Not So Different after All: The Status of Interpretive Rules in the Medicare Act

Graham Haviland†

The Medicare Act is not subject to the informal rulemaking requirements of the Administrative Procedure Act (APA). Instead, it has its own provision that mandates notice and comment for proposed regulations. Courts have come to different conclusions regarding the scope of the Medicare Act's notice-and-comment requirement. This Comment interprets this Medicare Act provision to determine whether its requirement is equivalent in scope to that of the APA. This Comment presents arguments from text and legislative history to demonstrate that, as in the APA, interpretive rules are exempt from notice and comment. Finally, this Comment explains why this outcome is desirable as a policy matter: there is no reason to think that the ability to quickly promulgate interpretive rules is any less beneficial in the context of Medicare than it is in those areas of administrative law governed by the APA.

† BA 2011, The University of Chicago; JD Candidate 2019, The University of Chicago Law School.

INTRODUCTION

The Administrative Procedure Act[1] (APA) distinguishes between "legislative rules" that bind with the force of law and "interpretive rules" that merely interpret existing statutes or rules.[2] Legislative rules must go through notice and public comment, but interpretive rules do not. Legislative rules are further subjected to so-called "hard look review," under which courts hold rules with significant substantive or procedural shortcomings to be "arbitrary and capricious."[3] Interpretive rules, on the other hand, are usually challenged on the ground that they are not *truly* interpretive rules but rather invalid legislative rules improperly promulgated without notice and comment.[4]

Interpretive rules therefore represent a lower-cost alternative to legislative rules because they are procedurally easier to

---

1 60 Stat 237 (1946), codified as amended in various sections of Title 5.

2 The relevant statutory language uses the term "interpretative rules," 5 USC § 553(b)(1)(A), but the majority approach within administrative law scholarship is to refer to them as "interpretive rules." "Legislative rules" is also a term of art in that body of scholarship. See generally, for example, Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 Admin L J Am U 1 (1994).

3 Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 Duke L J 1385, 1411 (1992), citing *Motor Vehicle Manufacturers Association v State Farm Mutual Auto Insurance Co*, 463 US 29, 43 (1983).

4 See, for example, *American Mining Congress v Mine Safety and Health Administration*, 995 F2d 1106, 1108–10 (DC Cir 1993).

produce and subject to less judicial scrutiny.[5] The lower cost allows agencies to efficiently and quickly issue authoritative interpretations of existing law, freeing up agency resources for more resource-intensive tasks like legislative rulemaking. However, forgoing notice and comment involves a trade-off: agencies are able to promulgate rules more swiftly and efficiently, but regulated parties may not have notice of the impending regulation and may be denied the opportunity to play a role in the rulemaking process.[6]

Though the Medicare Act[7] is not subject to the APA's rulemaking section,[8] it has, until recently, been understood to contain an interpretive rule exemption akin to that of the APA. The Medicare Act has its own section, 42 USC § 1395hh, that provides procedures for promulgating "regulations." This section contains a notice-and-comment requirement, but courts disagree whether it applies to interpretive rules. Given the efficiency benefits of the interpretive rule exception and the countervailing risk of notice-and-comment evasion, the resolution of this question has high stakes for agencies, regulated parties, and the public.

The First, Sixth, Eighth, Ninth, and Tenth Circuits have all held that interpretive rules promulgated to carry out the Medicare Act are exempt from that statute's notice-and-comment requirement.[9] The DC Circuit recently broke with the other circuits in *Allina Health Services v Price*,[10] holding that interpretive rules are not exempt from the Medicare Act's notice-and-comment requirement.[11] Because any party challenging the validity of an interpretive rule promulgated by the Secretary of the Department of Health and Human Services (HHS) may do so in the DC Circuit,[12] this decision has significant consequences for Medicare rulemaking. Even though there is technically a circuit split, the

---

5 David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 Yale L J 276, 303–04 (2010).

6 See McGarity, 41 Duke L J at 1441–42 (cited in note 3).

7 Social Security Amendments of 1965 ("Medicare Act"), Pub L No 89-97, 79 Stat 286, codified at 42 USC § 1395 et seq.

8 See 5 USC § 553(a)(2) (exempting benefit programs).

9 See *Warder v Shalala*, 149 F3d 73, 79 n 4 (1st Cir 1998); *Omni Manor Nursing Home v Thompson*, 151 Fed Appx 427, 431 (6th Cir 2005); *Baptist Health v Thompson*, 458 F3d 768, 776 n 9 (8th Cir 2006); *Erringer v Thompson*, 371 F3d 625, 633 (9th Cir 2004); *Via Christi Regional Medical Center, Inc v Leavitt*, 509 F3d 1259, 1271 n 11 (10th Cir 2007).

10 863 F3d 937 (DC Cir 2017).

