. The court noted that the language in the Medicare law, not the language in the Administrative Procedure Act (APA), was applicable.

It all began with changing policies. The hospitals involved in this matter were hospitals subject to disproportionate share hospital (DSH) payments. Those payments were reduced significantly in 2014 due to changing policies. Since Medicare Part C allows beneficiaries to choose to have the government pay their private insurance premiums rather than pay for their hospital care directly, the question for the government agency overseeing the program became whether Part C patients should be counted as "entitled to benefits under" Part A when calculating a hospital's Medicare fraction.

The agency changed its policies and procedures on that topic over the years:

- In 2004 a final rule is issued declaring that the agency would count Part C patients, but that rule was later vacated after hospitals filed legal challenges.
- In 2013 a new rule is issued prospectively readopting the policy of counting Part C patients.
- In 2014, unable to rely on the vacated 2004 rule or the prospective 2013 rule, the agency posted on its website the Medicare fractions for fiscal year 2012, noting that they included Part C patients.

The hospitals filed suit, claiming, among other things, the government had violated the Medicare Act's requirement to provide public notice and a 60-day comment period for any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services," §1395hh(a)(2) (see *Allina II decision: Too soon to declare a win for providers?*, September 12, 2017).

High Court's analysis. The U.S. Supreme Court found that the government's arguments failed to support its conclusion that no notice was required. The Court noted that the government's interpretation—that because the policy of counting Part C patients in the Medicare fractions would be treated as interpretive rather than substantive under the APA, it had no statutory obligation to provide notice and comment before adopting its new policy—could not be right. Among other reasons, the court stated that the Medicare Act does not use the word "substantive" in the same way the APA does.

The Court said that all available evidence showed that the phrase "substantive legal standard," appearing in §1395hh(a)(2), (and apparently nowhere else in the U.S. Code) was not the same as the term "substantive rule" in the APA. However, the Court would not go so far as to say that the hospitals' interpretation, adopted by the court of appeals, was correct in every instance. The government argued that statute "does not speak directly to the issue" and "leaves a gap." In response, the Court held that when the government establishes or changes an admitted "gap"-filling policy, it can't evade its notice-and-comment obligations on its current arguments.

Commentary and Reactions

American Hospital Association. Shortly after the U.S. Supreme Court *Allina* decision was decided, the American Hospital Association (AHA), issued a release applauding the decision. AHA stated, "... the Department of Health and Human Services violated the Medicare Act when it changed Medicare's reimbursement formula for disproportionate share hospitals without providing notice and opportunity to comment...more public participation in policymaking, including by hospitals and health systems, leads to better-thought-out policies with a deeper understanding of their direct impact on health care providers and those they serve."

Expert Perspectives

Wolters Kluwer posed the following questions to Stephanie A. Kennan, Senior Vice President, Federal Public Affairs at McGuireWoods Consulting, Kenneth R. Marcus, Partner, at the Honigman Business Law Firm, and Susan R. Huntington, Partner, and George Mikhail, Associate, at the law firm Day Pitney.

Question: Do you agree with the Supreme Court's decision in *Allina* on June 3, 2019, and why?

Susan R. Huntington and George Mikhail: The decision in *Allina* is a straightforward analysis that re-enforces basic legal tenets—words matter and process matters. Like most legal disputes, the issue revolved around the interpretation of what statutory language applied (the Medicare Act or the APA)

to the word, "substantive." The Court, in a well-reasoned analysis, recognized that the applicable legal standard was that set forth in the Medicare Act and therefore the public has the right to receive notice and have an opportunity to comment on proposed Medicare payment changes.

If the Court followed the logic of the Centers for Medicare and Medicaid Services (CMS) in its arguments, payment changes would not require a notice and comment process and therefore could be made through pronouncements in any forum, including the CMS Administrator's blog posts or through its weekly email updates. The formal notice and comment period is necessary for health care providers and Medicare beneficiaries to know where to look to keep abreast of the complicated and ever-changing Medicare rules. The expanding tactic by CMS of burying rule changes in announcements or other publications has been unfair and, as confirmed by *Allina*, not legal.

Kenneth R. Marcus: As legal counsel for hospitals litigating this issue, I have a vested interest in and, naturally, I agree with the decision. Objectively speaking, however, I believe the decision was correct. The Court distinguished between the more generous provisions of the APA, which provides an exception for interpretive or policy actions, from the stricter provisions of the Medicare Act, §1395hh, the latter of which require CMS to comply with notice and comment rule making in this situation.

Stephanie A. Kennan. The essence of *Allina* is that the notice-and-comment requirement under the Medicare statute is more extensive than what is required under the APA. The APA standard exempts sub-regulatory policy statements and manual guidance that explain how agency regulations are interpreted and applied from notice-and-comment requirements. The Court held that some policy statements may address a "substantive legal standard," which would subject these statements to the Medicare statute's separate notice-and-comment requirement.

