

COMMENTS

Necessary “Procedures”: Making Sense of the Medicare Act’s Notice-and-Comment Requirement

Josh Armstrong[†]

The Supreme Court’s recent decision in Azar v Allina Health Services, Inc opened and then declined to resolve a new question of administrative law. In that case, the Court affirmed the DC Circuit’s holding that the Medicare Act, unlike the Administrative Procedure Act (APA), did not exempt so-called “interpretive rules” from notice and comment. Crucially, however, the Supreme Court declined to give any further guidance as to what rules the Medicare Act’s notice-and-comment provision does cover. This lack of guidance added further confusion to an already-murky area of law: the DC Circuit’s current interpretation of the Medicare statute, which is the only one presently left standing, has no fixed limits and is tethered only to a dictionary definition. This Comment argues that courts should clarify the reach of the Medicare Act’s notice-and-comment provision by looking to existing case law interpreting the APA’s exemption to notice and comment for procedural rules. This reading would provide the administrators of the Medicare system with much-needed guidance as to which rules they must subject to notice and comment. With the effective administration of over sixty million Americans’ health insurance on the line, clarifying the statute’s notice-and-comment requirement is a necessary “procedure.”

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[†] BA 2017, The University of Texas at Austin; JD Candidate 2021, The University of Chicago Law School. Many thanks to Professor Jennifer Nou for her help and advice throughout the drafting process.

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INTRODUCTION

Perhaps no problem has caused more consternation and out-right confusion in administrative law circles than the Administrative Procedure Act’s¹ (APA) exemptions to notice-and-comment rulemaking, the process by which agencies present proposed rules to the public for feedback before issuing them in final form. In particular, the exemption for “interpretative rules,”² a term the statute does not define, has spawned a multitude of conflicting tests in the courts and various proposed solutions in the scholarly literature.³ All the while, in more than half a century since the

¹ Pub L No 89-554, 80 Stat 378 (1966), codified in various sections of Title V.

² 5 USC § 553(b)(A). Courts and scholars use the words “interpretative” and “interpretive” interchangeably.

³ See, for example, Nadav D. Ben Zur, Note, *Differentiating Legislative from Nonlegislative Rules: An Empirical and Qualitative Analysis*, 87 Fordham L Rev 2125, 2144–48, 2165 (2019); Jacob E. Gersen, *Legislative Rules Revisited*, 74 U Chi L Rev 1705, 1708–09, 1718–21 (2007); Richard J. Pierce Jr, *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin L Rev 547, 566 (2000); Robert A. Anthony, “Interpretive” Rules, “Legislative” Rules and Spurious Rules: *Lifting the Smog*, 8 Admin L J Am U 1, 15–17 (1994).

APA’s enactment, the Supreme Court has never explained in detail what qualifies as an interpretive rule.⁴

In 2019, the Court heard *Azar v Allina Health Services*⁵ (*Allina II*), a case which administrative law scholars hoped would offer a shred of guidance concerning interpretive rules—but they were disappointed. In that case, the Centers for Medicare and Medicaid Services⁶ (CMS), which administers the Medicare program, had decided without notice and comment to adjust the calculations for deciding how much reimbursement hospitals would receive for treating a “disproportionate share” of low-income patients.⁷ The plaintiffs’ challenge turned not on the APA’s notice-and-comment provision, but on a similar provision in the Medicare Act⁸ requiring notice and comment for any Medicare rule creating or changing a “substantive legal standard.”⁹ The DC Circuit had broken with every other circuit to hold that this provision in the Medicare Act did not incorporate the APA’s exemption for interpretive rules.¹⁰ On appeal, the Supreme Court agreed with the DC Circuit that the phrase “substantive legal standard” in the Medicare Act *did not* exempt interpretive rules, thereby rejecting the position of the majority of circuit courts.¹¹ But the Court also created a new, unresolved question of law by refusing to explain

⁴ See *Perez v Mortgage Bankers Association*, 135 S Ct 1199, 1204 (2015) (declining to “wade into that debate” over the “precise meaning” of “interpretative rule”).

⁵ 139 S Ct 1804 (2019).

⁶ CMS is an agency under the Department of Health and Human Services (HHS), the secretary of which was the nominal plaintiff in the *Allina II* case. Courts sometimes refer to CMS by name, see, for example, *Select Specialty Hospital-Denver, Inc v Azar*, 391 F Supp 3d 53, 62 (DDC 2019), and sometimes refer to it simply as “the agency,” see, for example, *Allina II*, 139 S Ct at 1809–10. In certain factual scenarios, courts may also refer to “the Secretary.” See *Clarian Health West, LLC v Hargan*, 878 F3d 346, 352 (DC Cir 2017) (*Clarian II*). This is because the secretary of HHS, at least formally, has some personal involvement in certain aspects of the Medicare scheme, including the issuance of final rules and the final disposition of reimbursement appeals. See 42 USC §§ 1395hh(a)(1), 1395oo(f). In general, this Comment refers to CMS by name, even where formal authority rests with the HHS secretary.

⁷ See *Allina Health Services v Price*, 863 F3d 937, 938–42 (DC Cir 2017) (*Allina I*), citing 42 USC § 1395ww(d)(5)(F)(i)(I).

⁸ Pub L No 89-97, 79 Stat 286 (1965), codified at 42 USC § 1395 et seq.

⁹ 42 USC § 1395hh(a)(2).

¹⁰ See *Allina I*, 863 F3d 937 at 943. See also *Allina II*, 139 S Ct at 1810 (noting that when “the court of appeals sided with the hospitals” in *Allina I*, it “created a conflict with other circuits”).

¹¹ See *Allina II*, 139 S Ct at 1814.

exactly what that phrase *did* cover and by expressing no opinion on the particulars of the DC Circuit's interpretation.¹²

The disappointment of those who are kept up at night pondering the meaning of a few words in the APA is not the gravest consequence of the *Allina II* decision.¹³ Far more troubling is the uncertainty facing the Medicare system, the country's second-largest domestic spending program, which provides health insurance to over sixty million Americans at a cost of over \$700 billion per year.¹⁴ The DC Circuit's interpretation of the phrase "substantive legal standard" in the Medicare Act was pulled directly from *Black's Law Dictionary* and is noncommittal at best: "A 'substantive legal standard' *at a minimum* includes a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'"¹⁵ And the Supreme Court expressly declined to say whether this interpretation was correct. Suddenly, CMS has no nationally binding guidance (and somewhat uncertain guidance in the DC Circuit) as to which policies it must subject to notice and comment.

CMS could benefit greatly from a clear statement specifying what notice-and-comment standard it will be held to under the Medicare Act. Certainty on that front could lead to more effective administration of the Medicare system for its millions of beneficiaries. To that end, this Comment prescribes a "procedure" to cure the uncertainty: Instead of attempting to divine the distinction between substance and procedure from a dictionary definition, courts hearing notice-and-comment challenges to Medicare rules should look to existing doctrine. Specifically, courts should focus on the case law concerning the APA's other notice-and-comment exemption for "rules of agency organization, procedure, or practice."¹⁶ This interpretation would presumably be permissible under current precedent, as *Allina II* never expressly rules out the possibility that the Medicare statute in effect borrows that exemption.

¹² See id. ("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. . . . Other questions about the statute's meaning can await other cases.").

¹³ I say this as someone who has spent many a sleepless night pondering the meaning of a few words in the Medicare Act.

¹⁴ See *Allina II*, 139 S Ct at 1808.

¹⁵ *Allina I*, 863 F3d at 943 (emphasis added), quoting *Black's Law Dictionary* (West 10th ed 2014).

¹⁶ 5 USC § 553(b)(A).

Part I explains the statutory and precedential background leading up to the *Allina* case, the case itself, and subsequent developments. Part II develops what I term the “reconciled procedural reading” and argues that the Medicare Act’s notice-and-comment provision is most naturally read as the mirror image of the APA’s exemption to notice and comment for “rules of agency organization, procedure, or practice.”¹⁷ Part III applies the prevailing test for that exemption to the facts of existing Medicare cases involving notice-and-comment challenges to illustrate how the test would work in application. Part IV argues that the reconciled procedural reading is better suited than the DC Circuit’s current approach to addressing the policy concerns that both *Allina* decisions left unresolved, and then responds to counterarguments. Given the blows CMS suffered in both *Allina* decisions, I conclude that fixing the limits of the Medicare Act’s notice-and-comment provision isn’t just a matter of statutory interpretation—it’s medically necessary.

I. BACKGROUND

Understanding the questions left open by both *Allina* decisions “requires a tour of the ‘labyrinthine world of Medicare reimbursements’”¹⁸ and of notice and comment more generally. This Part explains the statutory bases for notice-and-comment rulemaking under the APA and the Medicare Act, as well as the relevant case law interpreting both statutes’ notice-and-comment provisions.

A. The APA and Notice-and-Comment Rulemaking

Under the APA, an agency seeking to adopt a new administrative rule ordinarily must first give notice of the proposed rule and subject it to a period of public comment.¹⁹ This procedure imparts important benefits in terms of the rule’s efficacy, respect for

¹⁷ *Id.*

¹⁸ *Community Health Systems, Inc v Burwell*, 113 F Supp 3d 197, 202 (DDC 2015), quoting *District Hospital Partners, LP v Burwell*, 786 F3d 46, 48 (DC Cir 2015). See also *Rehabilitation Association of Virginia, Inc v Kozlowski*, 42 F3d 1444, 1450 (4th Cir 1994) (“There can be no doubt but that the statutes and provisions . . . involving the financing of Medicare and Medicaid[] are among the most completely impenetrable texts within human experience.”).

¹⁹ See 5 USC § 553.

the regulated public's settled expectations, and public accountability for the administrative state.²⁰ The APA makes exceptions to its notice-and-comment requirement, however, for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,"²¹ as well as when there is "good cause" to deviate from notice-and-comment procedures.²² When an agency makes a rule that does not fall under one of the statute's exemptions without notice and comment, it risks a court holding the rule procedurally invalid and therefore not binding on parties.

A complicated taxonomy has evolved to describe different types of rules which are or are not subject to the APA's notice-and-comment requirement. Courts often refer to any rule which is subject to notice and comment as a "substantive" rule, as opposed to an "interpretive" or "procedural" rule, but this practice obscures what are actually two distinctions. The first is between "interpretative rules" and "general statements of policy" on the one hand (sometimes collectively referred to as "nonlegislative rules"),²³ and what scholars generally call "legislative rules" on the other.²⁴ The second is between "substantive" and "procedural"

²⁰ As Professor Richard J. Pierce puts it:

The APA rulemaking procedure has many advantages. It enhances the quality of rules by allowing the agency to obtain a better understanding of a proposed rule's potential effects in various circumstances and by allowing the agency to consider alternative rules that might be more effective in furthering the agency's goals or that might have fewer unintended adverse effects. Second, it enhances fairness by providing all potentially affected members of the public an opportunity to participate in the process of shaping the rules that will govern their conduct or protect their interests. Finally, it enhances political accountability by providing the President and members of Congress a better opportunity to influence the rules that agencies issue.

Pierce, 52 Admin L Rev at 550 (cited in note 3) (citations omitted).

²¹ 5 USC § 553(b)(A).

²² 5 USC § 553(b)(B).

²³ There is also a distinction between "interpretative rules" and "general statements of policy," 5 USC § 553(b)(A), but courts often speak of these categories in the same breath. Indeed, the *Allina II* Court treats the interpretive rule and policy statement exemptions as one. See *Allina II*, 139 S Ct at 1813 ("If, as the government supposes, Congress had also wanted to borrow the *other* APA exemption, for interpretive rules and policy statements, it could have easily cross-referenced that exemption in exactly the same way.") (emphasis in original).

²⁴ See Gersen, 74 U Chi L Rev at 1708–09 (cited in note 3) (discussing various terms used in the literature to distinguish between "legislative" and "nonlegislative" rules).

rules.²⁵ To avoid conflating the two distinctions, this Comment uses the term “legislative” only as the opposite of “interpretive” and “substantive” only as the opposite of “procedural.”²⁶ The following sections describe how courts have attempted to draw the lines as to each of these distinctions, with the DC Circuit’s approach predominating in each.²⁷

1. Legislative versus interpretive rules.

The distinction between legislative and interpretive rules is a notoriously intractable question of administrative law. It has become a cliché in scholarship to refer to a “considerable smog” clouding this distinction.²⁸ For over half a century, the Supreme Court has refused to offer detailed guidance as to what makes a rule interpretive within the meaning of the APA. Recently, in *Perez v Mortgage Bankers Association*,²⁹ the Court insisted that it “need not, and [would] not, wade into [the interpretive rule] debate here.”³⁰ Instead, the Court maintained, “It suffices to say 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.’”³¹

The lower courts have thus been left to define the line between legislative and interpretive rules on their own—a task which has proved challenging, to say the least. Since this distinction determines whether an agency must put a new rule through the costly notice-and-comment process before issuing it, indeterminacy in line drawing has very real consequences.