11 Id at 942–45.

12 See 28 USC § 1391(e)(1).

DC Circuit's decision is likely to be the only one that truly matters—the Secretary can no longer promulgate many interpretive rules without going through notice and comment because the United States District Court for the District of Columbia will strike these rules down under *Allina Health Services*.[13]

The statutory interpretation conducted by the various courts of appeals has not led to a satisfactory resolution of the question. The First, Sixth, Eighth, Ninth, and Tenth Circuits have all held without significant analysis that the Medicare Act created a distinction between legislative and interpretive rules akin to that of the APA, exempting interpretive rules from the notice-and-comment requirement. These courts focused narrowly on individual provisions that appear to exempt interpretive rules by implication[14] without considering the conspicuous absence of interpretive rules from the list of express notice-and-comment exemptions.[15] But the DC Circuit moved too far in the other direction, holding that the list of express exemptions precluded the existence of an interpretive-rule exception after only brief analysis of the provision's scope. No court has thoroughly considered which agency actions constitute "regulations" subject to the notice-and-comment requirement of § 1395hh.

A more thorough analysis of § 1395hh suggests that interpretive rules are not an *exception* to the notice-and-comment requirement of the statute but in fact fall entirely outside the scope of its notice-and-comment provision. The scope of that provision is limited to "regulations," which are defined as agency actions that pertain to "substantive legal standard[s]."[16] Because interpretive rules do not *change* substantive law, they do not affect "substantive legal standards" in the normal sense of that term and are thus not "regulations" that must go through notice and comment. The structure of the statute, surrounding text, and relevant legislative history strongly support this interpretation of the Medicare Act.

This Comment proceeds in three parts. Part I describes informal rulemaking under the APA—focusing on the distinction be-

---

13 The DC Circuit's approach requires notice and comment only if a rule changes a substantive legal standard. Only some interpretive rules do this; others do not. See Part I.B.

14 See 42 USC § 1395hh(a)(2), (c)(1).

15 See 42 USC § 1395hh(b).

16 42 USC § 1395hh(a)(2).

tween legislative and interpretive rules—and presents the relevant procedural provisions and amendment history of the Medicare Act. It also discusses the consequences of procedural hurdles to rulemaking, giving salience to this question of statutory interpretation. Part II presents courts' interpretations of § 1395hh, focusing on the split that has developed among the circuits. Part III critiques the existing approaches, engages in a thorough interpretation of the key statutory provisions, and concludes that interpretive rules are not "regulations" subject to notice and comment under the scope provision, § 1395hh(a)(2). It also discusses why this outcome is desirable as a matter of policy.

I. BACKGROUND LAW: THE APA AND THE MEDICARE ACT

Understanding the APA is crucial to interpreting the relevant provisions of the Medicare Act. Though the Medicare Act's procedural requirements differ from those of the APA, there is a great deal of similarity between the two statutes. Furthermore, the APA is the foundational law of federal administrative procedure. Even if a program is exempt from its rulemaking requirements, courts often view the parallel administrative procedure of the program through the lens of the APA.[17] Consequently, Medicare rulemaking must be viewed in the broader context of the APA.

A. Rulemaking under the APA: Notice and Comment

The APA provides the procedural requirements for most informal agency rulemaking. It defines "rules" broadly as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency."[18]

Informal rulemaking is the dominant method by which agencies create regulatory law, and it has only a few statutory requirements.[19] First, the agency must give notice of the proposed rulemaking by providing "(1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the

---

17 As Part II.A describes, courts have been all too ready to assume—without sufficient analysis—that the Medicare Act operates in exactly the same way as the APA.

18 5 USC § 551(4).

19 *Formal* rulemaking involves "onerous trial-type hearings," Franklin, 120 Yale L J at 282 (cited in note 5), "has become almost extinct," Akhil Reed Amar and Catharine A. MacKinnon, *The Supreme Court, 1999 Term*, 114 Harv L Rev 23, 374 n 44 (2000), and therefore lies beyond the scope of this Comment.

legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved."[20] Second, the agency must provide interested parties the opportunity to submit comments on proposed rules.[21] Then, "[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose."[22] Together, these provisions provide the "notice-and-comment" requirement for informal rulemaking.

While the statutory requirements for informal rulemaking are superficially limited, courts have interpreted the APA broadly to require extensive release of information in a notice of proposed rulemaking and in-depth justification for rulemaking when responding to comments. The DC Circuit has held that "[i]t is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data, or on data that, [to a] critical degree, is known only to the agency."[23] Under the "hard look" doctrine, courts examine the rulemaking process (including, at least indirectly, the substance of the rule) to ensure that the agency has adequately explained the reasoning behind its action and responded to the material concerns of commenting parties.[24] Knowing that such review may await it after the rule is promulgated, an agency must invest significant resources in the notice-and-comment process in order to generate a record that will allow the rule to survive judicial scrutiny.[25] This further raises the costs of notice-and-comment rulemaking.

---

20 5 USC § 553(b).

21 5 USC § 553(c).

22 5 USC § 553(c).

23 *Portland Cement Association v Ruckelshaus*, 486 F2d 375, 393 (DC Cir 1973). See also *American Radio Relay League, Inc v Federal Communications Commission*, 524 F3d 227, 237 (DC Cir 2008) ("It would appear to be a fairly obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during rulemaking in order to afford interested persons meaningful notice and an opportunity for comment."). For a critique of this view, see id at 246 (Kavanaugh concurring in part and dissenting in part).

24 See *Motor Vehicle Manufacturer's Association of the United States, Inc v State Farm Mutual Automobile Insurance Co*, 463 US 29, 43 (1983) ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made.") (quotation marks omitted).