In reading the legislative history and intent, it is clear that the government's argument was incorrect. In *Allina,* the Court focused on the Medicare statute's general applicability to policy statements that establish or change a "substantive legal standard," finding that this terminology does not necessarily exclude all "interpretive rules" and "general statements of policy" from its notice-and-comment requirement.

The government also argued that to subject Medicare to such a standard would create an undue burden on CMS for day-to-day business. While the agency may not be able to be as nimble, the value of transparency in a program that impacts access and the delivery of health care to many vulnerable elderly patients is important. CMS already has many annual rules that contain policy changes every year. It should not be an undue burden to ensure transparency and clarity on the impact of potential policy changes.

Question: What consequences do you think may result from the notice and comment requirements the court indicated are needed for calculation and other changes?

Susan R. Huntington and George Mikhail: The ruling has the potential to change how CMS administers the Medicare program moving forward. CMS should construe the decision's applicability to its rulemaking broadly, and therefore engage in more notice-and-comment rulemaking.

Kenneth R. Marcus: In light of the Court's *Allina* decision, CMS is well advised to carefully consider whether to comply with notice and comment requirements when establishing policy. The decision does not impose an untoward burden on CMS, however, because on an annual basis CMS issues voluminous proposed and final amended rules for virtually every aspect of the several Medicare provider, physician and supplier payment programs. And, there will continue to be CMS actions that do not trigger the §1395hh requirements, as illustrated in the relatively recent DC Circuit decision in *Clarian Health West, LLC v. Hargan*, (December 26, 2017), which held that sub-regulatory authority was sufficient in identifying hospitals violating outlier payment rules.

Stephanie A. Kennan. The implications of the *Allina* decision should be of interest to anyone who interacts with Medicare. The decision could have significant repercussions for CMS policy statements beyond DSH payments. Payment policies presented only in Medicare manuals, through announcements that CMS issued as clarification, or interpretations of long-standing rules could be subject to challenges by providers.

Question: How do you think providers seeking disproportionate share hospital (DSH) payments will benefit?

Kenneth R. Marcus: Before the Supreme Court the Secretary of HHS estimated an impact of $3 to 4 billion. That may have been an overestimate to attempt to sway the Court in favor of the government's position. But, there likely are 50 or more cases pending at the DC District Court, amounting to hundreds of hospitals and fiscal years, that have all been stayed pending the *Allina* decision. CMS has not to date announced its posture in these cases, but certainly these hospitals will seek relief in light of Allina. And, there likely are at least that number of cases pending before the Provider Reimbursement Review Board in which the hospitals will claim entitlement to relief.

Stephanie A. Kennan. Many hospitals preserved appeal rights for their 2004-2014 cost reports that are eligible to appeal this issue. In addition, some [Medicare Administrative Contractors (MACs)] alerted hospitals that the MAC would unilaterally reopen the hospital cost report if there was a final decision in *Allina* that changed the hospital's DSH payments.
It is not yet known how CMS will address hospitals that are eligible to appeal. CMS could take steps to recalculate the fractions in the formula of cost reports that have been appealed or are still subject to appeal.

Question: Do you have any other comments on why you found the *Allina* decision interesting?

Kenneth R. Marcus: First, this was the first case in more than 30 years that the Secretary of HHS has lost before the Supreme Court. Second, *Allina* revisited the notice and comment rule making issue presented before the Court in *Shalala v. Guernsey* (which is cited in *Allina*). The difference, however, is that §1395hh did not apply in Guernsey. In that case the Court decided 5-4 in favor of the Secretary of HHS. Three of those Justices are still on the Court: Ginsburg, Breyer and Thomas. In *Guernsey,* Ginsburg and Breyer were in the majority. In *Allina,* Ginsburg changed her vote and was in the majority of 7 along with Thomas. Breyer remained in favor of the agency and was the lone dissent. Finally, *Allina* renders a somewhat definitive interpretation of §1395hh, which has been in force for years but has received scant judicial attention prior to *Allina*.

Stephanie A. Kennan. Prior to the decision, some had opined that this case provided the Court with the opportunity to address the distinction between an interpretative and substantive rule. However, the Court did not define specifically a "substantive legal standard." The Court merely concluded in this instance that the DSH Medicare fraction calculation clearly met the threshold.

Going forward, the question of what types of policies do, or do not, affect a "substantive legal standard" remains subject to interpretation.

What's Next?

Although experts have different reactions and perspectives, all interviewed here shared the belief that *Allina* will bring changes. The days of CMS putting instructions on its website in a given year to fill an admitted gap are likely over. And, as Stephanie A, Kennan noted, "…watch for situations that create or change a substantive legal standard governing the scope of benefits, payment for services, or eligibility to provide or receive services under Medicare. If such a change occurs without notice-and-comment, that could be a violation of the standard established in *Allina*."