Brigham Young University Journal of Public Law

Volume 36 | Issue 1 Article 13

Spring 2-1-2022

Implications of Azar v. Allina Health Services on Rulemaking: How to Know When Notice and Comment is Required Under the Medicare Act

John Geilman

Implications of *Azar v. Allina Health Services* on Rulemaking: How to Know When Notice and Comment is Required Under the Medicare Act

Hell hath no fury
Like a woman scorned or a
Hospital cheated

I. INTRODUCTION

In *Azar v. Allina Health Services*, the Supreme Court held in a 7–1 decision that the Department of Health and Human Services ("HHS") could not unilaterally change the reimbursement formula that dictates how much providers are paid for services rendered to individuals covered by Medicare.[1] HHS claimed that it was an interpretive rule change that could be done unilaterally, while the hospitals argued that the Medicare Act required HHS to engage in a notice-and-comment session before making the change.[2] The Supreme Court agreed with the hospitals.[3]

This ruling has caused some serious heartburn for HHS. The result of *Azar v. Allina Health Services* is that more rules promulgated by HHS will need to go through the notice-and-comment process, a process that agencies typically avoid at all costs. Despite HHS' pain, the larger problem is the confusion that has been introduced into the marketplace. As neither hospitals nor HHS are sure what needs to go through the notice-and-comment process, there exists some market uncertainty regarding the efficacy of new rules.

This paper reviews the holding of *Azar v. Allina Health Services* (hereinafter "*Allina II*"),[4] looks to previous tests used by courts under the Administrative Procedure Act (APA) to determine whether a rule was

1. 139 S. Ct. 1804, 1804 (2019).

2. *Id.* at 1811.

3. *Id.*

4. Some papers have begun referring to this decision as *Allina II*, and I have adopted this shorthand. *Allina I*, for those who are curious, is the D.C. Circuit's ruling in a 2014 case involving the 2004 attempt by Medicaid to change the reimbursement formula. *E.g.*, Josh Armstrong, Comment, *Necessary "Procedures": Making Sense of the Medicare Act's Notice-and-Comment Requirement*, 87 U. CHI. L. REV. 2175, 2177 (2020); Lee Nutini, *Supreme Court Will Review Allina II DSH Part C Decision to Resolve Circuit Split on Medicare Rulemaking Requirements*, JDSUPRA (Oct. 9, 2018), https://www.jdsupra.com/legalnews/supreme-court-will-review-allina-ii-dsh-89898/ (last visited Apr. 28, 2021).

substantive or not, examines lower court holdings regarding the substantive boundary under the Medicare Act, and then proposes a test to help hospitals determine whether a rule is substantive in nature and therefore requires the notice-and-comment process.

II. THE ADMINISTRATIVE PROCEDURE ACT

As will be shown in the next section, the main principle in *Allina II* is that the Medicare Act is not the same as the APA. Because *Allina II* is so focused on the differences between the Medicare Act and the APA, a quick summary of the history and pertinent requirements under the APA is appropriate.

In 1933 Franklin Roosevelt became President of the United States with a "New Deal" plan that would end the Great Depression through intense regulations[5] and government spending. To implement his plan, he created and relied on new government agencies, headed by his trusty aide James Landis.[6] He created so many new agencies that his critics (and possibly even his supporters) referred to the acronym-bearing entities as an "alphabet soup."[7]

The New Deal was a massive expansion "of federal agency involvement in people's lives" and "an across-the-board retreat from constitutional doctrines of federalism and separation of powers that had foreclosed the emergence of an activist administrative state."[8] This expansion caused individuals to worry the government had become too powerful and invasive. After a decade of fierce debate over the size and nature of the administrative state, the APA was created, passing unanimously.[9] The APA was designed to regulate the regulators by providing boundaries and safeguards. It reflects the tension between the ideals of an efficient administrative state and an accountable one.

The APA provides multiple methods for agencies to promulgate rules. One such method is referred to as "informal rulemaking."[10] Under this

5. For example, FDR created various Codes of Fair Competition for industries. These codes were very granular and focused on the smallest industries possible. In one instance, instead of lumping the production of foodstuffs as the "food industry," he would regulate the "poultry industry" specifically. A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 521 (1935).

6. Louis L. Jaffe, *James Landis and the Administrative Process*, 78 HARV. L. REV. 319, 319 (1964).

7. TONYA BOLDEN, FDR'S ALPHABET SOUP: NEW DEAL AMERICA, 1932–1939, 36 (2010).

8. GARY LAWSON, FEDERAL ADMINISTRATIVE LAW 322 (8th ed. 2019).

9. *Id.* at 323.