²⁵ See, for example, *Allina II*, 139 S Ct at 1811 (describing the plaintiffs’ contention that 42 USC § 1395hh(a)(2) was intended to distinguish between substantive and *procedural* rules, not substantive and *interpretive* rules).

²⁶ “Interpretive” and “procedural” are each sufficient (but not individually necessary) conditions to exempt a rule from the APA’s notice-and-comment requirements. 5 USC § 553(b)(A). Only rules which are both legislative and substantive must undergo notice and comment under the APA.

²⁷ The DC Circuit is widely considered to be the most influential court of appeals on matters of administrative law, largely due to its geographic jurisdiction over the seats of most federal agencies and, as a result, its comparatively larger administrative law docket. See generally Arthur E. Bonfield, *The Contribution of the DC Circuit to Administrative Law*, 40 Admin L Rev 507 (1988).

²⁸ See, for example, Anthony, 8 Admin L J Am U at 4 (cited in note 3) (“It helps no one for the courts repetitiously to incant clichés about how the distinctions are ‘fuzzy’ or ‘enshrouded in considerable smog.’”) (citations omitted).

²⁹ 135 S Ct 1199 (2015).

³⁰ Id at 1204.

³¹ Id, quoting *Shalala v Guernsey Memorial Hospital*, 514 US 87, 99 (1995).

The most cited case on the distinction between legislative and interpretive rules is the DC Circuit's opinion in *American Mining Congress v Mining Safety & Health Administration*,³² holding that the relevant question is:

[W]hether 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.³³

This four-part test won much adoration in the academy after its announcement,³⁴ but its effect in clearing the smog was limited. While other courts have cited *American Mining Congress* with approval, few have applied it mechanically, and many have supplemented it in ways that have further confused the doctrine.³⁵ Even the DC Circuit altered the test in subsequent decisions, first downplaying the Code of Federal Regulations factor³⁶ and then changing the fourth factor (whether a rule amends a prior *legislative* rule) to ask whether the rule amends a prior *interpretive* rule (a factor the Supreme Court has since rejected).³⁷ The current

³² 995 F2d 1106 (DC Cir 1993).

³³ Id at 1112.

³⁴ See Pierce, 52 Admin L Rev at 561 (cited in note 3) (describing how the *American Mining Congress* test "was widely praised in casebooks, treatises, and hornbooks").

³⁵ See id at 548 n 16 (collecting cases).

³⁶ See *Health Insurance Association of America, Inc v Shalala*, 23 F3d 412, 423 (DC Cir 1994) (noting that "[i]n none of the cases citing the distinction [between legislative and interpretive rules] . . . has the court taken publication in the Code of Federal Regulations, or its absence, as anything more than a snippet of evidence of agency intent").

³⁷ See *Paralyzed Veterans of America v DC Arena*, 117 F3d 579, 586–87 (DC Cir 1997), abrogated, *Mortgage Bankers Association*, 135 S Ct at 1206. The Court in *Mortgage Bankers Association* rejected the DC Circuit's new formulation of the factor because it found no textual support in the APA for the proposition that changing a prior *interpretive* rule requires notice and comment. *Mortgage Bankers Association*, 135 S Ct at 1206. It did not rule out the possibility that changing a prior *legislative* rule requires notice and comment. Id at 1210.

state of the doctrine is not so much a competition between definitive tests as a sea of different factors that courts mix and match selectively to differentiate legislative from interpretive rules.³⁸

2. Substantive versus procedural rules.

The APA also exempts “rules of agency organization, procedure, or practice” from notice-and-comment rulemaking.³⁹ Again, the Supreme Court has provided little guidance as to what constitutes a procedural rule, except to imply that a rule being confined to mere “housekeeping” measures is a sufficient condition for falling under that exemption.⁴⁰ The APA’s procedural rule exemption seems to be litigated less often than its interpretive rule exemption, leading to somewhat underdeveloped case law in some circuits and even conflation of interpretive and procedural rules.⁴¹ While the circuits have yet to coalesce around a single approach to the procedural rule exemption, the tests currently in use are at least simpler than those for the interpretive rule exemption. The DC Circuit and the Fifth Circuit offer the two clearest alternative approaches to identifying procedural rules under the APA.

While the DC Circuit has not used precisely the same language in every case, it staked out its basic position regarding the procedural rule exemption—what I call the “substantive-value-judgment test”—in *American Hospital Association v Bowen*.⁴² Under *American Hospital Association*, a rule is not substantive simply because of its practical effect on regulated parties; it must “also encode[] a substantive value judgment or put[] a stamp of approval or disapproval on a given type of behavior.”⁴³ In other words, the DC Circuit looks not only to a rule’s impact, but also to its underlying purpose, “reflect[ing] a candid recognition that even unambiguously procedural measures affect parties to some

³⁸ For analysis of these different factors and of their relative popularity and effect on outcomes, see generally Ben Zur, 87 Fordham L Rev 2125 (cited in note 3). Since the Supreme Court has held that the Medicare Act does not exempt interpretive rules from notice and comment, see *Allina II*, 139 S Ct at 1814, this Comment forgoes any further attempt to make sense of the doctrine surrounding that exemption.

³⁹ 5 USC § 553(b)(A).

⁴⁰ See *Chrysler Corp v Brown*, 441 US 281, 311–12 (1979).

⁴¹ See, for example, *Chao v Rothermel*, 327 F3d 223, 227 (3d Cir 2003) (“*Interpretive, or ‘procedural,’ rules do not themselves shift the rights or interests of the parties, although they may change the way in which the parties present themselves to the agency.*”) (emphasis added).

⁴² 834 F2d 1037 (DC Cir 1987).

⁴³ *Id* at 1047.

degree.”⁴⁴ The DC Circuit further elaborated this nuanced approach in the now-vacated case of *Air Transport Association of America v Department of Transportation*,⁴⁵ emphasizing the importance of the language Congress chose: “In using the terms ‘rules of agency organization, procedure, or practice,’ Congress intended to distinguish not between rules affecting different *classes of rights*—‘substantive’ and ‘procedural’—but rather to distinguish between rules affecting different *subject matters*—‘the rights or interests of regulated’ parties, . . . and agencies’ ‘internal operations.’”⁴⁶

While *Air Transport’s* precedential value is now uncertain,⁴⁷ it illustrates how the substantive-value-judgment test first announced in *American Hospital Association* looks beyond a rule’s practical effect on regulated parties. Roughly speaking, the DC Circuit’s procedural rule test differentiates between rules that deal primarily with the behavior of the regulated public (substantive rules) and those that deal primarily with the internal workings of the agency (procedural rules), regardless of incidental impacts on regulated parties.

The Fifth Circuit, by contrast, applies a blunter instrument to distinguish substantive from procedural rules: the substantial-impact test.⁴⁸ Under that test, any “agency rule that modifies substantive rights and interests can only be nominally procedural,” and therefore must undergo notice and comment.⁴⁹ This approach may seem to follow intuitively from the distinction between substance and procedure, but it has proven controversial. Other circuits have rejected the substantial-impact test out of concern that it jettisons the text of the procedural rule exemption altogether and swallows up a number of rules Congress did not intend to subject to notice and comment.⁵⁰

⁴⁴ *Id.*

⁴⁵ 900 F2d 369 (DC Cir 1990), vacd as moot, 933 F2d 1043 (DC Cir 1991).

⁴⁶ *Id.* at 378 (emphasis in original), quoting *American Hospital Association*, 834 F2d at 1041, 1047.

⁴⁷ For discussion of *Air Transport* and the extent to which it is still good law, see notes 172–75 and accompanying text; note 181.

⁴⁸ See *Texas v United States*, 787 F3d 733, 765–66 (5th Cir 2015) (endorsing the substantial-impact test as “the primary means . . . [to] look beyond the label ‘procedural’ to determine whether the rule is of the type Congress thought appropriate for public participation”) (quotation marks omitted) (alteration in original), quoting *Department of Labor v Kast Metals Corp*, 744 F2d 1145, 1153 (5th Cir 1984).

⁴⁹ *Texas v United States*, 787 F3d at 765–66, quoting *Kast Metals Corp*, 744 F2d at 1153.

⁵⁰ See, for example, *Sequoia Orange Co v Yeutter*, 973 F2d 752, 757 (9th Cir 1992) (“We have rejected the notion that procedural rules with a substantive impact are subject

All else equal, agencies almost certainly prefer that courts scrutinize their putative procedural rules under the substantive-value-judgment test. It is easy to see why. Asking whether a rule has a “substantial impact” on “substantive rights and interests” might seem cleaner than the DC Circuit’s “more intricate process.”⁵¹ Without the limiting principle of the substantive-value-judgment test, however, the Fifth Circuit’s test is less forgiving to agencies seeking to administer their programs without the constant burden of notice and comment. Aside from the obvious implications on the rights of regulated parties, the choice between the two involves a trade-off between agency flexibility and judicial economy. As we shall see later,⁵² when flexibility is of special concern, the substantive-value-judgment test is an attractive choice.

B. The Medicare Act Amendments of 1987

1. History of the amendments and early case law interpreting § 1395hh(a)(2).

Generally speaking, public benefits programs like Medicare are not subject to the APA’s notice-and-comment requirement.⁵³ Nonetheless, for much of its early history, CMS’s predecessor, the Health Care Financing Administration (HCFA), subjected many of its rules to notice and comment voluntarily.⁵⁴ During the 1980s,

to the notice and comment requirements.”) (quotation marks omitted), opinion amended on denial of rehearing, 985 F2d 1419 (9th Cir 1993). See also *American Hospital Association*, 834 F2d at 1047 (“The [DC Circuit’s] gradual move away from looking solely into the substantiality of the impact reflects a candid recognition that even unambiguously procedural measures affect parties to some degree.”). In the past, some courts also employed the substantial-impact test to differentiate legislative from interpretive rules, but the test has since been roundly rejected in that context. For an excellent account of the factors that led to the substantial-impact test’s near-demise, see generally Kathleen Taylor, Note, *The Substantial Impact Test: Victim of the Fallout from Vermont Yankee?*, 53 Geo Wash L Rev 118 (1984).

⁵¹ *Texas v United States*, 787 F3d at 765–66.

⁵² See Part III.

⁵³ See *Allina II*, 139 S Ct at 1808. This is because § 553, which governs the notice-and-comment process, does not apply to any “matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.” 5 USC § 553(a)(2). Unless the organic statute (that is, the statute authorizing the agency to act) specifies otherwise, the agency is free to issue any rule concerning this subject matter without notice and comment regardless of whether it falls under one of the § 553(b) exemptions outlined above.

⁵⁴ See *Allina II*, 139 S Ct at 1820–21 (Breyer dissenting) (describing the impetus for and history of the Medicare Act amendments of 1987). See also Part II.B.

however, HCFA loosened its commitment to this practice.⁵⁵ In response, Congress amended the Medicare Act in 1986⁵⁶ and again in 1987⁵⁷ to codify a requirement that certain Medicare rules go through notice and comment. The final statutory provision read in relevant part:

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a *substantive legal standard* governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under [42 USC § 1395hh(a)(1)].⁵⁸

The Medicare Act amendments included some notable deviations from the APA. Most importantly, whereas the APA specifies which rules are *exempt from* notice and comment,⁵⁹ the Medicare Act specifies which rules are *subject to* notice and comment: “substantive legal standard[s].”⁶⁰ In other words, the APA defines its notice-and-comment coverage in the negative, while the Medicare Act defines its notice-and-comment coverage in the positive. As we shall see later,⁶¹ this framing difference could have important implications on the proper interpretation of the Medicare Act.

Just a few years ago, the Medicare Act amendments would have seemed of no special significance to the notice-and-comment debate. For decades, the courts of appeals that confronted the question universally held that the scope of the term “substantive legal standard” in the Medicare Act was coextensive with that of legislative rules under the APA. Therefore, courts agreed that the Medicare Act, like the APA, did not subject interpretive rules to

⁵⁵ See *Allina II*, 139 S Ct at 1820–21 (Breyer dissenting). The legislative history and the Federal Register contain little indication of why HCFA drifted away from notice and comment, but it is easy to imagine the temptation of an agency not statutorily bound by § 553 to issue rules without jumping through procedural hoops when the agency thinks it can get away with that.

⁵⁶ Omnibus Budget Reconciliation Act of 1986, Pub L No 99-509 § 9321(e), 100 Stat 1874, 2017–18 (1986), codified at 42 USC § 1395hh. For discussion of the 1986 amendments, see Part II.B.2.

