The Supreme Court's *Allina* Decision:

How the DSH Ran Away with the APA's Notice and Comment Rulemaking Requirement

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Notice and comment rulemaking is a bedrock requirement in administrative law. Until recently, it was generally assumed that the Medicare program was subject to the same Administrative Procedure Act (APA) notice and comment (N&C) rulemaking requirements that applied to all other administrative agencies. The Supreme Court's 7-1 decision in *Azar v. Allina Health Services (Allina)* decisively dispelled that assumption.[1]

In its opinion, the Court held that the distinct N&C language Congress used in the Medicare statute could not be read as incorporating the APA's exception to N&C for "interpretative rules," i.e., rules that merely interpret an existing statutory requirement and do not themselves create binding law. The Court's decision means that Medicare must subject even interpretive *policies* to N&C if those policies establish or change a substantive legal standard governing reimbursement.

The Supreme Court's holding was issued in the context of a challenge to the Secretary's calculation of disproportionate share hospital (DSH) payments. *Allina*, therefore, represents a major win for providers that serve a disproportionate share of indigent patients. The government's own estimates are that the Centers for Medicare & Medicaid Services (CMS) policy reduced payments to providers by $3–$4 billion over the nine-year period at issue.[2] Perhaps equally important, however, are the decision's implications for other CMS policies that significantly affect reimbursement but have not been subjected to N&C rulemaking.

How a Holding on an Esoteric DSH Dispute Affects All of Medicare Notice and Comment Rulemaking

Under the inpatient prospective payment system (IPPS), Medicare generally pays hospitals a set, pre-determined amount for a specific patient diagnosis (assigned based on Medicare Severity Diagnosis Related Group codes). Congress recognized, however, that hospitals treating a disproportionate share of indigent patients require an increase in payments because they tend to be costlier to treat given additional co-morbidities and other factors. To determine which hospitals treat a disproportionate share of indigent patients, the DSH statute asks two questions: how many of a hospital's traditional Medicare patients are entitled to supplemental security income (SSI), and how many of the hospital's other patients, that is, its non-Medicare patients, are eligible for Medicaid. Under the statute, a patient is a Medicare patient if the patient is "entitled to benefits under Part A."[3] Part A of the Medicare statute covers what is known as traditional Medicare.

In 1997, Congress introduced Part C of the Medicare program.[4] Part C provides an alternative to traditional Medicare known as Medicare Advantage. Under Medicare Advantage, CMS pays private insurers a per capita amount to provide health care benefits to those eligible for Medicare. The substantive question in *Allina* was whether a Medicare enrollee who elects coverage under Part C remains entitled to "benefits under Part A."

Until 2004, the Secretary's regulation stated that only days that were "covered" under Part A, that is, only days that were actually *paid* under Part A, would be included in the Medicare/SSI fraction. Part C days are clearly not *paid* under Part A and the Secretary's practice in 2004, in fact, was to exclude Part C days from the Medicare/SSI fraction.[5]

In a 2003 proposed rulemaking, the Secretary proposed to codify the policy of *excluding* Part C days from the Medicare/SSI fraction.[6] In the 2004 *final* rule, however, the Secretary pulled a "switcheroo" (the D.C. Circuit's word).[7] Instead of codifying the practice as proposed, the Secretary adopted a final policy doing the opposite.[8] That is, the Secretary finalized a policy to treat Part C days as being days "entitled to benefits under Part A." This unannounced switch cost hospitals billions of dollars, as Part C beneficiaries tend to be wealthier and qualify for SSI benefits at a lower rate than traditional Part A enrollee. The vast majority of hospitals saw a decrease in their Medicare/SSI fraction.

In addition to decreasing a hospital's Medicare/SSI fraction, at least some of those Part C enrollees also will be eligible for Medicaid. But, since CMS treats those Part C beneficiaries as being entitled to traditional Medicare, they are categorically excluded from the Medicaid fraction. The Secretary's policy, therefore, invariably also reduces a hospital's Medicaid fraction.