10. Aaron L. Nielson, *In Defense of Formal Rulemaking*, 75 OHIO STATE L.J. 237, 238-39 (2014).

method, an agency must publish the proposed rule and give the public time to comment on the proposed rule.[11] As one can imagine, this "notice-and-comment" method of creating rules takes significant time and effort by the agencies.

The APA provides for several exemptions that agencies can use to avoid the notice-and-comment requirements. One such exemption is for "interpretative rules," in which an agency does not need to promulgate a new rule through the notice-and-comment process if its statement is merely interpreting existing rules or statutes.[12] Another exemption is for "rules of agency organization, procedure, and practice."[13] A third exemption is for "general statements of policy" that agencies can give as guidance to regulated parties.[14] Agencies, in their attempts to avoid the notice-and-comment requirements, have often stretched the boundaries of what sort of guidance can be considered to be interpretive, procedural, or a policy statement. Many cases hinge on whether a rule is substantive[15] (thus requiring notice and comment) or is interpretive, procedural, or a policy statement (thus avoiding notice and comment).

Of particular importance is the fact that the APA is only the *default* for governing agency actions. Statutes can specifically provide for different standards and procedures. Thus, although a statute may require an agency to go through a notice-and-comment procedure, that requirement may be separate from the APA and therefore not governed by APA case law. This distinction is of particular importance in *Allina II*.

III. *AZAR V. ALLINA HEALTH SERVICES*

The debate over the line between substantive and nonsubstantive Medicare rules reached the Supreme Court in *Azar v. Allina Health Services* in 2019.[16] The government has traditionally given extra Medicare payments to hospitals that serve low-income patients. The payment amount is determined by the hospital's "Medicare fraction." "The numerator is the time the hospital spent caring for Part-A-entitled patients who were *also* entitled to income support payments under the Social Security Act," while the "denominator is the time the hospital spent caring

11. 5 U.S.C. § 553.

12. 5 U.S.C. § 553(b)(3)(A). Interpretative rules are often referred to as "interpretive."

13. *Id.*

14. *Id.*

15. It is worth noting that this paper uses the terms "substantive rules" and "legislative rules" interchangeably.

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

for patients who were 'entitled to benefits under' Medicare Part A."[17] Justice Gorsuch summed up the result of this costly arithmetic by stating, "[t]he bigger the fraction, the bigger the payment."[18]

As any fifth grader studying fractions could tell you, there are two ways to decrease a fraction—you decrease the numerator or increase the denominator. The government, mindful of the looming insolvency of the Medicare trust fund,[19] sought to decrease the Medicare fraction and the resulting Medicare payments by increasing the denominator. To increase the denominator, the government tried to include Medicare Part C patients as patients who were entitled to benefits under Medicare Part A. As "Part C enrollees . . . tend to be wealthier than patients who opt for traditional Part A coverage. . . . counting them makes the fraction smaller and reduces hospitals' payments considerably—by between $3 billion and $4 billion over a 9-year period, according to the government."[20]

Originally, HHS had not included Part C patients in the Medicare fraction. It promulgated a rule in 2004 that attempted to include them, but the Court of Appeals, D.C. Circuit, vacated that rule.[21] In response to these legal developments, HHS issued a new, still pending rule in 2013 that prospectively would count Part C patients in the Medicare fraction.[22]

The pertinent dispute in *Allina II* arose in 2014, when HHS calculated the Medicare fractions for the 2012 fiscal year.[23] HHS still wanted to decrease costs, but it could not rely on the pending 2013 rule or the vacated 2004 rule.[24] To get around this, the agency "posted on a website a spreadsheet announcing the 2012 Medicare fractions for 3,500 hospitals nationwide and noting that the fractions included Part C patients."[25] In response to the change, the hospitals brought this action.

The Supreme Court sided with the hospitals and held that the notice-and-comment process was required. The relevant statutory language that governed the dispute is in 42 U.S.C. § 1395hh(a)(2), which is part of the Medicare Act. It requires the government to provide notice and an

17. *Id.* at 1809.

18. *Id.*

19. Rebecca Pifer, *CBO Finds COVID-19 Puts Medicare Trust Fund Insolvency Just 4 Years Away*, HEALTHCAREDIVE (Sept. 4, 2020) https://www.healthcaredive.com/news/cbo-finds-covid-19-puts-medicare-trust-fund-insolvency-just-4-years-away/584725/ (last visited Mar. 27, 2021).