⁵⁷ See Omnibus Budget Reconciliation Act of 1987, Pub L No 100-203 § 4035(b)(2), 101 Stat 1330-55, 1330-78 (1987), codified at 42 USC § 1395hh(a)(2).

⁵⁸ 42 USC § 1395hh(a)(2) (emphasis added).

⁵⁹ See 5 USC § 553(b).

⁶⁰ 42 USC § 1395hh(a)(2).

⁶¹ See Part II.B.

notice and comment.⁶² A few circuits declined to decide the question,⁶³ while those that did typically disposed of it in one or two sentences without much analysis.⁶⁴ It would be decades before any court took a contrary position.

2. The *Allina* case.

In 2017, the DC Circuit issued its opinion in *Allina Health Services v Price*⁶⁵ (*Allina I*), becoming the first court to hold that the Medicare Act’s notice-and-comment requirement for “substantive legal standard[s]”⁶⁶ was different from the APA’s for legislative rules.⁶⁷ The case concerned CMS’s decision to start including Medicare Part C beneficiaries in the “fractions” it used to calculate reimbursement to hospitals treating disproportionate numbers of low-income patients.⁶⁸ Since Part C beneficiaries are typically wealthier than other Medicare beneficiaries, the inclusion of Part C patients in the calculation resulted in some hospitals receiving significantly less “disproportionate share” reimbursement.⁶⁹ The plaintiffs, hospitals that treated a significant number of Part C beneficiaries, argued that § 1395hh(a)(2) required CMS to subject its new policy to notice and comment.⁷⁰

In a unanimous opinion by then-Judge Brett Kavanaugh, a panel of the DC Circuit agreed. The Government argued that the change in calculations amounted to an interpretive rule within the meaning of the APA, but the court saw that issue as irrelevant because “the Medicare Act does not incorporate the APA’s interpretive-rule exception to the notice-and-comment requirement.”⁷¹ After describing the textual differences between the two

⁶² See, for example, *Via Christi Regional Medical Center, Inc v Leavitt*, 509 F3d 1259, 1271 n 11 (10th Cir 2007); *Baptist Health v Thompson*, 458 F3d 768, 776 n 9 (8th Cir 2006); *Omni Manor Nursing Home v Thompson*, 151 F Appx 427, 431 (6th Cir 2005); *Warder v Shalala*, 149 F3d 73, 79 n 4 (1st Cir 1998).

⁶³ See *Erringer v Thompson*, 371 F3d 625, 633 (9th Cir 2004); *Monmouth Medical Center v Thompson*, 257 F3d 807, 814 (DC Cir 2001).

⁶⁴ See, for example, *Baptist Health*, 458 F3d at 776 n 8 (“As a corollary, [the plaintiff] argues that the change in position violates Medicare rule-change procedures in 42 U.S.C. § 1395hh(a)(2). . . . However, we agree with the courts that have held that this provision imposes no standards greater than those established by the APA.”).

⁶⁵ 863 F3d 937 (DC Cir 2017).

⁶⁶ 42 USC § 1395hh(a)(2).

⁶⁷ *Allina I*, 863 F3d at 944.

⁶⁸ *Id* at 938–40.

⁶⁹ *Id*.

⁷⁰ *Id* at 940–41.

⁷¹ *Allina I*, 863 F3d at 944.

statutes, the court concluded that it “must respect Congress’s use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA.”⁷² The court did not go into much detail, however, in explaining precisely *how* the Medicare Act’s requirement differs from the APA’s. In what I term the “dictionary approach,” it cited a dictionary definition of “substantive law” for the proposition that “[a] ‘substantive legal standard’ at a minimum includes a standard that ‘creates, defines, and regulates the rights, duties, and powers of parties,’” and reasoned that “[t]hat is precisely what HHS’s 2012 Medicare fractions do.”⁷³ The DC Circuit in *Allina I* thus created a circuit split as to whether the APA and Medicare Act’s notice-and-comment requirements are coextensive,⁷⁴ but offered an incomplete answer as to precisely where the Medicare Act draws the line.

Partial resolution of this circuit split came in short order. In *Allina II*, the Supreme Court affirmed the DC Circuit’s holding that the Medicare Act did not incorporate the APA’s interpretive rule exemption. Justice Neil Gorsuch’s majority opinion, however, expressly declined to say where the Medicare Act drew the line between rules that are subject to notice and comment and those that are not. The Court decided the issue on perhaps the narrowest grounds possible, holding simply that “the phrase ‘substantive legal standard,’ which appears in [§ 1395hh(a)(2)] and apparently nowhere else in the U.S. Code, cannot bear the same construction as the term ‘substantive rule’ in the APA.”⁷⁵ The Court found it unnecessary to “go so far as to say that the [plaintiffs’] interpretation,

⁷² *Id.*

⁷³ *Id.* at 943, quoting *Black’s Law Dictionary* (West 10th ed 2014).

⁷⁴ See *Allina I*, 863 F3d at 945 (“We recognize that we are breaking with several other courts of appeals by holding that the Medicare Act does not incorporate all of the APA’s exceptions to the notice-and-comment requirement.”). For an argument (made before the Supreme Court decided the issue) that the DC Circuit was wrong to do so, see Graham Haviland, Comment, *Not So Different After All: The Status of Interpretive Rules in the Medicare Act*, 85 U Chi L Rev 1511, 1527–40, 1542 (2018) (“[T]he DC Circuit misinterpreted the term ‘substantive legal standard’ and unduly emphasized the statute’s express exceptions in arguing that interpretive rules are subject to the statute’s notice-and-comment requirement.”).

⁷⁵ *Allina II*, 139 S Ct at 1814. Note that the Court used the word “substantive” here as the opposite of “interpretive” rather than as the opposite of “procedural.” See *id.* at 1811 (“Under the APA, ‘substantive rules’ are those that have the ‘force and effect of law,’ while ‘interpretive rules’ are those that merely ‘advise the public of the agency’s construction of the statutes and rules which it administers.’”), quoting *Mortgage Bankers Association*, 135 S Ct at 1204.

adopted by the court of appeals, is correct in every particular.”⁷⁶ Instead, it concluded, “It is enough to say the government’s arguments for reversal fail to withstand scrutiny.”⁷⁷ The Court thus established that whatever the Medicare Act *did* exempt from notice and comment, it *did not* exempt interpretive rules.

As the lone dissenter,⁷⁸ Justice Stephen Breyer criticized this lack of guidance, accusing the majority of “not only leav[ing] the APA behind,” but also “fail[ing] to substitute any reasonably clear alternative standard.”⁷⁹ He noted that CMS “has issued tens of thousands of pages of manual instructions, interpretive rules, and other guidance documents.”⁸⁰ Justice Breyer worried that application of the *Allina I* standard, which the majority did not rule out, might invalidate a significant number of these rules, and could “substantially undermine and even cripple the administration of the Medicare scheme.”⁸¹ He further warned that the majority’s “lack of explanation” concerning the appropriate standard could “lead to legal challenges to the validity of interpretive rules (or even procedural rules) previously thought to have been settled”⁸² and gave a list of provisions in CMS’s Provider Reimbursement Manual that could be in danger.⁸³

The majority downplayed Justice Breyer’s concerns, pointing out that he cited “only eight manual provisions that courts have deemed interpretive over the last four decades.”⁸⁴ Moreover, the majority claimed, the Government had not argued “that providing notice and comment for these or any other specific manual provisions would prove excessively burdensome,” nor had it pointed to “any court decision invalidating a manual provision under

⁷⁶ *Allina II*, 139 S Ct at 1814.

⁷⁷ *Id.*

⁷⁸ Justice Kavanaugh, the author of the DC Circuit’s opinion, took no part in the consideration of the case on appeal. See *id.* at 1808.

⁷⁹ *Id.* at 1823 (Breyer dissenting).

⁸⁰ *Allina II*, 139 S Ct at 1822 (Breyer dissenting).

⁸¹ *Id.* (quotation marks omitted).

⁸² *Id.* at 1824.

⁸³ *Id.* at 1822–23.

⁸⁴ *Allina II*, 139 S Ct at 1816 (majority) (emphasis omitted).

§ 1395hh(a)(2) in the nearly two years since” *Allina I* was decided.⁸⁵ Nevertheless, the majority refused to provide its own definition of “substantive legal standard,” insisting that “[o]ther questions about the statute’s meaning can await other cases.”⁸⁶

So here is the effect of *Allina II*: The Supreme Court has closed one question and left another wide open. We now know that “substantive legal standard” does not mean the same thing as “legislative rule,” but we have no idea what it does mean. In essence, the Court merely ruled out one of many possible interpretations of the Medicare statute. The DC Circuit has offered one plausible (if incomplete) interpretation, and now the other circuits can choose either to adopt that interpretation or to propose a new one, so long as it is not coextensive with the definition of legislative rules under the APA. With the ink barely dry on *Allina II*, it remains to be seen whether courts will take that decision as an invitation to innovate.

3. Subsequent developments.

In the DC Circuit, which is still committed to its dictionary approach, only two further cases implicating the Medicare Act’s notice-and-comment requirement have received a final judgment on the merits since *Allina I*. These cases reached opposite conclusions. In *Clarian Health West, LLC v Hargan*⁸⁷ (*Clarian II*), decided before the Supreme Court’s *Allina II* decision, the DC Circuit held that new guidance concerning when to *apply* an old reimbursement formula did not alter a substantive legal standard because it did not change the plaintiff hospitals’ entitlement to reimbursement—it simply changed the procedures for *processing* that reimbursement.⁸⁸ *Clarian II* did not alter the dictionary approach and presumably remains good law in the DC Circuit following the Supreme Court’s refusal to take a position on that approach in *Allina II*.

⁸⁵ Id. The first of these contentions took some liberty in characterizing the Government’s argument. The Government did in fact argue that “the court of appeals’ rationale, if taken to its logical conclusion, would subject nearly *all* of CMS’s nonbinding manuals and interpretive materials to the notice-and-comment process” and that it would be “difficult even to estimate the disruptive effect that would have on the Medicare program.” Brief for the Petitioner, *Azar v Allina Health Services*, No 17-1484, *42 (US filed Nov 13, 2018) (alteration in original) (available on Westlaw at 2018 WL 5962884) (*Azar* Brief).

⁸⁶ *Allina II*, 139 S Ct at 1814.

⁸⁷ 878 F3d 346 (DC Cir 2017).

⁸⁸ Id at 354–56.

Following *Allina II*, the DC District Court decided *Select Specialty Hospital-Denver, Inc v Azar*.⁸⁹ In that case, CMS had required that providers obtain a certain form, available in some states only to Medicaid-participating providers, in order to receive reimbursement for unpaid debts of patients eligible for both Medicare and Medicaid.⁹⁰ Some of the plaintiff hospitals were unable to enroll in Medicaid under state law.⁹¹ The court held that the rule *did* alter a substantive legal standard because it “essentially changed the eligibility criteria for reimbursement . . . by requiring provider participation in the state Medicaid program.”⁹² In a subsequent opinion denying HHS’s motion for reconsideration, the court explained that under the DC Circuit’s interpretation, § 1395hh(a)(2) “‘distinguishes a substantive from a procedural legal standard,’ and requires that CMS conduct notice and comment rulemaking for changes to the former but not to the latter type of standard.”⁹³

Taking *Allina I*, *Clarian II*, and *Select Specialty Hospital* as the only three data points for courts bound by the DC Circuit’s dictionary approach to § 1395hh(a)(2), it is difficult to produce any more than a rough sketch of that interpretation’s limits. It cannot be a pure substantial-impact test, as the policy at issue in *Clarian II* cost the plaintiff hospital over \$2 million in reimbursement.⁹⁴ But *Select Specialty Hospital*’s invalidation of a rule that, in at least some applications, seems to have been aimed at procedural efficiency might imply that the dictionary approach affords agencies somewhat less flexibility than does *American Hospital Association*’s substantive-value-judgment test.⁹⁵

At least one court outside the DC Circuit has offered a unifying theory of the cases applying the dictionary approach. In *Po-lansky v Executive Health Resources, Inc*,⁹⁶ the Eastern District of

⁸⁹ 391 F Supp 3d 53 (DDC 2019).

⁹⁰ *Id.* at 58–60.

⁹¹ *Id.*

⁹² *Id.* at 69.

⁹³ *Select Specialty Hospital-Denver, Inc v Azar*, 2019 WL 5697076 at *3 (DDC) (emphasis in original) (alteration omitted), quoting *Allina II*, 139 S Ct at 1811.

⁹⁴ *Clarian II*, 878 F3d at 351–52.