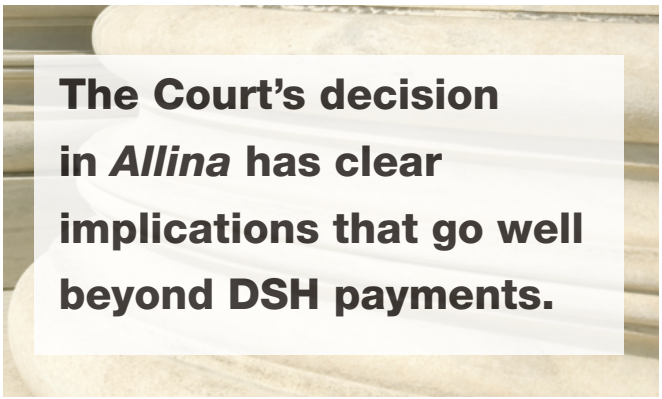
Hospitals appealed the Secretary's finalized policy, and the D.C. Circuit held in *Allina I* that, by adopting a policy that was the opposite of both the prior practice and the proposed policy, the Secretary failed to provide the fair notice required by N&C rulemaking under the APA.[9] The D.C. Circuit invalidated the Secretary's final rule of including Part C days in the Medicare/SSI faction.[10] This, unfortunately, did not settle the issue, as the D.C. Circuit explicitly left open the question of whether the Secretary was *required* to undertake N&C rulemaking before adopting the finalized policy.[11]

Within weeks of the D.C. Circuit's decision in *Allina I*, the Secretary made his position clear by posting 2012 Medicare/SSI fractions, inclusive of Part C days, online without N&C. Plaintiff hospitals challenged these 2012 fractions in the case that reached the Supreme Court, i.e., *Allina II*.

The Underlying D.C. Circuit Decision the Supreme Court Upheld

The key legal question in *Allina II* was whether the Secretary was *required* to undertake N&C rulemaking before adopting a policy of treating Part C days as being Part A days. The Secretary argued that N&C was *not* required because his policy represented a mere "interpretation" of the Medicare statute and the APA exempts "interpretations" from N&C rulemaking.

The *Allina II* hospitals, however, changed the terms of the debate by arguing that, the APA aside, the *Medicare statute* independently required N&C *even if* the Secretary's policy was indeed a mere interpretation of the statute. The Medicare statute states that "[n]o . . . 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."[12] By explicitly applying N&C to "statements of policy," the hospitals argued, Congress made clear that the Medicare statute has broader application than the APA since, under the APA, "policies" are categorically exempted from N&C rulemaking.



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In a decision authored by now-Justice Kavanaugh, the D.C. Circuit court agreed with the hospitals,[13] and the Supreme Court upheld the D.C. Circuit's decision, 7-1. Justice Kavanaugh recused himself because of his role in the decision below.

The Supreme Court's Decision

The primary debate before the Supreme Court was whether the word "substantive" in the phrase "substantive legal standard" used in the Medicare statute meant "binding," as it generally would under the APA (the government's position), or whether it encompassed any standard that was more than merely "procedural" (the hospitals' position).

Rather than fully defining the contours of the Medicare statute's N&C rulemaking requirement, the Court settled for a more modest holding. The Court stated it was "persuade[d] of at least one thing: The government's interpretation can't be right."[14] Contrary to the government's position, the Court held that "the term 'substantive legal standard' in the Medicare Act appears to carry a more expansive scope than that borne by the term 'substantive rule' under the APA."[15] The Court rested its holding on several factors including the Medicare statute's statement that even some policies or statements of general applicability were subject to N&C rulemaking (which would not be the case under the APA's interpretive rule exception) and that the Medicare statute could have easily incorporated the APA's N&C exception for interpretative rules if that is what Congress intended. The Court was equally unmoved by the Secretary's policy arguments regarding the burden to which the agency would allegedly be subjected under the hospitals' interpretation, stating that "[i]f the government doesn't like Congress's notice-and-comment policy choices, it must take its complaints there."[16]

Decision's Implications on DSH Payments

As explained above, the focus of the Supreme Court's decision was CMS' calculation of the *Medicare/SSI* fraction of the DSH payment adjustment. Since the Court held that the Secretary's attempt to apply Medicare/SSI fractions that included Part C days violated the Medicare statute's N&C requirements, the obvious implication is that the Secretary should recalculate the Medicare/SSI fractions to restore the prior practice of excluding Part C days from the Medicare/SSI fraction. The Secretary has the information needed to recalculate Medicare/SSI fractions, a relatively straightforward process. Logistically, the Secretary would then likely issue revised notices of program reimbursement with the revised calculations.

There is slightly more ambiguity regarding the decision's implications for the Medicaid fraction since, again, *Allina II* focused on the Secretary's publication of Medicare/SSI fractions. Although the Court did not specifically discuss the Medicaid fraction, the logic of its decision seems inescapable. The DSH statute creates a binary decision—either a patient is "entitled to benefits under Part A," in which case those patient days belong in the Medicare/SSI fraction, or the patient is not "entitled to benefits under Part A," in which case, if the patient is eligible for Medicaid, those patient days belong in the numerator of the Medicaid fraction. The Court's invalidation of the Secretary's policy of treating Part C days as days entitled to benefits under Part A, therefore, would seem to require a recalculation of the Medicaid fraction as well. While there have been some indications that the Secretary recognizes the decision's implications for both fractions (e.g., the Secretary has requested that cases that clearly appealed both fractions be remanded to the agency for further action consistent with *Allina II*), the Secretary has not adopted a formal position in this regard.