20. *Azar*, 139 S. Ct. at 1809.

21. Allina Health Servs. v. Sebelius, 746 F.3d 1102, 1108 (D.C. Cir. 2014).

22. *Azar*, 139 S. Ct. at 1810.

23. *Id.*

24. *Id.*

25. *Id.*

opportunity to comment on any "rule, requirement, or other statement of policy . . . that establishes or changes a *substantive legal standard* governing . . . the payment for services."[26]

In defense of its unilateral change, the agency argued that (1) § 1395hh(a)(2) differentiated substantive legal standards from *interpretive* legal standards, (2) the change was an interpretive rule, and therefore (3) no notice-and-comment process was required.[27] The hospitals suggested that "the statute means to distinguish a substantive from a *procedural* legal standard."[28] The Supreme Court stated that "[s]everal statutory clues persuade us of at least one thing: The government's interpretation can't be right."[29]

The Supreme Court determined that the Medicare Act does not use the word "'substantive' in the same way as the APA." "[T]he Medicare Act contemplates that 'statements of policy' like the one at issue here *can* establish or change a '*substantive* legal standard' . . . . . Yet, by definition under the APA, statements of policy are *not* substantive; instead they are grouped with and treated as interpretive rules."[30] Another indication that the Medicare Act does not use the word "substantive" like the APA does is that Congress did not reference the APA's notice-and-comment requirements when it wrote § 1395hh(a)(2) even though it specifically referenced the APA in other provisions of the Medicare Act.[31]

The majority opinion pointedly declined to glean a meaning out of legislative history that was "ambiguous at best."[32] It also refuted the government's policy argument that a broad notice-and-comment requirement would be too onerous, as "the government failed to document any draconian costs associated with notice and comment."[33] The majority notably praised the benefits of the notice-and-comment system, as it provides fair warning to affected parties and "affords the agency a chance to avoid errors and make a more informed decision."[34] The Supreme Court summarized its ruling by stating that,

> In the end, all of the available evidence persuades us that the phrase "substantive legal standard," which appears in § 13955hh(a)(2) and

26. 42 U.S.C. § 1395hh(a)(2) (emphasis added).
27. *Azar*, 139 S. Ct. at 1811.
28. *Id.*
29. *Id.*
30. *Id.*
31. *Id.* at 1813.
32. *Id.* at 1814.
33. *Id.* at 1816.
34. *Id.*

> apparently nowhere else in the U.S. Code, cannot bear the same construction as the term "substantive rule" in the APA. We need not, however, go so far as to say that the hospitals' interpretation, adopted by the court of appeals, is correct in every particular. To affirm the judgment before us, it is enough to say the government's arguments for reversal fail to withstand scrutiny. Other questions about the statute's meaning can await other cases. The dissent would like us to provide more guidance . . . but the briefing before us focused on the issue whether the Medicare Act borrows the APA's interpretive-rule exception, and we limit our holding accordingly. In doing so, we follow the well-worn path of declining "to issue a sweeping ruling when a narrow one will do."[35]

This case has several implications. First, based on the high praise given to the notice-and-comment process, it is clear that the Supreme Court prefers for HHS to go through the notice-and-comment process as it makes changes.[36] Second, the threshold requirement for an agency action to need the notice-and-comment process is different under the Medicare Act than it is under the APA. Third, the threshold is much lower under the Medicare Act. Fourth, it is unclear how much lower that threshold is. Indeed, the Supreme Court specifically declined to give a bright line standard, or any standard at all, as to when notice and comment is required. Fifth, while the Supreme Court stated that the line between substantive and interpretive rules under the Medicare Act does not track the boundary in the APA, it did not state whether the Medicare Act similarly rejected the APA boundary between substantive and procedural rules.[37]

IV. PRIOR METHODS OF DETERMINING WHEN RULES REQUIRE NOTICE AND COMMENT

A. APA Cases

With the unmooring of the Medicare Act from the APA's boundary between substantive and interpretive rules, parties involved in the Medicare industry are left with a vaguer standard to determine when notice and comment is needed. A quick review[38] of methods lower courts have used to determine what an interpretive rule or policy statement is under

35. *Id.* at 1814 (quoting McWilliams v. Dunn, 137 S. Ct. 1790, 1800 (2017)).

36. *Id.* at 1816.

37. *Id.* at 1811.