25 See McGarity, 41 Duke L J at 1410–12 (cited in note 3).

B. Exceptions to Notice and Comment

There are, however, a number of exceptions to the APA's notice-and-comment requirement. Broad areas of subject matter are exempt, specifically military affairs, foreign affairs, matters of agency management or personnel, public property, loans, grants, contracts, and—of particular importance for the Medicare Act—benefits.[26]

Furthermore, the APA provides an exception for interpretive rules and policy statements[27] (collectively "nonlegislative rules"[28]). These rules, in contrast to legislative rules, lack the force of law and, at least in theory, simply clarify the law or provide guidance rather than legally bind the public or the agency.[29] The line between "legislative" (or "substantive") rules subject to the notice-and-comment requirement and interpretive rules exempt from the requirement is far from clear. The APA does not define the terms,[30] and courts have had a great deal of difficulty articulating a test to distinguish between the two.[31] The dominant approach is currently the "legal effects" test, first articulated by the DC Circuit in *American Mining Congress v Mine Safety and Health Administration*:[32]

> [I]nsofar as our cases can be reconciled at all, we think it almost exclusively on the basis of whether the purported

---

26 5 USC § 553(a).

27 5 USC § 553(b)(3)(A).

28 This term comes from courts and administrative law scholarship. It is not used in the APA. See generally, for example, John F. Manning, *Nonlegislative Rules*, 72 Geo Wash L Rev 893 (2004).

29 See id at 894.

30 It is worth noting that the *Attorney General's Manual on the Administrative Procedure Act* (United States Department of Justice, 1947) provides useful definitions roughly contemporaneous with the APA. It defines substantive rules as "rules, other than organizational or procedural . . . issued by an agency pursuant to statutory authority and which implement the statute. . . . Such rules have the *force and effect of law*." Id at 30 n 3 (emphasis added). It defines interpretive rules as "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." Id. The Supreme Court has given some deference to the *Attorney General's Manual* because it was drafted contemporaneously with the APA and because the Department of Justice played a role in drafting the APA. See *Vermont Yankee Nuclear Power Corp v Natural Resources Defense Council, Inc*, 435 US 519, 546 (1978).

31 See Richard J. Pierce Jr, *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin L Rev 547, 547–48 (2000) ("Courts often refer to the distinction between the two types of rules as 'fuzzy,' 'tenuous,' 'blurred,' 'baffling,' and 'enshrouded in considerable smog.'") (citations omitted).

32 995 F2d 1106 (DC Cir 1993).

> 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]

But these are just a few of the many factors that courts have looked to in answering the more general question of "whether a nominal 'interpretive rule,' in fact, merely interprets a statute or legislative regulation rather than makes new law."[34] All agency rules involve policymaking to some extent because any resolution of ambiguity requires policy judgment, and if the statute were not ambiguous, no interpretive rule would be necessary.[35] Nevertheless, it is generally understood under the legal effects test that, even if an interpretive rule guides agency action to some extent through its interpretation of the underlying law, it is the underlying statute or legislative rule that provides the legal basis for agency action.

The APA also contains a "good cause" exception. If an agency finds that "notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," the agency may forgo notice and comment on the condition that the agency explain in the rule why it is invoking the exception.[36] Common forms of rulemaking under the good cause exception include interim final

---

33 Id at 1112.

34 Manning, 72 Geo Wash L Rev at 920 (cited in note 28).

35 Id at 894. *American Mining Congress* is illustrative. In that case, the DC Circuit held that an agency rule stating that certain x-ray results constitute a positive "diagnosis" for purposes of another agency rule was indeed interpretive. 995 F2d at 1108–13. While it is perfectly reasonable to say that a given numerical test result constitutes a diagnosis, it is not purely interpretive. "Diagnosis" could easily mean a diagnosis from a doctor, for example. And it is not clear that the x-ray cutoff settled upon by the agency is the only one that they could have chosen consistent with the statutory language. If there are multiple interpretations of a rule, all of which are more or less equally plausible, then choosing among the various possible interpretations constitutes policymaking. The result of the inquiry is not dictated by the text of the original legislative rule or other source of legal meaning, so the agency is doing more than simply determining the best meaning of a term; rather, it is actively creating policy. See Manning, 72 Geo Wash L Rev at 920 (cited in note 28).

36 5 USC § 553(b)(3)(B).

rulemaking, in which an agency issues a final rule before considering comments, and direct final rulemaking, in which an agency announces a rule that will go into effect if no one objects to it.[37]

C. Ossification and the Significance of Nonlegislative Rulemaking

The burdensome notice-and-comment requirement and hard-look review have generated a significant literature decrying the "ossification" of informal rulemaking.[38] The ossification hypothesis posits that these procedural burdens have increased the costs of creating or changing regulations. In the face of such increased costs, agencies will necessarily regulate less.[39] If one accepts the premise that agencies enact regulatory policies to increase social welfare (and are at least sometimes successful in doing so), then ossification is a problem to the extent that it drives rulemaking below the welfare-maximizing level.[40] While even proponents of the ossification theory acknowledge that there are likely trade-offs between administrative efficiency and the various benefits

---

[37] See Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 Admin L Rev 703, 704–06 & n 12 (1999); Ronald M. Levin, *More on Direct Final Rulemaking: Streamlining, Not Corner-Cutting*, 51 Admin L Rev 757, 763 (1999).