⁹⁵ I admit this characterization lacks some nuance. For a thorough discussion of how the dictionary approach and the *American Hospital Association* test might differ as applied to *Select Specialty Hospital*, see Part III.B.2.

⁹⁶ 422 F Supp 3d 916 (ED Pa 2019). The facts of this case are not important for understanding the court’s treatment of the dictionary approach, but they become relevant in contrasting that approach with the substantive-value-judgment test. Accordingly, I explain the facts later. See notes 208–12 and accompanying text.

Pennsylvania adopted the DC Circuit's interpretation of § 1395hh(a)(2)⁹⁷ and fleshed out that interpretation by comparing the facts and dispositions of *Allina I*, *Clarian II*, and *Select Specialty Hospital*.⁹⁸ According to the *Polansky* court, those cases

illuminate[] a distinction between, on the one hand, rules that determine reimbursement and, on the other, statements that set forth enforcement policies. If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a “substantive legal standard” under the Circuit's definition. Conversely, if 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.”⁹⁹

If this characterization is correct, it seems conceptually different from the DC Circuit's approach to procedural rules under the APA, which focuses on a rule's subject matter rather than the rule's outcome-determinacy alone.¹⁰⁰ It is not clear that this distinction is what the DC Circuit had in mind when it decided *Allina I* and *Clarian II*, but it is perhaps the most persuasive explanation of how those cases fit together with each other and with *Select Specialty Hospital*. At any rate, *Polansky* is currently the only decision outside the DC Circuit to offer a detailed explanation of its interpretation of § 1395hh(a)(2).¹⁰¹ It remains to be seen whether other courts will offer alternative interpretations.

II. THE RECONCILED PROCEDURAL READING

In some sense, *Allina II* has sent the search for the meaning of “substantive legal standard” back to square one. The Supreme

⁹⁷ *Polansky*, 422 F Supp 3d at 934 (“This Court adopts the District of Columbia Circuit's definition for ‘substantive legal standard’ and will assess the Medicare Act's notice and comment requirement as it applies to the [challenged policy] accordingly.”).

⁹⁸ See id at 934–36.

⁹⁹ Id at 934–35.

¹⁰⁰ See Part I.A.2.

¹⁰¹ Two other cases implicating *Allina* bear mentioning. In *Agendia, Inc v Azar*, 420 F Supp 3d 985 (CD Cal 2019), the Central District of California appeared to adopt the DC Circuit's dictionary approach in the process of deciding that § 1395hh(a)(2) applies to local coverage determinations made by CMS's contractors even though the statute expressly exempts national coverage determinations made by CMS. Id at 987–89, 997. And in *Yale New Haven Hospital v Azar*, 2020 WL 2204197 (D Conn), the District of Connecticut expressed no opinion on the proper interpretation of the phrase “substantive legal standard,” simply concluding in a footnote that it was “undisputed” that the rule at issue in that case established such a standard. Id at *11 n 10.

Court remained agnostic as to whether § 1395hh(a)(2) was intended to differentiate substantive from procedural rules.¹⁰² The DC Circuit has suggested as much, but it has thus far refrained from applying its more nuanced test for the APA’s procedural rule exemption¹⁰³ in the Medicare context. Instead, it has offered some general meditations on substance and procedure, supported only by a dictionary definition and untethered to any preexisting body of case law.

Rather than conjuring a novel definition of “substantive legal standard” out of thin air, I argue that the best reading of § 1395hh(a)(2) is one that draws precisely the same line that the APA draws between substantive and procedural rules. This Part lays out what I term the “reconciled procedural reading”—a reading that explains how Congress could have attempted to accomplish the same effect between the two statutes by using different language. Part II.A explains how the text of the APA’s procedural rule exemption fits into the logic of *Allina II* and the Medicare statute. Part II.B examines the legislative history of the Medicare Act amendments and argues that incorporating the APA’s procedural rule exemption is likely what Congress had in mind all along.

A. The Logic of *Allina II* and the Puzzle of the Medicare Act’s Text

The *Allina II* majority spent a great deal of time comparing the text of the Medicare Act with that of the APA to rule out the possibility that the former exempts interpretive rules from notice and comment. Section 553(b) of the APA includes four exemptions to that statute’s notice-and-comment requirement: “[1] interpretive rules, [2] general statements of policy, . . . [3] rules of agency organization, procedure, or practice,” and “[4] good cause.”¹⁰⁴ The Court in *Allina II* set out to take stock of these categories in the text of the Medicare Act, but it only counted to three.

In the majority’s view, the text of the Medicare statute expressly eschews the APA’s exemption to notice and comment for “general statements of policy.”¹⁰⁵ First, the Court noted that § 1395hh(a)(2) itself “contemplates that ‘statements of policy’ . . .

¹⁰² See Part I.B.2.

¹⁰³ See Part I.A.2.

¹⁰⁴ 5 USC § 553(b)(A)–(B).

¹⁰⁵ 5 USC § 553(b)(A).

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.”¹⁰⁶ The Court then pointed out that another provision of the statute, § 1395hh(e)(1), “gives the government limited authority to make retroactive ‘substantive change[s]’ in, among other things, ‘interpretative rules’ and ‘statements of policy.’”¹⁰⁷ The Court concluded that “this statutory authority would make no sense if the Medicare Act used the term ‘substantive’ as the APA does,” because “interpretive rules and statements of policy—and any changes to them—are *not* substantive under the APA by definition.”¹⁰⁸ Notably, the subsection the Court pointed to makes no mention of procedural rules.¹⁰⁹ Thus, the Court did not expressly rule out the possibility that the Medicare Act adopts the APA’s procedural rule exemption.

The good cause exemption¹¹⁰ is even easier, because the Medicare Act incorporates it expressly by cross-reference in § 1395hh(b)(2)(C).¹¹¹ The Court viewed this fact as another indication that Congress did not intend to borrow the interpretive rule exemption because the statute’s drafters “could have easily cross-referenced that exemption in exactly the same way” but chose not to.¹¹² So far, so good: the policy statement exemption is not incorporated into the Medicare Act, the good cause exemption is, and the procedural rule exemption is still theoretically in play.¹¹³

The Court then concluded that the Medicare Act does not borrow the APA’s exemption for interpretive rules.¹¹⁴ It did so for three main reasons. First, the Medicare Act groups interpretive

¹⁰⁶ *Allina II*, 139 S Ct at 1811 (emphasis and citation omitted).

¹⁰⁷ *Id* at 1812 (alteration in original).

¹⁰⁸ *Id* (emphasis in original). Again, the Court uses “substantive” in the sense of “legislative” rather than as the opposite of “procedural.” See note 75.

¹⁰⁹ See 42 USC § 1395hh(e)(1)(A) (explaining the retroactive applicability of any “substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability”).

¹¹⁰ 5 USC § 553(b)(B).

¹¹¹ See 42 USC § 1395hh(b)(2)(C).

¹¹² *Allina II*, 139 S Ct at 1813.

¹¹³ Of course, the drafters of § 1395hh(a)(2) also failed to cross-reference the APA’s procedural rule exemption. But that failure seems far less fatal to the procedural rule exemption than it was to the interpretive rule exemption since the plain meaning of the word “substantive,” which the drafters ultimately chose, is the opposite of “procedural.” See note 162 and accompanying text.

¹¹⁴ *Allina II*, 139 S Ct at 1814.

rules with policy statements and makes the former subject to notice and comment.¹¹⁵ Second, the Medicare Act does not cross-reference the APA’s interpretive rule exemption like it does the good cause exemption.¹¹⁶ Third, the Court found no indication in the legislative history that Congress had interpretive rules in mind.¹¹⁷ On the final count, then, the Medicare Act borrows the APA’s good cause exemption and leaves behind its interpretive rule exemption and its policy statement exemption. But that accounts for only three of § 553(b)’s four exemptions. What of the remaining exemption—“rules of agency organization, procedure, or practice”?¹¹⁸ The Court mentioned this exemption only in passing¹¹⁹ and engaged in no analysis of whether the Medicare Act borrows it.

Allina II thus left the puzzle unsolved as to what happened to the APA’s procedural rule exemption in the drafting of the Medicare Act. On the one hand, the Medicare Act does not “expressly borrow[]”¹²⁰ the phrase “rules of agency organization, procedure, or practice,” either by reproduction or by cross-reference. If failure to expressly borrow one exemption indicates that Congress did not intend to incorporate that exemption in the new statute, one might ask why the same logic would not also apply to the other exemption. Justice Breyer appears to have anticipated this concern and thus worried in his dissent that the majority opinion “may also lead to legal challenges to the validity of interpretive rules (*or even procedural rules*) previously thought to have been settled.”¹²¹ On the other hand, as the DC Circuit seems to have recognized, the most natural reading of “substantive” is as the opposite of “procedural.” Once one examines the legislative history of the Medicare statute, a picture begins to emerge as to why Congress may have chosen the “phrase ‘substantive legal standard,’ which appears in [§ 1395hh(a)(2)] and apparently nowhere else in the U.S. Code.”¹²²

¹¹⁵ Id at 1811–12.

¹¹⁶ Id at 1812–14.

¹¹⁷ Id at 1814–16.

¹¹⁸ 5 USC § 553(b)(A).

¹¹⁹ See *Allina II*, 139 S Ct at 1812, quoting 5 USC § 553(b)(A); *Allina II*, 139 S Ct at 1815 (rejecting an argument based on *American Hospital Association* because that case “was mostly about the APA’s treatment of *procedural* rules”) (emphasis in original).

¹²⁰ *Allina II*, 139 S Ct at 1813.

¹²¹ Id at 1824 (Breyer dissenting) (emphasis added).

¹²² Id at 1814 (majority).

B. The Legislative History of the Medicare Act Amendments

This Section explores how the legislative history of the Medicare Act amendments can help solve the puzzle of their text. While the Court in *Allina II* found the legislative history “murky” with respect to the interpretive rule exemption,¹²³ congressional intent to carry over the procedural rule exemption appears more clearly.

1. The voluntary notice-and-comment era.

Long before Congress amended the Medicare statute to codify notice-and-comment procedures for CMS (then HCFA), the agency voluntarily subjected its rules to notice and comment.¹²⁴ This practice began formally in 1971, when the Department of Health, Education, and Welfare—the department of which HCFA was a part—issued a policy statement that, “[e]ffective immediately, all agencies and offices of the Department which issue rules and regulations relating to public . . . benefits . . . are directed to utilize the public participation procedures of the APA.”¹²⁵ Proposed regulations from this period suggest that HCFA took this command at face value.¹²⁶ Presumably, HCFA would have looked to § 553 not only for the procedures it sets out, but also for the exemptions it includes. Indeed, prior to 1986, the agency repeatedly invoked the good cause exemption in particular.¹²⁷ It was against this backdrop, with HCFA having previously followed the APA’s notice-and-comment requirements, that Congress

¹²³ *Id.* at 1815.

¹²⁴ See *Allina II*, 139 S Ct at 1820–21 (Breyer dissenting) (describing the impetus for and history of the Medicare Act amendments of 1987). See also Part I.B.1.

¹²⁵ Department of Health, Education, and Welfare, Office of the Secretary, Public Participation in Rule Making: Statement of Policy, 36 Fed Reg 2532, 2532 (1971), citing 5 USC § 553.

¹²⁶ See, for example, Health Care Financing Administration, Medicare and Medicaid; Payment for the Cost of Malpractice Insurance, 51 Fed Reg 11142, 11194 (1986) (“We voluntarily follow the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553) in issuing Medicare rules.”).

¹²⁷ See, for example, Department of Health, Education, and Welfare, Health Care Financing Administration, Training for Medicaid, 42 Fed Reg 60566, 60566 (1977) (“Since these are merely technical conforming amendments, the Department finds that there is good cause to waive public notice and opportunity for comment.”); Department of Health, Education, and Welfare, Health Care Financing Administration, Medicare Program; Court Ordered Regulations Regarding Prospective Payment Amount and Administrative Review, 50 Fed Reg 27208, 27210 (1985) (“[The notice and comment] requirement does not apply when an agency finds good cause that such a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest. . . . [W]e find good cause to waive proposed rulemaking.”).

amended the Medicare statute. Thus, one would expect that statute's new notice-and-comment provision to carry over the workings of the APA's provision, at least to some extent.