Updating the Medicaid fraction may be a tougher lift for providers, since it may require onerous audits and copious documentation to prove that the Part C enrollees at issue were, in fact, Medicaid eligible. If final settlement is delayed, providers that have appealed the issue to federal court will continue to earn interest on the amounts at issue until final receipt of payment.

While revising both fractions seems like the logical outcome of the Court's decision, the Secretary has stated he is considering a different and, to providers at least, disturbing, alternative. The Secretary has argued he is p*rohibited* from merely reinstating the prior practice of excluding Part C days from the Medicare/SSI fraction because that practice too has not been subject to N&C.[17] The Secretary reasons that he must undertake new rulemaking, consider the issue "afresh," and apply the outcome of that new rulemaking "retroactively."[18] The Secretary was specifically agnostic regarding whether the outcome of this process would lead to any additional funds to providers stating that only "*[i]f* Plaintiffs ultimately are entitled to collect additional payments as a result of this litigation after further proceedings on remand, they may claim litigation interest at that time."[19] In other words, the Secretary has argued that he could, upon remand from the Supreme Court, adopt the same policy of treating Part C days as days entitled to benefits under Part A, and apply that policy retroactively back to 2004.[20]

Not surprisingly, the Allina hospitals have strongly refuted the Secretary's logic in this regard. They pointed out, for example, that the Secretary had a valid regulation in 2004, one that was subjected to N&C, stating that only "covered," i.e., paid, Part A days would be included in the Medicare/SSI fraction.[21]

While the outcome of this debate is uncertain, one thing is clear: any attempt by the Secretary to simply maintain the status quo despite the Supreme Court's adverse decision would undoubtedly lead to years of additional litigation.

Implications Beyond DSH

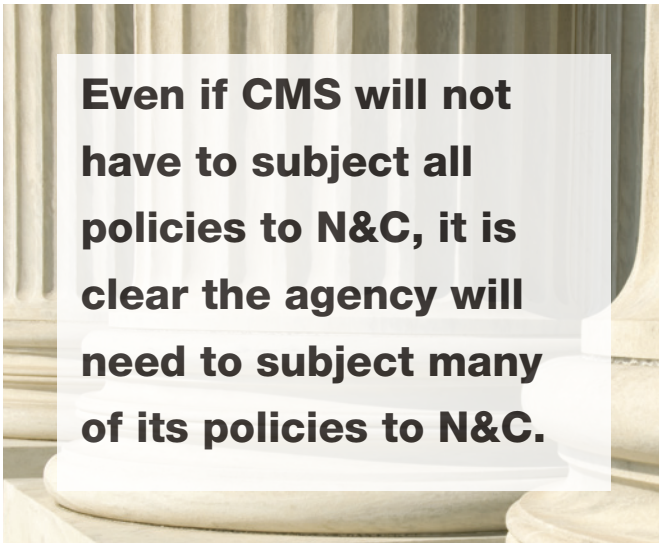
Other Agency Policies That Have Not Undergone N&C May Be at Risk

The Court's decision in *Allina* has clear implications that go well beyond DSH payments. Throughout its history of running the Medicare program, CMS has relied heavily on policies contained in its multiple manuals, such as the Provider Reimbursement Manual. Many of those policies have not been subjected to N&C. In the *Allina* dissent, Justice Breyer catalogued multiple instances where a CMS policy survived a court challenge only because the court determined that the policy being challenged was an "interpretation" under the APA. All those decisions are now in question.

CMS' policies governing Medicare bad debt reimbursement provide a good example. Many of CMS' bad debts policies, such as that (1) a provider must subject its Medicare bad debts to the same collection efforts as its non-Medicare bad debts of like amount, (2) a provider must-bill Medicaid before claiming a dual-eligible patient's bad debt (even if Medicaid policy is clear that the debt will not be paid), and (3) in addition to verifying salary, providers also must inquire about a patient's assets and expenses before determining a patient is too indigent to pay his or her debt, are found only in the Provider Reimbursement Manual.