38. The complexity of these cases cannot be understated, and the following case summaries have deliberately sacrificed some completeness for parsimony, as the purpose of this paper is to give suggestions about what hospitals can do in the future, not to contain an exhaustive treatise on interpretive rules under the APA.

the APA provides context and guidance as to what sort of standards hospitals and the HHS should rely on going forward when interpreting the Medicare Act.

It is worth noting that the Supreme Court has not issued a standard, either under the APA or the Medicare Act, regarding whether a rule is substantive, interpretive, or a statement of policy. In 2015 the Court pointedly declined to "wade into that debate."[39] The Court only stated "that the critical feature of interpretive rules is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'"[40] This definition does not give much aid in divining whether a rule is interpretive or not. As such, the lower courts have invented multiple tests in attempts to solve this problem.

The "legal effects" test was used in *Pacific Gas & Electric Co. v. FPC* by the United States Court of Appeals for the D.C. Circuit ("D.C. Circuit") to determine whether the notice-and-comment procedure should have been used by the Federal Power Commission when it made its decision as to which customers would be given higher priority to receive natural gas in the event of a shortage.[41] The court held that notice and comment was not required. The court described the difference between a substantive rule and a general statement of policy by holding that "[a] properly adopted substantive rule establishes a standard of conduct . . . . A general statement of policy, on the other hand, does not establish a 'binding norm.' It is not finally determinative of the issues or rights to which it is addressed."[42] The legal effects test was not without flaws. Professor Gary Lawson pointed out that because regulated parties go to great lengths to comply with agency policy statements, the "*practical effect* of such rules on regulated parties may be hard to distinguish from the practical effect of legislative rules."[43] This test is still in use.[44]

In *American Mining Congress v. Mine Safety & Health Administration*, Judge Williams created a new variant of the legal effects test with his own four-prong test. While Judge Williams later changed this

39. Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015).

40. *Id.* at 97 (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)).

41. Pac. Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 38 (D.C. Cir. 1974).

42. *Id.* at 38 (quoting Reginald Parker, *The Administrative Procedure Act: A Study in Overestimation*, 60 YALE L.J. 581, 597–98 (1951)).

43. LAWSON, *supra* note 8, at 446.

44. *Id.* at 447 n.43.

four-part test by eliminating the second prong,[45] the original test he used is still instructive. He wrote,

> Accordingly, insofar as our cases can be reconciled at all, we think it almost exclusively on the basis of whether the purported interpretive rule has "legal effect", which in turn is best ascertained by asking (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule.[46]

Another test used was the "substantial impact" test, which mainly asked "whether the agency action had an impact on the rights and interests of private parties."[47] The substantial impact test was widely used as a way to stop agencies from circumventing the legal effects test.[48] However, the Supreme Court decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*[49] was widely read as a rejection of the substantial impact test, and the test is no longer used.[50]

The venerable Judge Laurence Silberman in *United States Telephone Association v. FCC* (D.C. Cir.) used the "impact on agencies" test to determine that the FCC had unlawfully created its forfeiture standards.[51] The impact on agencies test focused on whether the agency was bound to its alleged policy statement.[52] The court held that the agency was bound to its alleged policy statement, as the agency had departed from the policy only once in over 300 cases.[53] The court held that this reliance was conclusive evidence that the alleged policy statement was actually a substantive rule.[54] In short, the agency was too bound by its own policy for the rule to be anything but substantive.

In *Syncor International Corp. v. Shalala*, the D.C. Circuit applied the *American Mining* legal effects test but with a strong emphasis on the third

45. Thomas J. Fraser, *Interpretive Rules: Can the Amount of Deference Accorded Them Offer Insight into the Procedural Inquiry?*, B.U. L. REV. 1303, 1315 (2010).

46. Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993).

47. Cabais v. Egger, 690 F.2d 234, 237 (D.C. Cir. 1982).

48. LAWSON, *supra* note 8, at 446.

49. 98 S.Ct. 1197 (1978).

50. LAWSON, *supra* note 8, at 447.

51. United States Tel. Ass'n v. FCC, 28 F.3d 1232, 1236 (D.C. Cir. 1994).

52. *Id.* at 1234.

53. *Id.* at 1235.