2. Congress codifies a notice-and-comment requirement.

In a first attempt to respond to concerns that HCFA was beginning to shirk the notice-and-comment obligations it had voluntarily assumed, Congress added a provision to the Medicare Act in 1986 requiring notice and comment "before issuing in final form any [Medicare] regulation" that did not fall under the APA's good cause exemption.¹²⁸ This amendment evidently did not have its intended effect. In a report on an earlier version of the 1987 amendments, the House Budget Committee expressed concern that the 1986 notice-and-comment "provision did not [] define a regulation for that purpose," and thus "that important policies [were] being developed without benefit of the public notice and comment period and, with growing frequency, [were] being transmitted, if at all, through manual instructions and other informal means."¹²⁹

As a result, the House passed a version of the 1987 bill requiring that any rule with a "significant effect" on Medicare payments undergo notice and comment.¹³⁰ The Budget Committee opined that this language would apply to "all [rules] which are of general applicability and have a significant effect on Medicare enrollees, on providers, or on the administration of the program," including

any policy that had an effect on the eligibility of individuals for Medicare, on the scope of benefits, on the payment methodology or amount of payment for services, or on the qualifications of practitioners or providers to furnish reimbursable services or the terms under which such services can be furnished.¹³¹

According to at least some members of the enacting Congress, then, this earlier draft subjected a remarkably broad swath of Medicare rules to notice and comment.

¹²⁸ Omnibus Budget Reconciliation Act of 1986 § 9321(e)(1), 100 Stat at 2017.

¹²⁹ HR Rep No 100-391(I), 100th Cong, 1st Sess 430 (1987).

¹³⁰ HR 3545, 100th Cong, 1st Sess (Oct 26, 1987), in 133 Cong Rec 29966, 30019 (Oct 29, 1987).

¹³¹ HR Rep No 100-391(I) at 430 (cited in note 129).

After different versions of the bill passed in the House and Senate, however, the conference committee amended the provision to include its current language, purportedly “to clarify that *only* policies establishing or changing a substantive legal standard governing benefits, payment, or eligibility must be promulgated as regulations,” and to “reflect[] recent court rulings.”¹³²

To be sure, the conference committee did not change the heading “Publication as Regulations of *Significant Policies*” in the final bill,¹³³ and the House Ways and Means Committee still expressed its understanding that the final version of the notice-and-comment requirement would extend to “[s]ignificant policy changes.”¹³⁴ But the change in the text and the conference committee’s stated rationale for it could offer a significant clue as to what Congress meant when it enacted the final statute.

3. Making sense of the conference committee report.

The conference committee report’s reference to “recent court rulings” suggests that, in amending the earlier draft’s broader language, Congress intended to incorporate the APA’s procedural rule exemption as interpreted in *American Hospital Association*. The phrases “significant effect”¹³⁵ and “substantive legal standard”¹³⁶ echo terminology used throughout that then-recent landmark decision, in which the DC Circuit announced what I referred to as the substantive-value-judgment test.¹³⁷ Recall that under this test, a rule may be procedural if it is aimed primarily at the agency’s internal workings, even if it has an incidental effect on the rights and duties of regulated parties.¹³⁸ Prior to *American Hospital Association*, the DC Circuit had sometimes applied the substantial-impact test to differentiate substantive from procedural rules under the APA.¹³⁹ In *American Hospital Association*,

¹³² HR Conf Rep No 100-495, 100th Cong, 1st Sess 566 (1987) (emphasis added).

¹³³ Omnibus Budget Reconciliation Act of 1987 § 4035(b), 101 Stat at 1330-78 (emphasis added).

¹³⁴ House Committee on Ways and Means, 100th Cong, 1st Sess, Summary of Conference Agreement on Reconciliation Provisions Within the Jurisdiction of the Committee on Ways and Means 13 (Comm Print 1987).

¹³⁵ HR 3545 at 30019 (cited in note 130).

¹³⁶ 42 USC § 1395hh(a)(2).

¹³⁷ See Part I.A.2.

¹³⁸ See *id.*

¹³⁹ See, for example, *Pickus v United States Board of Parole*, 507 F2d 1107, 1113 (DC Cir 1974) (“[A] matter ‘relating to practice or procedure’ means technical regulation of the form of agency action and proceedings. This category [] should not be deemed to include

the court acknowledged its shift from “asking whether a given procedure has a ‘substantial impact’ on parties . . . to inquiring more broadly whether the agency action also encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior.”¹⁴⁰ Throughout its opinion, the court repeatedly measured the rule in question against the “substantive standard[s]” of the organic statute.¹⁴¹

Indeed, once one takes a closer look at then-extant case law, it is hard to imagine the conference committee’s reference to “recent court rulings”¹⁴² as being to any other case. *American Hospital Association* appears to be the only case decided prior to the 1987 Medicare Act amendments in which a court discussed “substantive standards” in relation to any serious notice-and-comment analysis under 5 USC § 553(b).¹⁴³ And a “recent court ruling[]”¹⁴⁴ it was. *American Hospital Association* was decided on December 4, 1987— just over five weeks after the original version of the Medicare Act amendments passed the House,¹⁴⁵ and eighteen days before the conference committee issued its report.¹⁴⁶ The committee lawyers who were likely drafting the final version would have had just enough time to learn about this important case and incorporate its language so as “to clarify that *only* policies establishing or changing a substantive legal standard governing benefits, payment, or eligibility must be promulgated as regulations.”¹⁴⁷

any action which goes beyond formality and *substantially affects the rights* of those over whom the agency exercises authority.” (emphasis added).

¹⁴⁰ *American Hospital Association*, 834 F2d at 1047.

¹⁴¹ *Id.* at 1055.

¹⁴² HR Conf Rep No 100-495 at 566 (cited in note 132).

¹⁴³ Three possible exceptions warrant mention. The District of Colorado used the phrases “substantive requirements” and “substantive standards” in distinguishing *American Hospital Association* from the facts of its own case. See *Estate of Smith v Bowen*, 675 F Supp 586, 589–90 (D Colo 1987). Two other district courts each used the phrase in brief, near-identical footnotes declining to decide notice-and-comment challenges to the same regulation. See *Dixon v Heckler*, 589 F Supp 1494, 1506 n 34 (SDNY 1984); *Wilson v Heckler*, 622 F Supp 649, 654 n 8 (D NJ 1985). Given that the first of these cases simply distinguished *American Hospital Association* and the others were decided years before the House drafted the original version of the bill, it seems unlikely that any of these cases were what the conference committee had in mind.

¹⁴⁴ HR Conf Rep No 100-495 at 566 (cited in note 132) (emphasis added).

¹⁴⁵ See HR 3545 at 30019 (cited in note 130).

¹⁴⁶ See HR Conf Rep No 100-495 at 566 (cited in note 132).

¹⁴⁷ *Id.* (emphasis added).

But I am not the first to seize on this language in the conference committee report. Citing this language and similar terminology in *American Hospital Association*, the Government in *Allina II* argued that *American Hospital Association* “forms the backdrop for the very language (‘establishes or changes a substantive legal standard’) that Congress enacted to ‘reflect[] recent court rulings.’”¹⁴⁸ The Court rejected this argument because even if the conference committee report contained “an oblique reference to [*American Hospital Association*],” that case “was mostly about the APA’s treatment of *procedural* rules.”¹⁴⁹ In the Court’s view, then, it was “at least equally plausible that the conference committee revised the House’s language because it feared that language would have subjected procedural rules to notice-and-comment obligations.”¹⁵⁰

In other words, the Government may have been right that the statute’s drafters were thinking of *American Hospital Association*, but its principal mistake was failing to recognize that that case “was mostly about the APA’s treatment of *procedural* [rather than interpretive] rules.”¹⁵¹ Furthermore, as the Government neglected to emphasize in its brief, *American Hospital Association* was not just “[o]ne of the most significant then-recent court rulings”¹⁵²—it was the *only* significant then-recent ruling that used the words “substantive” and “standard” in a manner similar to § 1395hh(a)(2).¹⁵³ Thus, the conference report, read in conjunction with *American Hospital Association*, would seem to support a reading of § 1395hh(a)(2) as the mirror image of the APA’s procedural rule exemption, despite the failure of a similar argument concerning interpretive rules in *Allina II*. It appears the drafters of § 1395hh(a)(2) were thinking not merely of a general distinction between substance and procedure, but of a specific interpretation (*American Hospital Association*’s) of the distinction a specific statute (the APA) drew.

¹⁴⁸ Azar Brief at *36–37 (cited in note 85) (alteration in original), quoting HR Conf Rep No 100-495 at 566 (cited in note 132).

¹⁴⁹ *Allina II*, 139 S Ct at 1815 (emphasis in original).

¹⁵⁰ *Id.*

¹⁵¹ *Id.* (emphasis in original).

¹⁵² Azar Brief at *36 (cited in note 85).

¹⁵³ See note 143 and accompanying text.

4. Tying it all together: positive framing and drafting procedure.

Still, one might ask: If Congress had the APA’s procedural rule exemption in mind, why did it not cross-reference that exemption expressly, as it did with the good cause exemption?¹⁵⁴ The answer may lie in the constraints of language and the realities of drafting procedure. The APA’s notice-and-comment provision defines only which rules *are not* subject to notice and comment.¹⁵⁵ The Medicare Act’s notice-and-comment provision, by contrast, defines which rules *are* subject to notice and comment—and it has done so since its first iteration in 1986.¹⁵⁶ Recall that according to the House Budget Committee, the impetus behind the 1987 amendments was that the 1986 version “did not . . . define a regulation” for the purposes of the notice-and-comment requirement.¹⁵⁷ In seeking to “define a regulation,” the statute’s drafters were already working with an existing text that defined the notice-and-comment requirement in positive rather than negative terms. The earlier version of the 1987 bill that passed the House retained this positive framing, again specifying which rules were subject to notice and comment.¹⁵⁸

At this point, the conference committee was not writing on a clean slate. If it indeed sought to incorporate the APA’s procedural rule exemption as interpreted in *American Hospital Association*, it could have done so by rewriting the entire subsection in the negative terms of exemptions. But it would have been far easier to change the clause specifying which rules were subject to notice and comment to one that conveyed precisely the opposite meaning of “rules of agency organization, procedure, or practice.”¹⁵⁹ It seems likely that the conference committee attempted to do just that when it changed the type of rule covered by the notice-and-comment provision from one “that has (or may have) a

¹⁵⁴ See Part II.A.

¹⁵⁵ See 5 USC § 553(b).

¹⁵⁶ See note 128 and accompanying text.

¹⁵⁷ HR Rep No 100-391(I) at 430 (cited in note 129).

¹⁵⁸ See HR 3545 at 30019 (cited in note 130).

¹⁵⁹ 5 USC § 553(b)(A). For a similar argument emphasizing the “piecemeal construction” of the Medicare Act amendments but without emphasizing the positive and negative framing issue, see Haviland, Comment, 85 U Chi L Rev at 1539 (cited in note 74).

significant effect”¹⁶⁰ to one that “that establishes or changes a substantive legal standard.”¹⁶¹ After all, “substantive” ordinarily connotes the opposite of “procedural,”¹⁶² and the court in *American Hospital Association* indicated that “substantive standard[s]” are relevant in determining whether a rule is exempt from notice and comment.¹⁶³ On this reading, Congress did not simply forget about the APA’s exemption for “rules of agency organization, procedure, or practice”¹⁶⁴ when it drafted the Medicare Act amendments—it incorporated that exemption by negative implication. All four of the APA’s exemptions would therefore be accounted for: the procedural rule and good cause exemptions made the jump from the APA to the Medicare Act, while the interpretive rule and policy statement exemptions did not.

III. THE READING IN PRACTICE

Having laid out the case for the reconciled procedural reading as a matter of statutory interpretation, I turn now to its practical implications should courts accept it. As discussed above, largely by virtue of its outsized administrative law docket, the DC Circuit is the most influential court of appeals on matters of administrative law.¹⁶⁵ This Part therefore assumes that if courts adopted the reconciled procedural reading and interpreted the Medicare Act as borrowing the APA’s exemption for “rules of agency organization, procedure, or practice,”¹⁶⁶ the DC Circuit’s test for that exemption—the substantive-value-judgment test¹⁶⁷—would dominate Medicare notice-and-comment jurisprudence. Part III.A explores in greater detail the case law applying the substantive-value-judgment

¹⁶⁰ HR 3545 at 30019 (cited in note 130).

¹⁶¹ 42 USC § 1395hh(a)(2).

¹⁶² See Part I.A.2. As the DC Circuit rightly recognized in *Allina I*, dictionary definitions confirm that “substantive” and “procedural” are generally used as antonyms. See *Black’s Law Dictionary* (West 11th ed 2019) (defining “substantive law” as “[t]he part of the law that creates, defines, and regulates the rights, duties, and powers of parties. Cf. PROCEDURAL LAW”) (emphasis added); id (defining “procedural law” as “[t]he rules that prescribe the steps for having a right or duty judicially enforced, as opposed to the law that defines the specific rights or duties themselves. . . . Cf. SUBSTANTIVE LAW”) (emphasis added). Dictionaries are helpful for getting a general sense of common usage. I take issue only with quoting a dictionary definition as the most comprehensive statement of an important legal test that district courts will have to parse, as the DC Circuit did in *Allina I*. Rule by Article III judges is one thing—rule by Bryan A. Garner is quite another.