[38] See generally, for example, William S. Jordan III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals through Informal Rulemaking?*, 94 Nw U L Rev 393 (2000); Richard J. Pierce Jr, *Seven Ways to Deossify Agency Rulemaking*, 47 Admin L Rev 59 (1995); McGarity, 41 Duke L J 1385 (cited in note 3).

[39] See McGarity, 41 Duke L J at 1388–91 (cited in note 3).

[40] See id at 1391:

> Since most regulatory statutes were enacted to accomplish progressive public policy goals, the ossification of the informal rulemaking process hinders or defeats the agency's pursuit of those goals. To some extent, the fact that the air and waters of the United States are still polluted, workplaces still dangerous, motor vehicles still unsafe, and consumers still being deceived is attributable to the expense and burdensomeness of the informal rulemaking process.

But see generally Jason Webb Yackee and Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950–1990*, 80 Geo Wash L Rev 1414 (2012) (using Department of the Interior rulemaking data to challenge the ossification hypothesis). For a description of the potential benefits of ossification, see generally Aaron L. Nielson, *Sticky Regulations*, 85 U Chi L Rev 85 (2018). It is worth noting, however, that Professor Aaron Nielson's critique does not necessarily apply to interpretive rules. His primary argument is that ossification provides a valuable way for agencies to credibly commit to regulatory programs. Id at 116. If most interpretive rules are minor clarifications of law or agency policy unlikely to significantly affect the behavior of regulated parties, ossification is of limited value. This, of course, depends on the extent to which interpretive rules are surreptitiously crafting policy.

that come from more deliberative rulemaking procedures,[41] this does not render the ossification issue irrelevant. Rather, it points to the importance of determining the relative magnitudes of the costs and benefits of heightened procedural requirements and judicial review.

Interpretive rules—and nonlegislative rules more generally—have played a role in the ossification debate. Scholars have hypothesized that agencies promulgate interpretive rules instead of legislative rules in order to avoid the burdensome requirements of notice and comment, thereby lowering the costs of rulemaking and speeding up the rulemaking process.[42] Indeed, critics of ossification have expressed concern that increasing the costs of notice-and-comment rulemaking has produced a nefarious substitution effect, driving agencies toward less formal policymaking mechanisms, such as interpretive rulemaking, that provide parties with less notice and opportunity for input.[43] This is problematic because the increased flexibility of these forms of rulemaking comes at the price of accountability and participation by interested parties.[44] Under this theory, widespread use (or abuse) of interpretive rules is symptomatic of ossification and does not represent a solution to its core problem.

D. The Medicare Act and Its Procedural Rulemaking Provision

The Medicare Act (passed as the Social Security Amendments of 1965) was enacted to provide insurance programs for the elderly and disabled. As amended, it contains four main parts: Part A, which provides hospital benefits; Part B, which provides medical insurance; Part C, which permits private insurance companies to administer Medicare benefits; and Part D, which provides prescription drug benefits.[45] Today, Medicare is a massive public benefits program—over fifty-seven million Americans

---

41 See McGarity, 41 Duke L J at 1391–92 (cited in note 3) ("To be sure, other societal goals, such as fairness, allocative efficiency, and factual accuracy, may demand more deliberative rulemaking procedures."). See also Franklin, 120 Yale L J at 303–05 (cited in note 5) (describing the costs and benefits of nonlegislative rulemaking).

42 See, for example, McGarity, 41 Duke L J at 1441–43 (cited in note 3).

43 See id.

44 See id. One can imagine regimes in between interpretive rulemaking and notice-and-comment rulemaking. For example, agencies could be required to give notice and solicit input from the public but not be subjected to hard-look review.

45 See Eleanor D. Kinney, *The Accidental Administrative Law of the Medicare Program*, 15 Yale J Health Pol L & Ethics 111, 113 (2015).

receive benefits under Parts A and B[46]—and "is governed by a complex web of legislative rules, interpretive rules and manuals, [and] policy guidance."[47]

1. Overview of the Medicare Act's key rulemaking provisions.

Medicare is not subject to the APA's informal rulemaking requirements because it is a benefits program.[48] The original Medicare Act imposed no independent procedural requirements for Medicare rulemaking.[49] But in the intervening years, Congress has amended the statute numerous times to include provisions prescribing procedures for rulemaking under the Act.[50]

The Medicare Act, as amended, now contains a number of important procedural rulemaking provisions codified at 42 USC § 1395hh. Subsection (a)(1)—the "power-to-regulate provision"—authorizes the HHS Secretary to promulgate regulations to carry out the Medicare statute.[51] But such regulations are further subject to subsection (a)(2)—the "scope provision"—which provides that

> [n]o rule, requirement, or other statement of policy . . . 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 receive benefits] . . . under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).[52]

Pursuant to § 1395hh(b)(1)—the "notice-and-comment provision"—the Secretary is required to "provide for notice of the proposed regulation in the Federal Register and a period of not less

---

46 US Department of Health and Human Services, *2016 CMS Statistics* *2 (Centers for Medicare & Medicaid Services, 2016), archived at http://perma.cc/9VXW-R9VS.