54. *Id.*

prong—whether the agency has explicitly invoked its general legislative authority.[55] The court held that the FDA should have gone through the notice-and-comment procedure because its alleged interpretive rule "does not purport to construe any language in a relevant statute or regulation."[56] The alleged interpretive rule could not be interpretive because it was not interpreting anything at all—the only regulation it had relied on for its "interpretation" was the FDA's general power to regulate the industry.[57]

B. Medicare Act Cases

A few recent cases involving interpretive rules under the notice-and-comment requirements in the Medicare Act similarly prove instructive. In 2017 the D.C. Circuit held in *Clarian Health West, LLC v. Hargan* that the Medicare Act did not require HHS to go through the notice-and-comment process for a 2010 manual that included instructions for the reconciliation selection criteria for outlier payments.[58] The court concluded that the manual instructions embody a general statement of policy, not a legislative rule, and consequently did not need to be made through the notice-and-comment process. The court summarized its test as follows:

> Our case law sets out "two lines of inquiry" to guide the determination of whether an action constitutes a legislative rule or a general statement of policy. "One line of analysis considers the effects of an agency's action, inquiring whether the agency has '(1) impose[d] any rights and obligations, or (2) genuinely [left] the agency and its decisionmakers free to exercise discretion.'" The second "looks to the agency's expressed intentions," including "consideration of three factors: '(1) the [a]gency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency.'" As we have noted, the two lines of analysis overlap at the inquiry into whether the action has binding effect, and we have consistently emphasized that this factor is the most important.[59]

In 2019 the District Court for the D.C. Circuit heard *Select Specialty Hospital-Denver, Inc. v. Azar*.[60] Without undergoing the notice-and-comment process, the Center for Medicare and Medicaid Services

55. Syncor Int'l Corp. v. Shalala, 127 F.3d 90, 95 (D.C. Cir. 1997).
56. *Id.*
57. *Id.*
58. Clarian Health W., LLC v. Hargan, 878 F.3d 346, 349 (D.C. Cir. 2017).
59. *Id.* at 357 (citations omitted).
60. Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F. Supp. 3d 53 (D.D.C. 2019).

("CMS"), an agency within HHS, began requiring hospitals to obtain a State Remittance Advice (basically, a form from the state Medicaid program) and submit it before filing for "reimbursement for dual-eligible patients' bad debt."[61] The court acknowledged that this resembled an administrative or procedural requirement, especially considering that it did not change the amount of money owed to providers.[62] However, the court held that it was a substantive change, like the change in *Allina II*, because "CMS changed not just the steps that existing LTCHs must take, vis-à-vis CMS, to be reimbursed, but also changed whether such entities must form contracts with third parties, the state Medicaid programs."[63] Because this "essentially changed the eligibility criteria for reimbursement" by "requiring provider participation in the state Medicaid program," it was deemed a substantive change.[64] The court concluded that this was the sort of "bureaucratic nightmare" that Congress likely sought to avoid by enacting the notice-and-comment requirements of the Medicare Act.[65]

The third case that provides another data point for drawing the interpretive rule boundary line is *Polansky v. Executive Health Resources, Inc.*[66] The District Court of Pennsylvania directly adopted the D.C. Circuit's definition of a substantive legal standard as "a standard that creates, defines, and regulates the rights, duties, and powers of parties," which was the standard that the "Supreme Court stated it was neither adopting nor rejecting."[67] The court tried to reconcile the decisions made by the D.C. Circuit in *Allina II* and *Clarian* by stating that

> If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a "substantive legal standard" . . . . [I]f a policy does not affect the authority of CMS, but simply provides instructions for enforcement, it is more likely not to be characterized as a "substantive legal standard."[68]

61. *Id.* at 68.
62. *Id.*
63. *Id.* at 69.
64. *Id.*
65. *Id.* at 70.
66. Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916 (E.D. Pa. 2019).
67. *Id.* at 934 (quoting Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017)).
68. *Id.* at 934–35.

V. SUGGESTIONS FROM THE ACADEMIC COMMUNITY

One of the most thorough articles on *Allina II* is a law review article by Josh Armstrong, a J.D. candidate at the University of Chicago.[69] He argues that courts should clarify the distinction between substantive and nonsubstantive rules by looking to existing case law regarding the APA's *procedural* exemption to notice-and-comment rules. He argues that this reading would bring immediate clarity and would likely be acceptable "as *Allina [II]* never expressly rules out the possibility that the Medicare statute in effect borrows that exemption."[70]