¹⁶³ See *American Hospital Association*, 834 F2d at 1055.

¹⁶⁴ 5 USC § 553(b)(A).

¹⁶⁵ See note 27 and accompanying text.

¹⁶⁶ 5 USC § 553(b)(A).

¹⁶⁷ See Part I.A.2.

test under the APA. Part III.B applies the test to the facts of existing Medicare cases, illustrating how the substantive-value-judgment test would achieve similar results to the dictionary approach in many cases but could provide CMS with needed flexibility at the margins.

A. Case Law Outlining the Substantive-Value-Judgment Test

American Hospital Association and its progeny suggest a distinction between policies concerning two different subject matters: generally applicable enforcement policies (whatever their effect on regulated parties) and policies that single out particular populations because of their behavior or that vary “standards of review.” *American Hospital Association* itself was a complicated case concerning several documents in which HHS gave instructions to private organizations of doctors that Congress had tasked with reviewing hospitals’ Medicare reimbursement requests to screen for overbilling.¹⁶⁸ The three documents to which the APA’s procedural rule exemption was most relevant were two manuals and one directive that HHS issued explaining how the organizations would go about their daily operations and which (and how many) transactions they would review.¹⁶⁹ For example, they were to review a set percentage of patient readmissions.¹⁷⁰ One passage evaluating the first manual captures the thrust of the court’s reasoning with respect to all three documents:

The manual imposes no new burdens on hospitals that warrant notice and comment review. This is not a case in which HHS has urged its reviewing agents to utilize a different standard of review in specified medical areas; rather, it asks only that they examine a greater share of operations in given medical areas. . . .

At worst, Manual IM85–2 burdens hospitals by (1) making it more likely that their transgressions from Medicare’s standards will not go unnoticed and (2) imposing on them the incidental inconveniences of complying with an enforcement

¹⁶⁸ *American Hospital Association*, 834 F2d at 1041–44. The agency actions at issue in *American Hospital Association* would be governed by the Medicare Act’s notice-and-comment provision today, but they occurred before that provision existed, when HCFA ostensibly elected to follow the APA’s notice-and-comment provision. See *id.* (explaining the actions, all of which occurred prior to 1985). See also Part II.B.1 (describing HCFA’s notice-and-comment practices prior to 1986).

¹⁶⁹ *American Hospital Association*, 834 F2d at 1049–52.

¹⁷⁰ *Id.*

scheme. The former concern is patently illegitimate. . . . As for the second burden, case law clearly establishes that such derivative burdens hardly dictate notice and comment review.¹⁷¹

In other words, even if the policies affected the amount of reimbursement the hospitals ultimately received, they still qualified as procedural rules because they merely concerned enforcement of a value judgment Congress had already made concerning which expenses were reimbursable.

The DC Circuit's subsequent decision in *Air Transport* illustrates the substantive-value-judgment test in its most demanding permutation. In that case, the Federal Aviation Administration (FAA) issued a set of rules detailing the amounts to be assessed for various air-safety violations and establishing a "comprehensive adjudicatory scheme" for the assessment of penalties.¹⁷² As the court noted, even critics who were not parties to the case claimed the rules created a "systematic procedural bias in favor of the FAA," but the FAA nevertheless issued them without notice and comment, invoking the APA's procedural rule exemption.¹⁷³ The court held that the exemption did not apply, reasoning that the agency's "choices concerning what process civil penalty defendants are due" each "encoded a substantive value judgment' on the appropriate balance between a defendant's rights to adjudicatory procedures and the agency's interest in efficient prosecution."¹⁷⁴ *Air Transport* was vacated as moot for unrelated reasons¹⁷⁵ and is thus no longer binding precedent in the DC Circuit, but it is important because it represents the outer limit of what might qualify as a substantive value judgment in the eyes of a particularly skeptical court. It is probably best read as an outlier case whose logic is confined to situations in which a regulation determines the process due in quasi-criminal proceedings.

In addition to *American Hospital Association* and *Air Transport*, the DC Circuit has engaged in detailed analysis of whether a rule encodes a substantive value judgment in a handful of other cases. In *Reeder v FCC*,¹⁷⁶ several broadcasting companies

¹⁷¹ Id at 1051.

¹⁷² *Air Transport*, 900 F2d at 373.

¹⁷³ Id.

¹⁷⁴ Id at 376, quoting *American Hospital Association*, 834 F2d at 1047 (alteration, citation, and emphasis omitted).

¹⁷⁵ See generally *Air Transport Association of America v Department of Transportation*, 933 F2d 1043 (DC Cir 1991).

¹⁷⁶ 865 F2d 1298 (DC Cir 1989).

challenged a “no-substitution” policy the Federal Communications Commission (FCC) had adopted in allocating three new classes of FM radio stations, under which it would not consider applications from existing stations to upgrade to one of the new classes.¹⁷⁷ Invoking *American Hospital Association*, the court found it “quite obvious that the rules changed the substantive criteria for substitution and permanently foreclosed the petitioners from pursuing their upgrade plans” and therefore concluded that the procedural rule exemption did not apply.¹⁷⁸ In *JEM Broadcasting Co v FCC*,¹⁷⁹ a broadcaster challenged another policy for FM radio station applications, under which the FCC refused to consider applications that omitted some of the required information.¹⁸⁰ The plaintiff argued that the policy encoded a substantive value judgment, but the court disagreed, reasoning that stretching the test that far “threaten[ed] to swallow the procedural exception to notice and comment, for agency housekeeping rules often embody a judgment about what mechanics and processes are most efficient.”¹⁸¹ And in *Public Citizen v Department of State*,¹⁸² the court sustained as a procedural rule the State Department’s policy against disclosing documents generated after the date of an initial Freedom of Information Act (FOIA) request.¹⁸³ “Because the Department’s cut-off policy applies to all FOIA requests, making no distinction between requests on the basis of subject matter,” the court explained, “It clearly encodes no ‘substantive value judgment.’”¹⁸⁴

Assuming *Air Transport* was an aberration, these cases suggest that a nominally procedural rule “encodes a substantive value judgment”¹⁸⁵ and thus triggers notice and comment if it takes aim at a subset of the regulated industry that is behaving in a certain way, but not if it is aimed primarily at the agency’s

¹⁷⁷ Id at 1301–02.

¹⁷⁸ Id at 1305.

¹⁷⁹ 22 F3d 320 (DC Cir 1994).

¹⁸⁰ Id at 322.

¹⁸¹ Id at 328. Recognizing that *Air Transport* was no longer binding, the *JEM Broadcasting* court did not attempt to distinguish it, and in fact disavowed it to the extent that it required a contrary result. Id. But the distinction is not difficult to see. In comparison to an entire adjudicatory scheme that even included the amounts of fines, a requirement that paperwork be substantially completed hardly seems a judgment about “what process [broadcasters] are due.” *Air Transport*, 900 F2d at 376.

¹⁸² 276 F3d 634 (DC Cir 2002).

¹⁸³ Id at 641.

¹⁸⁴ Id, quoting *American Hospital Association*, 834 F2d at 1047.

¹⁸⁵ *American Hospital Association*, 834 F2d at 1047.

own internal workings and applies to the entire industry equally. With this basic principle in mind, the substantive-value-judgment test may not be the easiest for courts to administer, but it affords agencies far more flexibility in calibrating their internal procedures than does the Fifth Circuit's substantial-impact test.¹⁸⁶ And as we shall see, the substantive-value-judgment test is probably also more agency-friendly than the dictionary approach to the Medicare Act's notice-and-comment requirement.

B. Applying the Substantive-Value-Judgment Test to Medicare Cases

1. Existing Medicare cases applying the substantive-value-judgment test.

Before speculating as to how the substantive-value-judgment test would apply in recent Medicare notice-and-comment cases, it is worth noting that at least two district courts bound by *American Hospital Association* did apply the test in Medicare cases prior to *Allina I*.¹⁸⁷ The court in *Sierra-Nevada Memorial-Miners Hospitals, Inc v Shalala*¹⁸⁸ held that HCFA's decision to have hospitals seeking geographic reclassification submit their applications to their fiscal intermediaries instead of to HCFA directly fell under the APA's procedural rule exemption.¹⁸⁹ Invoking *American Hospital Association* and echoing its reasoning, the court explained that the "rule did not foreclose the plaintiffs' right to seek increased Medicare reimbursement" and "[d]id not authorize the intermediaries to apply new reviewing standards or a different level of scrutiny."¹⁹⁰

¹⁸⁶ See Part I.A.2.

¹⁸⁷ Of course, *American Hospital Association* itself was a Medicare case as well. See note 177 and accompanying text. In addition, at least one district court pre-*Allina I* applied *American Hospital Association* to uphold a rule as procedural without expressly using the phrase "substantive value judgment," but engaging in similar reasoning. See *Beverly Health & Rehabilitation Services, Inc v Thompson*, 223 F Supp 2d 73, 100-01 (DDC 2002) (concluding that a rule setting forth instructions for scrutinizing nursing home reimbursement requests was a procedural rule because it simply made it "more likely that plaintiffs' transgressions from Medicare's standards [would] not go unnoticed") (alteration and quotation marks omitted).

¹⁸⁸ 1994 WL 675720 (DDC).

¹⁸⁹ *Id.* at *5. The court apparently assumed without discussion that even after the Medicare Act amendments of 1987, the exact same notice-and-comment requirements applied under the Medicare Act as under the APA. Puzzlingly, the court did not even mention the Medicare Act's notice-and-comment provision.

¹⁹⁰ *Id.* at *4-5.

The second express application of *American Hospital Association* in the Medicare context pre-*Allina I* seems dubious, but it may be useful to illustrate the outer limits of the substantive-value-judgment test in that context. *Clarian Health West, LLC v Burwell*¹⁹¹ (*Clarian I*), was the district court precursor to *Clarian II*, and thus involved the same facts.¹⁹² Concerned that hospitals were abusing opportunities for “outlier” reimbursement (for unusually costly patients), CMS adopted a manual provision giving new guidance as to when contractors processing requests should apply an existing “reconciliation” formula designed to reduce unnecessary outlier payments.¹⁹³ The district court was not convinced that the Medicare statute borrowed the APA’s procedural rule exemption, but it offered an alternative holding applying the substantive-value-judgment test to support its later-reversed conclusion that notice and comment was required.¹⁹⁴ The court concluded that the new guidance as to when to resort to reconciliation “unquestionably ‘encode[d] a substantive value judgment’ about the hospital’s charges and cost reporting for Medicare reimbursements and ‘put a stamp of . . . disapproval’ on the hospitals that are singled out by the rule.”¹⁹⁵ The DC Circuit reversed in *Clarian II* without analyzing the district court’s alternative holding under the substantive-value-judgment test.¹⁹⁶ Regardless, the district court’s rationale under that test seems to be inconsistent with the reasoning of *American Hospital Association* insofar as the reconciliation provisions did not change the standard of review for outlier payments, but merely the frequency with which contractors would apply that standard to all providers in the first instance—the very sort of change to a generally applicable enforcement policy at issue in *American Hospital Association*.¹⁹⁷

Like *Air Transport* in another context, the district court’s decision in *Clarian I* arguably stretched the substantive-value-judgment test to its breaking point. Given its contrary conclusion

¹⁹¹ 206 F Supp 3d 393 (DDC 2016).

¹⁹² See notes 87–88 and accompanying text.

¹⁹³ *Clarian I*, 206 F Supp 3d at 397–403.

¹⁹⁴ *Id* at 414, 417.

¹⁹⁵ *Id* at 417 (alteration omitted), quoting *American Hospital Association*, 834 F2d at 1047.

¹⁹⁶ See 878 F3d at 359.

¹⁹⁷ See *American Hospital Association*, 834 F2d at 1051 (“This is not a case in which HHS has urged its reviewing agents to utilize a different standard of review in specified medical areas; rather, it asks only that they examine a greater share of operations in given medical areas.”).

on facts strikingly similar to those of *American Hospital Association*, *Clarian I* is probably not indicative of the notice-and-comment standard to which a court adopting the reconciled procedural reading would hold CMS. In other words, *Sierra-Nevada* would likely be the rule, and *Clarian I* the exception.