47 See Kinney, 15 Yale J Health Pol L & Ethics at 111 (cited in note 45).

48 See 5 USC § 553(a)(2).

49 See Medicare Act § 1871, 79 Stat at 331 (granting the HHS Secretary statutory authority to prescribe regulations but imposing no procedural requirements).

50 See 42 USC § 1395hh.

51 See 42 USC § 1395hh(a)(1) ("The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. When used in this title, the term 'regulations' means, unless the context otherwise requires, regulations prescribed by the Secretary.").

52 42 USC § 1395hh(a)(2).

than 60 days for public comment thereon."[53] That provision provides several exceptions to the notice-and-comment requirement, most importantly by explicitly incorporating the good cause exception of the APA.[54] But subsection (c)(1)—the "alternative publication provision"—provides an alternative route for the publication of interpretive rules, among other nonlegislative rules:

> The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, *interpretative rules*, statements of policy, and guidelines of general applicability which—(A) are promulgated to carry out this title, but (B) are not published pursuant to subsection (a)(1) and have not been previously published in a list under this subsection.[55]

2. The amendment history of § 1395hh.

To understand the significance of and interaction between the various provisions of § 1395hh, it is helpful to consider the sequence of amendments that added these key provisions to the statute. As noted above, the original Medicare Act was exempt from the APA and contained no independent procedural rulemaking requirements,[56] and § 1395hh initially consisted entirely of what is now the power-to-regulate provision.[57] In 1971, however, the Department of Health, Education, and Welfare (HEW)—now the HHS—issued a statement of policy directing agencies within the Department to "utilize the public participation procedures of the APA."[58] Informal rulemaking under Medicare was carried out under this voluntary arrangement for about fifteen years, at which point Congress stepped in.

In 1986, Congress amended § 1395hh, codifying notice-and-comment procedures.[59] The amendment explicitly incorporated

---

53 42 USC § 1395hh(b)(1). This provision requires a longer comment period than that required by the APA.

54 See 42 USC § 1395hh(b)(2).

55 42 USC § 1395hh(c)(1) (emphasis added).

56 See notes 48–50 and accompanying text.

57 See note 51 and accompanying text.

58 Department of Health, Education, and Welfare, Public Participation in Rule Making, 36 Fed Reg 2532, 2532 (1971), citing 5 USC § 553.

59 Omnibus Budget Reconciliation Act of 1986 § 9321, Pub L No 99-509, 100 Stat 1874, codified at 42 USC § 1395hh(b).

the APA's good cause exception and provided a few additional exceptions irrelevant to nonlegislative rulemaking.[60] In 1987, Congress once again amended § 1395hh, this time adding two provisions: the scope provision and the alternative publication provision.[61] This suggests that the scope provision was added specifically to clarify which agency actions are "regulations" subject to the notice-and-comment requirement created by the 1986 amendment.[62]

II. COURTS' INTERPRETATIONS OF THE MEDICARE ACT'S RULEMAKING PROVISIONS

A circuit split has recently arisen over whether the Medicare Act contains an interpretive rule exception akin to that of the APA. Before 2017, each court of appeals that had considered the question held that the Medicare Act included such an exception.[63] But in *Allina Health Services*, the DC Circuit broke with the other circuits by holding that interpretive rules promulgated under the Medicare Act must go through notice and comment if they fall within the scope provision.[64] This decision is significant because any party challenging the validity of an interpretive Medicare rule can file a lawsuit in the DC Circuit[65] and, given the choice of venue, will presumably choose the one with the more favorable precedent. Therefore, most litigation in this area will likely go through the DC Circuit and be subject to the rule from *Allina Health Services*.

A. The Majority Approach: Interpretive Rules Implementing Medicare Are Exempt from the Act's Notice-and-Comment Requirement

Courts that have found an interpretive rule exception in the Medicare Act have done so through two distinct interpretations

---

60 See Omnibus Budget Reconciliation Act of 1986, § 9321(e), 100 Stat at 1874, 2017–18.

61 Omnibus Budget Reconciliation Act of 1987 § 4035, Pub L No 100-203, 101 Stat 1330, 1330–77, codified at 42 USC § 1395hh(a), (c)(1).

62 The repeated amendments to the statute also provide a possible explanation for the inconsistencies among courts' interpretations of its provisions. The patchwork of statutory provisions does not fit together perfectly—or even very well—leaving the whole of § 13955hh ambiguous and open to a range of interpretations.

63 See note 9. The DC Circuit also endorsed this view in dicta. See *Monmouth Medical Center v Thompson*, 257 F3d 807, 814 (DC Cir 2001).

64 See *Allina Health Services*, 863 F3d at 942–45.

65 See 28 USC § 1391(e)(1).

of the statute. In one case, *Warder v Shalala*,[66] the First Circuit held that the alternative publication provision independently created an interpretive rule exception.[67] In another line of cases led by *Erringer v Thompson*,[68] courts have held that the scope provision exempts interpretive rules from the notice-and-comment requirement.[69] Even though these two approaches lead to the same outcome, they engage in dramatically different—and possibly incompatible—constructions of the statute.