His argument is not without flaws. First, the Medicare Act does not cross-reference the procedural rule exemption in the APA.[71] Mr. Armstrong does provide several possible reasons that the drafters of the Medicare Act chose not to make this cross-reference, such as the fact that the APA notice-and-comment provision is defined in negative language to which rules are not subject, while the Medicare Act is framed with positive language (to which rules *are* subject).[72] However, in *Allina II*, the Supreme Court found the lack of a cross-reference to the APA's interpretive exemption to be significant evidence that the line between substantive and interpretive rules was different in the Medicare Act than in the APA.[73] As such, despite Mr. Armstrong's good reasons, the lack of a cross-reference to the interpretive rule exemption would presumably again signal to the Court that the APA procedural exemption was not to be strictly borrowed in the Medicare Act. Second, Mr. Armstrong's underlying assumption is that the notice-and-comment requirements are a "burden."[74] The Supreme Court clearly feels differently, as it has held that the notice-and-comment process "affords the agency a chance to avoid errors and make a more informed decision."[75] As such, it is likely that the Supreme Court would not approve a wholesale adoption of the APA procedural exemption given that it prefers for Medicare, "a program where even minor changes to the agency's approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate," to have a tighter

69. Josh Armstrong, Comment, *Necessary "Procedures": Making Sense of the Medicare Act's Notice-and-Comment Requirement*, 87 U. CHI. L. REV. 2175 (2020).

70. *Id.* at 2178.

71. *Id.* at 2201.

72. *Id.*

73. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1813 (2019).

74. Armstrong, *supra* note 69, at 2185, 2211.

75. *Azar*, 139 S. Ct. at 1816.

regulatory leash.[76] It seems more likely that the Supreme Court would rule similarly to *Allina II* and hold that the procedural rule exemption to notice and comment under the Medicare Act is a higher bar to clear than it is under the APA.

Two other academics, Allison Cohen and Tesch West, speculate that the pre-*Allina II* case *Clarian Health West, LLC v. Hargan* gives an indication as to how the Supreme Court might rule in future cases.[77] Cohen and West speculate that the difference in how the D.C. Circuit ruled in *Allina II* (ruling that the payment changes required notice and comment) and in *Clarian* (holding that notice and comment was not required)

> seems to be whether the agency's action (i) creates a new legal standard affecting payment, benefits, or eligibility that was not articulated in and cannot be reasonably derived from a prior rule that has gone through notice-and-comment rulemaking (*Allina [II]*) or (ii) simply explains how to apply an existing legal standard that already has gone through notice-and-comment rulemaking (*Clarian*).[78]

Their prediction is that in the future,

> If a policy or manual guidance cannot be directly derived from a statute or prior regulation, but establishes or changes Medicare payment, scope of benefits, or eligibility, there is a strong argument that it should fall under the Medicare Act's notice-and-comment requirements, even if it could be exempt as an interpretive rule under the APA's rulemaking requirements.[79]

This article, while brief, is very cogent. *Clarian* was decided by the D.C. Circuit, the same circuit court whose ruling was affirmed in *Allina II*. Because the D.C. Circuit was correct in the boundary line in *Allina II*[80] and is typically viewed as the second most important court in the United States,[81] *Clarian* carries significant predictive value. The distinctions drawn by Cohen and West seem reasonable and do offer some predictive value.

76. *Id.*

77. Allison Cohen & Tesch West, *Supreme Court Holds that Under the Medicare Act Certain CMS Policy Statements Require Notice-and-Comment Rulemaking*, 21 J. HEALTH CARE COMPLIANCE 55, 57 (2019).

78. *Id.* at 57–58.

79. *Id.* at 59.

80. *Azar*, 139 S. Ct. at 1805.

81. Aaron L. Nielson, *D.C. Circuit Review—Reviewed: The Second Most Important Court?*, YALE J. ON REGUL.: NOTICE & COMMENT (Sep 4, 2015), https://www.yalejreg.com/nc/d-c-circuit-review-reviewed-the-second-most-important-court-by-aaron-nielson/.

VI. PROPOSED "SIMPLE SUBSTANTIVE TEST"

A. Simple Substantive Test

As is shown by the variety of legal tests used under both the APA and the Medicare Act, there is no consensus about what the "best" test is to determine the boundary between substantive and nonsubstantive rules. Indeed, there is no perfect test. Substantive boundary tests must be applied in a variety of situations, and this wide application means that each test has unique strengths and weaknesses. This paper makes no claim to have created the perfect test. Rather, this paper proposes a "rule of thumb" test that courts can use in determining whether a rule was unlawfully promulgated under the Medicare Act. This test is simple and would provide much needed guidance for CMS and for hospitals.