2. Applying the substantive-value-judgment test to the *Allina* line of cases.

A court applying the substantive-value-judgment test would likely reach the same result in most cases as the courts that have already followed the dictionary approach to the Medicare statute. There is, however, room for difference at the margins. The substantive-value-judgment test's overall consonance with the results reached in the DC Circuit's only two binding cases on the Medicare Act's procedural rule exemption, as well as the test's subtle differences from the dictionary approach, are both points in favor of the reconciled procedural reading for reasons discussed later.¹⁹⁸

a) *Allina*, *Clarian*, and *Polanksy*: a different route to the same result. The substantive-value-judgment test would have compelled the same result in *Allina*. Recall in that case that CMS had decided to start including often-wealthier Medicare Part C beneficiaries in calculations to determine reimbursement to hospitals for treating a "disproportionate share" of low-income patients.¹⁹⁹ It would be difficult to argue that this decision did not "encode[] a substantive value judgment."²⁰⁰ If the substantive-value-judgment test spans a continuum from *American Hospital Association* to *Reeder*—in which the FCC had adopted new classes of radio stations and categorically barred existing station owners from applying for them²⁰¹—the facts of *Allina* fall squarely on the *Reeder* side of the line. Changing the actual values plugged into a reimbursement formula is more akin to applying "a different standard of review" than to changing the frequency with which the standard is applied,²⁰² and it is "quite obvious that the rule[] changed the substantive criteria for" reimbursement.²⁰³ Adopting the reconciled procedural reading would therefore be consistent with the

¹⁹⁸ See Part IV.

¹⁹⁹ See *Allina I*, 863 F3d at 938–40.

²⁰⁰ *American Hospital Association*, 834 F2d at 1047.

²⁰¹ See notes 176–78 and accompanying text.

²⁰² *American Hospital Association*, 834 F2d at 1051.

²⁰³ *Reeder*, 865 F2d at 1305.

judgment in *Allina II*—the only decision interpreting § 1395hh(a)(2) that is nationally binding.

While the district court in *Clarian I* concluded in the alternative that the rule in that case would be classified as a substantive rather than procedural rule under the substantive-value-judgment test,²⁰⁴ as noted above, this conclusion seems dubious.²⁰⁵ The facts of *Clarian I* are remarkably similar to those of *American Hospital Association*, with CMS enforcing existing standards more aggressively to catch what already would have been considered excessive reimbursement.²⁰⁶ While the DC Circuit did not discuss the APA’s procedural rule exemption on appeal, it seems likely that most courts applying the agency-friendly substantive-value-judgment test would find that the rule fell under the procedural rule exemption and did not require notice and comment.²⁰⁷ The DC Circuit could thus adopt the reconciled procedural reading and clarify that the substantive-value-judgment test applies in Medicare cases without overturning any of its own precedent.

The reconciled procedural reading would likewise leave undisturbed the outcome of *Polansky*, in which the Eastern District of Pennsylvania endorsed the dictionary approach. That case involved a False Claims Act action in which the defendant was accused of falsely billing what should have been outpatient services as inpatient services to take advantage of a higher reimbursement rate.²⁰⁸ The Medicare Act’s notice-and-comment provision came into play because HCFA had issued a manual provision stating that providers should bill stays shorter than 24 hours as outpatient and those longer than 24 hours as inpatient.²⁰⁹ The court concluded that “the 24-hour policy must be included within the District of Columbia Circuit’s definition for substantive legal

²⁰⁴ *Clarian I*, 206 F Supp 3d at 417.

²⁰⁵ See Part III.B.1.

²⁰⁶ Compare *Clarian I*, 206 F Supp 3d at 397–403, with *American Hospital Association*, 848 F2d at 1041–44.

²⁰⁷ Compare *Clarian II*, 878 F3d at 355–56 (“The instructions merely set forth an enforcement policy that determines when [contractors] will report hospitals for reconciliation. They do not change the legal standards that govern the hospitals, and they do not change the legal standards that govern the agency.”), with *American Hospital Association*, 834 F2d at 1050 (“The requirements set forth in the transmittal are classic *procedural* rules, exempt under that distinctive prong of § 553. The bulk of the regulations in the transmittal set forth an enforcement plan for HHS’s agents in monitoring the quality of and necessity for various operations.”) (emphasis in original).

²⁰⁸ *Polansky*, 422 F Supp 3d at 918.

²⁰⁹ *Id.* at 932–33.

standard,” reasoning that “[j]ust as the respective policies in *Allina I* and *Select Specialty Hospital* were ‘substantive legal standards’ under the Circuit’s definition because they determined entitlement to reimbursement, [] the 24-hour policy delineates the circumstances in which a hospital is entitled to higher inpatient reimbursement.”²¹⁰ Here again the test announced in *American Hospital Association* would likely yield the same result, as the manual provision almost certainly “encode[d] a substantive value judgment”²¹¹ as to which hospital stays were long enough to warrant “higher inpatient reimbursement.”²¹²

b) *Select Specialty Hospital: potential differences.* The cases analyzed thus far do not demonstrate much of the difference between the DC Circuit’s current approach to § 1395hh(a)(2) and the substantive-value-judgment test. This is so because the classification of the rule in each of those cases is relatively clear almost irrespective of where one draws the line between substantive and procedural rules. *Select Specialty Hospital* presents a closer case. The plaintiff hospitals in that case were challenging a rule requiring providers to bill state Medicaid and obtain documents known as “remittance advices” in order to receive reimbursement for the bad debts of patients eligible for both Medicare and Medicaid.²¹³ Crucially, none of the state Medicaid offices the plaintiffs attempted to bill would issue remittance advices to providers not enrolled in Medicaid. None of the plaintiffs were enrolled in Medicaid, and many states barred their type of hospital from enrolling by law.²¹⁴ There is little question that the court reached the right result under the dictionary approach articulated in *Allina I*, as the rule in effect “create[d], define[d], and regulate[d] the rights, duties, and powers of parties”²¹⁵ by requiring the providers to participate in Medicaid or disqualifying them from reimbursement if they were unable to.

A court applying the *American Hospital Association* test for procedural rules, however, might have reached a different result.

²¹⁰ *Id.* at 935.

²¹¹ *American Hospital Association*, 834 F.2d at 1047.

²¹² *Polansky*, 422 F. Supp. 3d at 935.

²¹³ *Select Specialty Hospital*, 391 F. Supp. 3d at 58–60. See notes 89–92 and accompanying text.

²¹⁴ *Select Specialty Hospital*, 391 F. Supp. at 60–61.

²¹⁵ *Allina I*, 863 F.3d at 943, quoting *Black’s Law Dictionary* (West 10th ed 2014).

Leaving aside the providers that were unable to enroll in Medicaid,²¹⁶ CMS had indicated that state Medicaid offices were required to allow providers that did not wish to participate fully in Medicaid to enroll for the limited purposes of obtaining remittance advices.²¹⁷ In the Government’s view, it was not CMS’s fault that providers were unable to obtain these documents, but the fault of noncompliant state Medicaid officials.²¹⁸ The distinction between limited and full Medicaid participation was irrelevant under the dictionary approach, which focuses on the effect a rule has on reimbursement.²¹⁹ But if the court had also been bound to consider whether the rule “encode[d] a substantive value judgment,”²²⁰ it might have concluded that for the providers who were able to enroll, limited enrollment was a mere compliance cost more comparable to the informational requirements in *JEM Broadcasting*²²¹ than to the categorical exclusion of substitution applications in *Reeder*.²²² Within the meaning of the APA’s procedural rule exemption, the rule in *Select Specialty Hospital* in at least some applications might have been considered “procedural despite [its] sometimes harsh effects.”²²³ This subtle difference demonstrates how the DC Circuit’s more nuanced approach to procedural rules under the APA could afford CMS greater discretion at the margins to organize reimbursement procedures without the constant burden of notice and comment.²²⁴

²¹⁶ Application of the remittance advices requirement to these providers would almost certainly be considered a substantive rule under the substantive-value-judgment test, since they were excluded from receiving reimbursement for dual-eligible bad debts no matter what steps they attempted to take to comply. See *Reeder*, 865 F2d at 1305 (“[I]t is quite obvious that the rules changed the substantive criteria for substitution and permanently foreclosed the petitioners from pursuing their upgrade plans.”).

²¹⁷ *Select Specialty Hospital*, 391 F Supp 3d at 69–70.

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *American Hospital Association*, 834 F2d at 1047.

²²¹ See *JEM Broadcasting*, 22 F3d at 322. See also notes 179–81 and accompanying text.

²²² See *Reeder*, 865 F2d at 1301.

²²³ *Public Citizen*, 276 F3d at 640.

²²⁴ Note that even if CMS had greater flexibility to issue rules without notice and comment, judicial review of agency discretion would still provide an important check on rules that seem downright irrational. For example, the plaintiff hospitals in *Select Specialty Hospital* also argued that requiring them to submit a document they were actually unable to obtain was arbitrary and capricious within the meaning of the APA, see 5 USC § 706(2)(A), an argument which the court gave serious consideration in earlier, pre-*Allina I* stages of the same litigation, see *Cove Associates Joint Venture v Sebelius*, 848 F Supp 2d 13, 28 (DDC 2012) (“If, at some point, Plaintiffs can establish that they have submitted the correct forms and made the right applications, it may . . . be arbitrary and capricious

IV. ASSESSING THE ADVANTAGES OF THE RECONCILED PROCEDURAL READING

Having explained how both the dictionary approach and the reconciled procedural reading work in practice, I turn now to their comparative merits. This Part proceeds in two sections. The first Section assesses the extent to which the reconciled procedural reading addresses the policy concerns Justice Breyer raised in his *Allina II* dissent and argues that its success on this front provides a strong policy rationale for adopting the reading. The second anticipates and addresses counterarguments, concluding that while the reconciled procedural reading is not the only plausible interpretation of § 1395hh(a)(2), it is at least preferable to the DC Circuit's current reliance on the dictionary approach.

A. The Reconciled Procedural Reading Addresses Some of Justice Breyer's Concerns

Justice Breyer laid out the most salient policy concerns regarding the boundaries of the Medicare Act's notice-and-comment requirement in his *Allina II* dissent, providing a useful metric by which to measure the advantages and disadvantages of the reconciled procedural reading. Justice Breyer's basic apprehension was that administration of the Medicare system would become impracticable.²²⁵ This Section compares the reconciled procedural reading and the dictionary approach along the lines of two more specific concerns underlying this fear: (1) that CMS lacks sufficient guidance to regulate its own processes without fear of litigation,²²⁶ and (2) that courts will simply begin to require notice and comment in more instances than feasible.²²⁷

for the Secretary to not accept an alternative form of documentation or to require that the states comply with her regulations.”).

²²⁵ See *Allina II*, 139 S Ct at 1822 (Breyer dissenting) (“To imagine that Congress wanted the agency to use those procedures in respect to a large percentage of its Medicare guidance manuals is to believe that Congress intended to enact what could become a major roadblock to the implementation of the Medicare program.”).

²²⁶ See *id* at 1824 (“Nor does the Court’s resolution of this particular case offer clarity as to the scope of the statute.”).

²²⁷ See *id* at 1823:

Is it reasonable to believe that Congress intended to impose notice-and-comment requirements upon all, or most, or even many of these rules, requirements, or statements of policy? . . . In my view, the answer is clearly no. Yet the Court’s opinion might impose this unnecessary and potentially severe burden on the administration of the Medicare scheme.

As to the first concern, neither approach is a paragon of clarity, but the reconciled procedural reading and the substantive-value-judgment test that comes with it have a clear advantage over the dictionary approach. In evaluating a test for clarity, at least two factors seem relevant: the amount of available precedent and the test’s determinacy. There is no contest with respect to the amount of precedent. If courts adopted the reconciled procedural reading, CMS could look to a body of precedent spanning several decades in determining which arguably procedural rules it must subject to notice and comment.²²⁸ By contrast, if the DC Circuit stays its course, CMS will still only have two binding precedents to look to in its most important jurisdiction: *Allina I* and *Clarian II*.²²⁹ Of course, the DC Circuit is likely to build more precedent over time regardless. But if Justice Breyer was right about the sheer number of rules whose procedural validity is now up for grabs, the years it could take to build a meaningful body of case law will come at a critical time when CMS needs certainty more than ever.

Determinacy is a tougher question. Scholars have criticized the substantive-value-judgment test as too malleable in application, though that criticism to some extent centers on the vacated and partially repudiated *Air Transport* case.²³⁰ Still, the dictionary approach to § 1395hh(a)(2) remains largely untested and could suffer from its framing as a minimum. Moreover, a commitment to dictionary definitions itself invites an endless and indeterminate search for a “clear” meaning, divorced from the context of the statute’s enactment or practical operation.²³¹ Without any

²²⁸ See Part III.A.