The *Warder* court focused its analysis on the alternative publication provision. In evaluating the validity of a Health Care Financing Administration rule that classified a piece of medical equipment in a way that limited Medicare reimbursement,[70] the First Circuit held that "[t]he Medicare Act expressly incorporates the APA's exemption for interpretive rules."[71] The court inferred from Congress's prescription of an alternative publication process that the types of rules mentioned in that provision[72] were exempt from the notice-and-comment requirement set forth in the statute.[73] While the court noted that "the Medicare statute . . . phrases the distinction between substantive and interpretive rules slightly differently from the APA," it nevertheless held that the Medicare Act's "language, drafted after the APA's, can fairly be read to duplicate the APA on this score."[74] The court pointed to the scope provision as requiring notice and comment for rules that change a "substantive legal standard" but did not resolve the meaning of that provision. Rather, it held that the statute exempted interpretive rules by providing an alternative mode of publication for interpretive rules not promulgated as regulations.[75]

In *Erringer*, the Ninth Circuit identified the scope provision as the source of the interpretive rule exception.[76] The interpretive

---

66 149 F3d 73 (1st Cir 1998).

67 See id at 79.

68 371 F3d 625 (9th Cir 2004).

69 See id at 633.

70 *Warder*, 149 F3d at 75.

71 Id at 79.

72 The statute requires notice and comment under 42 USC § 1395hh(b) and mandates quarterly publication of "all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which . . . have not been previously published in a list under this subsection" under 42 USC § 1395hh(c).

73 *Warder*, 149 F3d at 79 n 4.

74 Id. It is not entirely clear how the court arrived at its conclusion that the Medicare Act reproduced the requirements of the APA.

75 See id.

76 *Erringer*, 371 F3d at 633.

rule in that case mandated the use of specific criteria in issuing coverage determinations affecting the claims of Medicare contractors.[77] In evaluating whether the statute exempted interpretive rules from notice and comment, the Ninth Circuit emphasized that the heading of the scope provision explicitly states that the provision governs *substantive* rules.[78] It inferred from that heading and the text of the provision that the Medicare Act drew a distinction between "substantive rules" subject to notice and comment and "interpretive rules" exempt from such requirements.[79] It acknowledged the possibility that the Medicare Act might "somehow draw[ ] the line between substantive and interpretive rules in a different place than the APA."[80] But the court "found no reason to explore the possibility of a distinction between the Medicare Act and the APA because the rule in question . . . was not close to the interpretive/substantive line."[81]

The Sixth, Eighth, and Tenth Circuits largely followed the reasoning of *Erringer*. In *Baptist Health v Thompson*,[82] the Eighth Circuit noted simply that § 1395hh "imposes no standards greater than those established by the APA" and went on to apply the APA's familiar interpretive/legislative framework.[83] In *Via Christi Regional Medical Center, Inc v Leavitt*,[84] the Tenth Circuit stated that, while "[t]he Medicare statute contains some additional language regarding the promulgation and effect of rules and policy statements, . . . courts generally interpret it to impose 'no standards greater than those established by the APA.'"[85] And in *Omni Manor Nursing Home v Thompson*,[86] the Sixth Circuit implicitly endorsed the majority approach by simply presenting the text of § 1395hh(a)(2) and applying the substantive/interpretive rule framework commonly employed by courts applying the APA.[87]

---

77 Id at 627–28.
78 Id at 633.
79 Id.
80 *Erringer*, 371 F3d at 633.
81 Id, citing *Monmouth Medical Center*, 257 F3d at 814.
82 458 F3d 768 (8th Cir 2006).
83 Id at 776 n 9, citing *Erringer*, 371 F3d at 633.
84 509 F3d 1259 (10th Cir 2007).
85 Id at 1271 n 11, quoting *Baptist Health*, 458 F3d at 776 n 8.
86 151 Fed Appx 427 (6th Cir 2005).
87 Id at 431.

B. The DC Circuit Approach: Interpretive Rules Are Not Exempt from the Medicare Act's Notice-and-Comment Requirement

In *Allina Health Services*, the DC Circuit held that the Medicare Act does not incorporate the APA's interpretive rule exception.[88] The court relied on a narrow interpretation of the scope provision and an *expressio unius* argument,[89] looking to the *explicit* exceptions of the notice-and-comment provision.[90] Like the *Erringer* court, the DC Circuit used the scope provision to determine which agency actions are subject to the Medicare Act's notice-and-comment requirement.[91] The court interpreted the term "substantive" in the substantive/procedural sense and, looking to a dictionary to define "substantive law," concluded that a "'substantive legal standard' at a minimum includes a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'"[92] The court concluded that the interpretive rule—which instituted a new formula for calculating reimbursements to hospitals treating low-income Medicare patients—created such a standard and that notice and comment was required by the scope provision.[93]

---

88 863 F3d at 944. The court also resolved the case on alternative grounds, holding that, even if the Medicare Act incorporated the APA's interpretive rule exception, notice and comment would still be required by § 1395hh(a)(4). *Allina Health Services*, 863 F3d at 945. This section stipulates that "a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule . . . shall be treated as a proposed regulation" and subject to further comment before it takes effect. 42 USC § 1395hh(a)(4).