As the D.C. Circuit's decision was upheld by the Supreme Court, it seems reasonable to adopt the D.C. Circuit's definition of a substantive legal standard as "a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'"[82] However, this overarching standard is still somewhat nebulous. As such, a more specific test would be more useful for courts who are seeking to apply the D.C. Circuit's definition.

In determining whether a rule is a substantive legal standard, courts should ask the following questions. First, is there a substantial financial impact from the new rule? Second, does the rule require hospitals to enter into new contracts? Third, is the rule grounded in a rule passed by Congress or in a rule already passed through the notice-and-comment process? A weighing of the answers to the above questions will give courts a simple method to determine whether the rule was unlawfully created. For ease of use, these questions will be referred to as the "simple substantive" test. If a hospital finds that it has experienced a substantial financial impact, or has been required to enter into new contracts, or that the rule is not grounded in legislative or other regulatory rules, the court should presume that the rule is unconstitutional. While this presumption can be rebutted after further analysis of the situation, it is a useful and simple starting point not only for the courts but also for the regulated parties.

82. Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017) (quoting *Substantive Law*, BLACK'S LAW DICTIONARY (10th ed. 2014)).

B. Substantial Financial and Contractual Impact

The first prong is whether there is a substantial financial impact from the new rule. This is somewhat of a paradigm shift. Many tests, such as the "impact on agencies" test, focus on the effect of the rule on the agency. Indeed, much of administrative law focuses on *how* the agency passes a rule rather than on the *substance* or *impact* of that rule.[83] A paradigm shift in this prong seems appropriate because the definition used by the D.C. Circuit focuses on the "rights, duties, and powers of parties," which includes the regulated parties. The right to own money and property was one of the rights fought for in the American Revolution, and much of the federal Constitution protects that right from government overreach.[84] As this is a critical right, it is appropriate to have a prong that uses money as a proxy to measure how much the government is overstepping its bounds.

The second prong similarly is a paradigm shift but focuses on the impact felt by the hospitals on their right and freedom to contract. This was a critical part of the analysis in *Select Specialty*, in which the District Court noted with disapproval that the substantive CMS policy required the hospitals to contract with and participate in state Medicare programs.[85] As the right to contract[86] is a fundamental right that courts have typically been solicitous of,[87] it is of little surprise that the District Court took care to strike down CMS' attempt to unilaterally force hospitals to contract with certain third parties. As that case is one of the few on point in this area of the law, a prong focusing on contracts seems worthy of inclusion in the simple substantive test.

It is worth noting that these first two prongs both resemble the "substantial impact" that was rejected by the Supreme Court in *Vermont Yankee*.[88] However, *Vermont Yankee* dealt with the standard under the APA, not the Medicare Act. Additionally, the Medicare Act decisions seem to be trending towards something resembling the substantial impact test. The Supreme Court in *Allina II* found the amount of money involved in the Medicare Act to be a significant part of its analysis. Additionally,

83. *E.g.,* Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973).

84. *E.g.,* U.S. CONST. amend. V (the Takings Clause).

85. Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F. Supp. 3d 53, 69 (D.D.C. 2019).

86. The right to contract includes not only the ability to enter into contracts but also the ability to choose who to enter into contracts with, as well as the ability to set terms.

87. The right to contract has long been part of American law and was derived from England. Perhaps the greatest example of the importance of the right to contract is the hesitation courts show to void contracts made by parties. They typically only do so when there is clear fraud or a party is deemed incapable of making a contract.

88. LAWSON, *supra* note 8, at 447.

the D.C. Circuit focused its definition on "the rights, duties, and powers" of the regulated parties under the Medicare Act. As such, it seems appropriate to focus on whether the promulgated rule had a substantial impact on the rights of the regulated parties.

It also seems appropriate to focus the analysis on the financial impact and contracting impact instead of on whether substantial impact is felt in *any* area by hospitals. The right to protect one's property and money from government interference is a fundamental right under the federal Constitution and played a significant role in *Allina II*. The right to contract has also long been viewed as a fundamental right[89] and was the crux of the matter in *Select Specialty*. Thus, it is reasonable to focus the simple substantive test on the impact felt in those two areas. While it is possible to group the two prongs together under a more general heading of "Is the government changing any key rights?," that question is too broad and nebulous to actually be of use to courts.