Importantly, however, the scope of the Medicare statute's N&C requirement is not unlimited. For example, CMS' thresholds for triggering the recoupment of interim outlier payments—namely, an interim cost to charge ratio that differs by more than 10% from the audited cost to charge ratio and outlier payments totaling more than $500,000—are only found in manuals. After issuing its decision in *Allina II*, the D.C. Circuit was called upon to decide whether those requirements required N&C under the Medicare statute.[22] In a decision that was surprising to many, the D.C. Circuit found that those policies did not require N&C rulemaking. Specifically, the D.C. Circuit held that those reconciliation instructions were not a "substantive legal standard governing payment" under the Medicare statute since they merely provided guidance to Medicare contractors on how to allocate limited auditing resources.[23] It did not affect the underlying substantive legal standard for reimbursement, the court reasoned, because that standard would allow for recoupment *whenever* the interim cost to charge ratio differed from the actual ratio.[24]

Even if CMS will not have to subject all policies to N&C, it is clear the agency will need to subject many of its policies to N&C. It is worth noting that CMS has a mechanism to meet this obligation. Specifically, CMS currently publishes multiple



major rulemakings each year, such as the IPPS rulemaking, that typically encompass hundreds of pages and affect multiple agency policies.

Implications of Allina on Fraud and Abuse Claims

Another area to monitor will be False Claims Act (FCA) enforcement actions where the government's theory of liability turns on failure to comply with a sub-regulatory rule. Although the Department of Justice's (DOJ's) recent "Brand Memo"[25] already stated that the DOJ will not treat a party's noncompliance with agency guidance as establishing that the party violated an applicable statute or regulation, those instructions have been subject to various interpretations by individual government attorneys and have had a somewhat limited impact. The Court's decision in *Allina*, however, may all but foreclose the government from pursuing FCA violations based on violations of agency sub-regulatory guidance. For example, the DOJ's continued pursuit of hospitals under the FCA for violations of CMS' so-called short-stay policy for periods prior to 2014 should cease since, prior to 2014, those standards were outlined only in manuals.

Conclusion

It is not often that the Supreme Court issues a decision directly addressing Medicare reimbursement. It is even rarer for that decision to be favorable to hospitals. Rarest of all is a favorable Medicare reimbursement decision from the Supreme Court that has broad implications for the entire Medicare program. Yet, that is precisely what the hospitals received in the Supreme Court's *Allina* decision. That alone is reason for hospitals to celebrate, however the ongoing DSH payment dispute turns out.

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Endnotes

1 *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (June 3, 2019).
2 Petition for a writ of certiorari at 23, *Azar v. Allina Health Servs.* (Apr. 27, 2018).
3 42 U.S.C. § 1395ww(d)(5)(F)(vi).
4 Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, codified at 42 U.S.C. § 1395w-21.
5 *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1106 (D.C. Cir. 2014) (*Allina I*).
6 68 Fed. Reg. 27154, 27208 (May 19, 2003).
7 *See Allina I*, 746 F.3d at 1108.
8 69 Fed. Reg. 48916, 49099, 49246 (Aug. 11, 2004).
9 *See Allina Health Servs. v. Price*, 863 F.3d 937 (D.C. Cir. 2017) (*Allina II*).
10 *See Allina I*, 746 F.3d at 1111.
11 While the D.C. Circuit's opinion in *Allina I* was pending, and perhaps having read the tea-leaves, the Secretary in 2013 issued a new rule that prospectively "readopt[ed] the policy" of treating Part C patients as being entitled to benefits under Part A. 78 Fed. Reg. 50496, 50620 (Aug. 19, 2013). This is why the Supreme Court's decision affects FFY 2004-2013. Challenges to the 2013 rule are pending in federal district court.
12 42 U.S.C. § 1395hh(a)(2).
13 *Allina II*, 863 F.3d at 945.
14 *Azar v. Allina Health Servs.,* at *1811.
15 *Id.* at *1813.
16 *Id.* at *1815.
17 Defendant's Response and Partial Opposition to Plaintiffs' Motion for Judgment at *2-3, *Allina II*, No. 1:14-cv-01415-TJK (July 24, 2019).
18 *Id.* at *3-4.
19 *Id.* at *4 (emphasis added).
20 While retroactive rulemaking is generally disfavored or even prohibited, the Medicare statute allows the Secretary to engage in retroactive rulemaking if he determined that it is "necessary to comply with statutory requirements" or a failure to do so "would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A)(i), (ii).
21 Plaintiffs' Reply in Support of Motion for Judgment at *3-4, *Allina II*, No. 1:14-cv-01415-TJK (July 31, 2019).
22 *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 351–55 (D.C. Cir. 2017).
23 *Id.* at 355-56.
24 *Id.*
25 *Available at* https://www.justice.gov/file/1028756/download.