89 The *expressio unius* canon of statutory interpretation, also known as the negative-implication canon, suggests that, when specific members of a class are mentioned, other members of the class are excluded by implication. See Antonin Scalia and Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 107 (West 2012).

90 See *Allina Health Services*, 863 F3d at 944.

91 Id at 943 ("[T]he Medicare Act requires notice-and-comment rulemaking for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'"), quoting 42 USC § 1395hh(a)(2).

92 *Allina Health Services*, 863 F3d at 943, quoting *Black's Law Dictionary* (West 10th ed 2014).

93 The position taken in *Allina Health Services* is somewhat surprising given that the DC Circuit had previously adopted the majority position in dicta. See *Monmouth Medical Center*, 257 F3d at 814. The court noted in that case that the alternative publication provision seemed to create an interpretive rule exception at least *similar* in scope to that of the APA but did not explicitly hold that the Medicare statute incorporated the interpretive-rule exception. Id. Interestingly, the DC Circuit—like the *Warder* court—found the interpretive rule exception in the alternative publication provision rather than in the scope provision, indicating that it thought that the presence of an alternative publishing method for interpretive rules was particularly compelling evidence. Id. As

The court then reasoned that § 1395hh(b)(2), which does not include an interpretive rule exception, constitutes an exhaustive list of exceptions to the notice-and-comment requirement.[94] Therefore, the statute does not contain an exception for interpretive rules.[95] This argument is strengthened by the fact that the statute explicitly incorporates by reference the APA's good cause exception.[96]

III. THE MEDICARE ACT'S NOTICE-AND-COMMENT REQUIREMENT DOES NOT APPLY TO INTERPRETIVE RULES

The existing case law provides incomplete interpretations of the statute. Courts have adopted three distinct interpretations of § 1395hh, each presenting a reasonable interpretation of an *individual* provision of the statute.[97] But the courts have not situated their readings of those provisions in the context of the statute as a whole.

A more holistic construction of the statute can help resolve its serious ambiguities. Under the scope provision, agency actions that pertain to "substantive legal standard[s]" are "regulations" that must go through notice and comment.[98] In isolation, it is not clear how the term "substantive legal standard" should be understood. But the nature of interpretive rules, the title of the scope provision, the distinction between "regulations" and "interpretive rules" presented elsewhere in the statute,[99] and legislative history strongly suggest that such standards can be created only by legislative rules.

Part III.B.3 discusses, the alternative publication provision is not particularly helpful in interpreting the statute. However, the *Monmouth Medical Center* court held that the regulation was a legislative rule under the APA, so the existence of an interpretive rule exception was irrelevant to the disposition of the case. Id at 814. The conclusion regarding § 1395hh is therefore dicta and, moreover, was explicitly rejected by the DC Circuit in *Allina Health Services*.

94 *Allina Health Services*, 863 F3d at 944.

95 Id.

96 Id ("Moreover, Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it wanted to. After all, the Medicare Act expressly incorporates other APA notice-and-comment exceptions. Specifically, the Medicare Act incorporates the APA's 'good cause' exception.").

97 Section 1395hh(a)(2) in *Erringer*, § 1395hh(c)(1) in *Warder*, and § 1395hh(b) in *Allina Health Services*.

98 42 USC § 1395hh(a)(2).

99 See 42 USC § 1395hh(e)(1).

This Part proceeds in four sections. Part III.A evaluates existing court interpretations of the Medicare Act. Part III.B engages in a thorough interpretation of § 1395hh, focusing on likely meanings of the key term in isolation, whole-act construction, and legislative history. It concludes that interpretive rules are not "regulations" subject to the Act's notice-and-comment requirement. Part III.C explains why this interpretation of the statute undercuts the *expressio unius* argument presented in *Allina Health Services*. Finally, Part III.D argues that the interpretive rule exception is desirable as a matter of policy.

A. Evaluation of the Existing Court Approaches

None of the existing approaches provides a complete account of the Medicare Act's rulemaking provision. In *Warder*, the First Circuit did not consider the scope provision and held with only brief justification that the alternative method of publication "exempt[ed] by implication" interpretive rules.[100] This seems unlikely because there is inherent tension in arguing that, although there is an express list of exemptions, a major implicit exemption nevertheless exists.[101] The scope argument—that interpretive rules are not subject to promulgation by regulation under the scope provision and therefore not subject to notice and comment—developed by later courts better supports the proposition that interpretive rules need not go through notice and comment.

In *Erringer*, the Ninth Circuit reasoned that the text of the scope provision requires legislative rules to be promulgated as "regulations" subject to notice and comment.[102] But the court did not justify its interpretation of the provision beyond drawing attention to its title: "Authority to prescribe regulations; ineffectiveness of *substantive rules* not promulgated by regulation."[103] And the court did not determine whether interpretive rules can create a "substantive legal standard." The statute is complicated and contains numerous provisions that inform the scope of the notice-and-comment requirement.[104] Though the conclusion of *Erringer* is correct, the court did not present enough evidence beyond the

---

100 *Warder*, 149 F3d at 79 n 4.

101 This is basically the *expressio unius* argument made in *Allina Health Services*, 863 F3d at 944–45.

102 *Erringer*, 371 F3d at 633.