C. Legal Justification

The third prong is whether the rule is grounded in a rule passed by Congress or in a rule already passed through the notice-and-comment process. This rule borrows somewhat from the first prong of Judge Williams' *American Mining* test, which asked in part "whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties."[90] This prong is part of the simple substantive test because of the strong preference demonstrated by the Supreme Court towards the notice-and-comment procedure in *Allina II*. The Supreme Court stated that the notice-and-comment process is vitally important as it provides fair warning to affected parties and "affords the agency a chance to avoid errors and make a more informed decision."[91]

This strong preference indicates that the Supreme Court prefers for rules to be made via notice and comment whenever possible. It also indicates that rules not made by that preference are more suspect in the eyes of the Supreme Court. As such, if a rule is not thoroughly grounded in legislative laws or rules made via notice and comment, it is more likely that the promulgated rule will be deemed to be substantive.

89. David P. Weber, *Restricting the Freedom of Contract: A Fundamental Prohibition*, 16 YALE HUM. RTS. & DEV. L.J. 51, 52 (2013).

90. Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993).

91. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1816 (2019).

D. Ignored Prior Tests

It is worth noting what tests were *not* incorporated into the proposed simple substantive test. The most prominent one that is missing is whether the promulgated rule has "legal effects." This question is the standard applied in *Pacific Gas* and *American Mining*, two APA cases, and is still used today. There are two reasons that this test was not incorporated into my proposed Medicare Act test. First, as Professor Gary Lawson has pointed out, the legal effects test still allows agencies to regulate through threat using policy statements because regulated parties go to great lengths to comply with policy statements.[92] Second, the test is hard to operationalize, as seen through the amount of variants that have been created of the legal effects test. Third, some prongs of Judge Williams' *American Mining* test, such as whether the rule is grounded in a legislative rule, are already incorporated into the above test.

The other prominent test that was not incorporated into the simple substantive test is the "impact on agencies" test from *United States Telephone*. This test was excluded because the test requires a significant sample size of agency action. In *United States Telephone*, the Supreme Court reviewed over 300 cases to determine whether the agency was bound to the rule.[93] Requiring a large sample size, by default, requires regulated parties to be regulated for a significant amount of time before challenging the action. It is more efficient to have a test that can be used to determine whether to challenge an agency action *before* the rule takes effect.

VII. CONCLUSION

In *Allina II*, the Supreme Court made clear that the APA boundary between substantive and nonsubstantive legal standards does not apply to the substantive boundary under the Medicare Act. This has caused some confusion in the Medicare industry. To ameliorate this confusion, this paper proposes a "rule of thumb" to aid hospitals in their decision-making. This "simple substantive test" consists of three prongs. First, is there a substantial financial impact from the new rule? Second, does the rule require hospitals to enter into new contracts? Third, is the rule grounded in a rule passed by Congress or in a rule already passed through the notice-and-comment process? If a court finds that the rule has a substantial

92. LAWSON, *supra* note 8, at 446.

93. U.S. Tel. Ass'n v. FCC, 28 F.3d 1232, 1235 (D.C. Cir. 1994).

financial impact, requires hospitals to enter into new contracts, or is not grounded in legislative or other regulatory rules, the court should presume that the rule is unlawful.

To be clear, this is not an easy question to answer. Judge Laurence Silberman himself stated that "the distinction between the two types of agency pronouncements has not proved an easy one to draw . . . ." If there were an easy solution, there would be no need for this paper. However, these suggestions may still prove useful to give not only courts but also CMS and hospitals an idea of the shadowy boundary between when notice and comment is required and when it is not.

In the long run, the Supreme Court's decision to require more rules to go through the notice-and-comment procedure will be useful for the healthcare industry. It may sacrifice some speed in creating regulations, but the greater industry input will lead to more tailored rules. More tailored rules will lead to decreased healthcare costs, as hospitals will need to spend less money complying with needless rules. It also will lead to greater ossification of CMS policy, which will create more stability in the market.

In short, *Azar v. Allina Health Services* was undoubtedly a hard pill for CMS and HHS to swallow. However, requiring more rules to be made through the notice-and-comment process will be good medicine for the Medicare industry.

*John Geilman**

* J. Reuben Clark Law School, J.D. 2021. Brigham Young University, B.A. 2018. This note is dedicated to my wife Sarah, whose loving support and selfless sacrifices have made my legal career possible. I also would like to thank Professor Aaron Nielson for introducing me to the world of administrative law, Professor Greg Matis for teaching me about healthcare and haikus, and James Lee and Ben Forsgren for helping me to pass law school with a smile on my face.