²²⁹ See Part I.B.3. To be sure, *Select Specialty Hospital* is persuasive precedent in the DDC—likely very persuasive given that it is the only case in that district applying the dictionary approach in final disposition on the merits post-*Allina II*. But it has no binding force in any court and thus provides only tenuous guidance to CMS in deciding whether to put a rule through notice and comment.

²³⁰ See, for example, Jeffrey S. Lubbers and Nancy G. Miller, *The APA Procedural Rule Exemption: Looking for a Way to Clear the Air*, 6 Admin L J Am U 481, 486–90 (1992) (explaining the substantive-value-judgment test and attacking its brisk discussion in *Reeder* and excessively functionalist application in *Air Transport*). Professor Jeffrey Lubbers and Nancy Miller wrote this article one year after the DC Circuit vacated *Air Transport*, but two years before it partially disavowed the reasoning of that case. See *JEM Broadcasting*, 22 F3d at 328.

²³¹ See A. Raymond Randolph, *Dictionaries, Plain Meaning, and Context in Statutory Interpretation*, 17 Harv J L & Pub Pol 71, 72 (1993) (“[C]iting to dictionaries creates [an illusion of certainty]. . . . Words in the definition are defined by more words, as are those words. The trail may be endless; sometimes, it is circular. Using a dictionary definition simply pushes the problem back.”).

express statement from a higher court fixing the upper bounds of what a “substantive legal standard”²³² includes, district courts presumably remain free to expand the definition of that phrase.²³³ Thus, CMS could be left playing appellate whack-a-mole as courts compete to further define the agency’s notice-and-comment obligations. A certain amount of this game is, of course, inherent in the common law process, but there is little policy sense in starting this process from scratch with respect to procedural rules under the Medicare Act when an earlier process in the APA context has already produced an acceptable alternative.

As to Justice Breyer’s second concern of subjecting too many rules to notice and comment, the reconciled procedural reading again seems to have an advantage, though perhaps only at the margins. The substantive-value-judgment test was designed to subject fewer rules to notice and comment than its predecessor, the substantial-impact test. The DC Circuit explained its move away from the substantial-impact test toward the substantive-value-judgment test as “reflect[ing] a candid recognition that even unambiguously procedural measures affect parties to some degree.”²³⁴ The *American Hospital Association* court was sensitive to the internal flexibility agencies need to function effectively, emphasizing that “[t]he distinctive purpose of” the APA’s procedural rule exemption “is to ensure ‘that agencies retain latitude in organizing their internal operations.’”²³⁵ While the dictionary approach does not seem as aggressive as the substantial-impact test in its few applications so far,²³⁶ it does not share in such strong terms *American Hospital Association*’s preference for agency flexibility. And the dictionary approach could prove more malleable than the substantive-value-judgment test—indeed, given its framing as a minimum, the dictionary approach seems even more

²³² 42 USC § 1395hh(a)(2).

²³³ In this sense, the DC Circuit may have set itself up for a repeat of the events leading up to *Vermont Yankee Nuclear Power Plant Corp v Natural Resources Defense Council, Inc.*, 435 US 519 (1978), in which the Supreme Court issued a harsh rebuke of the lower courts’ imposition on agencies of procedural requirements beyond those expressly contemplated by the APA. *Id.* at 524–25. Some credit *Vermont Yankee* with bringing about the near demise of the demanding substantial-impact test, which even the DC Circuit had previously applied. See, for example, Taylor, Note, 53 *Geo Wash L Rev* at 129–36 (cited in note 50).

²³⁴ *American Hospital Association*, 834 F2d at 1047.

²³⁵ *Id.*, quoting *Batterton v Marshall*, 648 F2d 694, 707 (DC Cir 1980).

²³⁶ See *Clarian II*, 878 F3d at 354–56 (concluding that CMS’s guidance concerning application of the reconciliation formula did not establish or change a “substantive legal standard” even though in effect it cost the plaintiff hospitals millions of dollars).

susceptible to an *Air Transport*-like attempt to stretch the notice-and-comment requirement to its absolute limit, frustrating CMS’s efforts to efficiently administer the country’s second-largest public benefits program. While such an attempt has not yet materialized, as the discussion of *Select Specialty Hospital* above suggests,²³⁷ adoption of the reconciled procedural reading could cabin the Medicare Act’s notice-and-comment requirement to afford CMS needed flexibility in close cases.

B. Addressing Counterarguments

While I contend that the reconciled procedural reading is preferable to the DC Circuit’s current dictionary approach to § 1395hh(a)(2), neither my reading nor the test that comes with it is perfect. A few potential counterarguments bear addressing. The first two question the reconciled procedural reading’s validity as a matter of statutory interpretation. The third questions the substantive-value-judgment test’s judicial administrability. Each of these counterarguments raises important concerns, but I maintain that the reconciled procedural reading is sound as a matter of both statutory interpretation and policy.

1. Returning to *Allina II*’s meaningful-variation argument.

First, one might argue that a reading of § 1395hh(a)(2) as borrowing the APA’s procedural rule exemption fails to give meaningful variation to the unique text of the Medicare statute as required by *Allina II*. After all, the majority in that case devoted a substantial portion of its opinion to highlighting the textual differences between the two statutes and explaining why those differences commanded a different interpretation.²³⁸ The argument would be that there is an insufficient basis in the text of the Medicare Act to conclude that Congress intended to borrow the APA’s procedural rule exemption, which the Medicare statute does not expressly mention.

But the meaningful-variation argument carries less force with respect to the APA’s procedural rule exemption than with respect to its interpretive rule exemption. The Government’s argument in *Allina II* relied on the premise that “substantive” was

²³⁷ See Part III.B.2.

²³⁸ See *Allina II*, 139 S Ct at 1812–14.

a term of art in notice-and-comment law that connoted the opposite of “interpretive.”²³⁹ Casting “substantive” as the opposite of “procedural” does not require the extra step of a term of art—the words are ordinarily used as antonyms.²⁴⁰ The only semantic leap to be made here is from the implied antonym “procedural legal standard” to “rule[] of agency organization, procedure, or practice.”²⁴¹

To be sure, this leap is not a foregone conclusion given some of the Court’s language in *Allina II*. In particular, the Court noted that while “the phrase ‘substantive *rule*’ . . . was a term of art in administrative law” prior to the Medicare Act amendments, Congress instead “introduced a seemingly new phrase to the statute books when it spoke of ‘substantive *legal standards*.’”²⁴² But as difficult as this passage may seem for the reconciled procedural reading, some of the language in *American Hospital Association*, which the statute’s drafters likely had in mind, suggests an understanding of “rule[] of agency organization, procedure, or practice”²⁴³ as a rule that does not alter a substantive legal standard.²⁴⁴ With *American Hospital Association* in mind then, the reconciled procedural reading is still defensible against the meaningful-variation argument.²⁴⁵

Moreover, rather than simply asking why Congress would seek to accomplish the same result with different language, one might just as well turn the question on its head: Why would Congress have chosen such a minor variation in language if it intended to subject Medicare rules to a meaningfully different notice-and-comment standard? Given that “substantive” is naturally read as the opposite of “procedural” (not “interpretive”), why attach so much significance to the choice of the word “standard” over “rule”? To do so, I think, gives far too much credit to a conference committee making eleventh-hour changes to a 473-page spending

²³⁹ See id at 1818 (Breyer dissenting).

²⁴⁰ See note 162 and accompanying text.

²⁴¹ 5 USC § 553(b)(A).

²⁴² *Allina II*, 139 S Ct at 1813 (emphasis in original).

²⁴³ 5 USC § 553(b)(A).

²⁴⁴ See notes 148–51 and accompanying text.

²⁴⁵ It is true that the Court in *Allina II* described the potential reference to *American Hospital Association* in the conference committee report as “oblique.” See *Allina II*, 139 S Ct at 1815. But as I argue above, a deeper dive into court decisions that were actually recent at the time of the conference report, as well as the timing of the report’s release, makes it hard to see the report as referencing any other case. See notes 142–47 and accompanying text. Any court willing to consider legislative history in statutory interpretation should take the likely reference to *American Hospital Association* and its implications regarding procedural rules seriously.

bill.²⁴⁶ Attempting to divine what was going through the committee lawyers’ heads when they chose the word “standard” might be an interesting intellectual exercise, but it seems in poor taste to indulge in this exercise any further than necessary if it leaves the insurer of over sixty million Americans guessing at how it is to administer its program. At any rate, meaningful variation is not the only canon of statutory interpretation, and it need not end the inquiry when the legislative history militates in favor of the reconciled procedural reading.²⁴⁷

2. The limits of purposivism.

Second, it is not obvious that the only policy preference Congress could have expressed in choosing the language “substantive legal standard”²⁴⁸ was one in favor of the agency’s internal flexibility. After all, the entire impetus for codifying a notice-and-comment requirement was that HCFA was not taking its notice-and-comment obligations seriously enough.²⁴⁹ But to the extent that courts are willing to consider legislative history, the conference committee’s decision to change the words “significant effect”²⁵⁰ to “substantive legal standard”²⁵¹ must reflect *some* degree of sensitivity to the need for flexibility. The conference committee’s stated rationale for the change was “to clarify that *only* policies establishing or changing a substantive legal standard governing benefits, payment, or eligibility must be promulgated as regulations.”²⁵² It would seem to follow that the point of changing the language was to subject fewer rules to notice and comment than the earlier draft of the subsection would have. It is hard to imagine an argument for limiting the scope of the notice-and-comment provision that does not include some concern for CMS’s ability to administer the Medicare system. So while the reconciled procedural reading is not the *only* plausible reading from a purposivist standpoint, it is surely at least *one* plausible reading.

²⁴⁶ See generally Omnibus Budget Reconciliation Act of 1987, 101 Stat 1330-55.

²⁴⁷ See Part II.B.

²⁴⁸ 42 USC § 1395hh(a)(2).

²⁴⁹ See notes 127–29 and accompanying text.

²⁵⁰ See HR 3545 at 30019 (cited in note 130).

²⁵¹ 42 USC § 1395hh(a)(2).

²⁵² HR Conf Rep No 100-495 at 566 (cited in note 132) (emphasis added).

3. The substantive-value-judgment test's indeterminacy.

Finally, one might argue that the DC Circuit's test for procedural rules under the APA presents too indeterminate a standard. The argument would be that courts applying the substantive-value-judgment test in the APA context have produced unpredictable results, making it difficult for agencies to determine which rules at the margins between substance and procedure they should subject to notice and comment. Adopting the reconciled procedural reading would thus lead only to more uncertainty in the world of Medicare and usher in a state of affairs little better than the "smog" surrounding the legislative/interpretive divide in the APA context.²⁵³

I do not contend that the substantive-value-judgment test is a *perfectly* determinate solution, nor will I spill any ink debating the relative merits of standards and bright-line rules in the law. I will only reply that this solution is *preferable* to the DC Circuit's continued reliance on the dictionary approach. The *Allina I* court conducted a brisk analysis under a "minimum" definition without articulating a maximum as to what the statute might require.²⁵⁴ The reconciled procedural reading would at least tie down interpretation of the statute to a body of existing cases that would help outline the contours of the notice-and-comment requirement.²⁵⁵ Furthermore, CMS only recently lost access to the important interpretive rule exemption. A certain degree of flexibility in the applicable test may be desirable so that courts can weigh the implications of their decisions on the continued administrability of the Medicare system and avoid completely blindsiding CMS, as a bright-line rule might require. Though the reconciled procedural reading cannot extinguish the fire the *Allina* decisions started, it can at least contain the flames.

CONCLUSION

Allina II may not have provided much clarity, but it did leave room to refine the DC Circuit's nascent interpretation of the Medicare statute. Treating § 1395hh(a)(2) as the mirror image of the

²⁵³ See note 28 and accompanying text.

²⁵⁴ *Allina I*, 863 F3d at 943.

²⁵⁵ See Part IV.A.

APA’s exemption to notice and comment for “rules of agency organization, procedure, or practice”²⁵⁶ is perhaps not the only plausible reading of the statute, but it is one of the most natural, and it comes with “the added virtues of clarity and stability.”²⁵⁷ Best of all, having committed to its dictionary definition only as a “minimum” and never having fixed the limits of the notice-and-comment provision’s coverage,²⁵⁸ the DC Circuit could adopt the reconciled procedural reading and cabin the Medicare Act’s notice-and-comment requirement without overturning any prior precedent. With the health insurance of over sixty million Americans on the line, providing a clearer statement of CMS’s notice-and-comment obligations is a necessary “procedure.”

²⁵⁶ 5 USC § 553(b)(A).

²⁵⁷ *Allina II*, 139 S Ct at 1823 (Breyer dissenting).

²⁵⁸ *Allina I*, 863 F3d at 943.