103 Id, quoting 42 USC § 1395hh(a) (quotation marks omitted).

104 See Part III.B.

title of the provision to support its interpretation. The circuits following *Erringer* were largely conclusory in their analyses.[105]

Allina Health Services more fully engaged with the text of the statute. The DC Circuit described and to some extent supported its interpretation of the phrase "substantive legal standard."[106] But like the Ninth Circuit in *Erringer*, the DC Circuit did not contemplate other reasonable interpretations of the text or square its interpretation of the provision with other parts of the statute that suggested its interpretation might be incorrect.[107] The court simply concluded from the text of the scope provision that *some* interpretive rules are subject to notice and comment. The court did not consider compelling evidence that the scope provision may specifically govern legislative rules and ignored contextual evidence from § 1395hh(e)(1) that the class of "regulations" subject to notice and comment does not include interpretive rules. Most importantly, the court did not *define* the key statutory term "regulation," which determines how the scope provision dictates the breadth of the notice-and-comment provision.

B. A Complete Interpretation of § 1395hh

A more rigorous interpretation of the statute could resolve the circuit split. One particularly important point that has not been sufficiently addressed in the court opinions interpreting § 1395hh is the ambiguity of the scope provision. Each court has equated the scope of Medicare's notice-and-comment requirement to that of the APA and focused its analysis on the presence (or lack thereof) of an *exception* for interpretive rules. Some courts have determined that the scope provision or the alternative publication provision exempts interpretive rules from notice and comment, but none has fully examined whether interpretive rules fall within the scope provision. In other words, no court has determined whether the "regulations" governed by the notice-and-comment provision of the Medicare Act are equivalent to what the APA considers "rules."[108] This Comment argues below that the

---

[105] See, for example, *Baptist Health*, 458 F3d at 776 n 9 (presenting the text of § 1395hh(a)(2) and stating simply that "this provision imposes no standards greater than those established by the APA").

[106] See *Allina Health Services*, 863 F3d at 943.

[107] See id at 943–45.

[108] In *Warder*, the First Circuit came close to considering this issue and distinguishing rules from regulations when it noted that § 1395hh(c) "requir[es] periodic publication of 'interpretive rules' that have not been issued as regulations." 149 F3d at 79 n 4.

two classes are distinct and that the Medicare Act's notice-and-comment provision[109] is fundamentally different in scope from that of the APA. While the APA applies generally to "rules," creating an exemption for interpretive rules, the Medicare Act applies to "regulations," defining that term to exclude interpretive rules. An express exception is therefore unnecessary.

This Section proceeds in five steps. First, it explains why the phrase "substantive legal standard" is the key phrase in the scope provision, and it explores several meanings that the phrase may have. Second, it analyzes the rest of the scope provision and concludes that the provision does not help resolve the question. Third, it looks to the other provisions of § 1395hh to provide context for interpreting the scope provision. This context supports a narrower reading of the scope provision. Fourth, it looks to the title of the scope provision, which suggests that the rules described in the scope provision are "substantive" rules. Last, it considers the relevant legislative history, which suggests that the language in the scope provision was chosen by Congress to reflect the test used by courts in distinguishing between legislative and interpretive rules. While the text of the scope provision may be ambiguous, the title, context, and legislative history provide compelling evidence that Congress intended only legislative rules to be subject to the notice-and-comment requirement.

1. The scope provision specifies which agency actions constitute "regulations" subject to notice and comment.

The status of interpretive rules in § 1395hh is established by the text of the scope provision.[110] The notice-and-comment provision takes as its object "any regulation under subsection (a),"[111] so the requirement is best understood to apply specifically to agency actions described as regulations in subsection (a).[112] And the scope

---

109 42 USC § 1395hh(b).

110 Both *Erringer*, 471 F3d at 633, and *Allina Health Services*, 863 F3d at 943, treated this provision as establishing the scope of the notice-and-comment requirement even if they disagreed on its meaning.

111 42 USC § 1395hh(b)(1).

112 It is worth noting that, even if the term "regulation" were not explicitly defined within the statute, it could bear two meanings, one including only legislative (substantive) rules and the other including all agency rules. The edition of *Black's Law Dictionary* contemporaneous with the key 1986 and 1987 amendments to the Medicare Act defines a "regulation" as a "rule or order having force of law issued by executive authority of government" and notes that "United States Government regulations appear first in the Federal Register . . . and are subsequently arranged by subject in the *Code of Federal Regulations*." *Black's Law Dictionary* 1156–57 (West 5th ed 1979). See also Manning, 72

provision is the component of subsection (a)—and within the statute as a whole—that most directly defines "regulations" for purposes of the statute. It states that a certain set of agency policies "shall [not] take effect unless . . . promulgated by the Secretary by regulation under paragraph (1)."[113] The provision refers to "regulation" as a process that certain agency actions must go through in order to "take effect."[114] Those actions that must be promulgated through the process of "regulation" are best understood as being coextensive with the "regulations" contemplated throughout § 1395hh, including the notice-and-comment provision.

The issue is whether interpretive rules fall within the scope provision and are thereby subject to notice and comment. The scope provision reads in full:

> 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 paragraph (1).[115]

As the DC Circuit correctly noted in *Allina Health Services*, the key phrase in the provision is "substantive legal standard."[116] The DC Circuit looked to a dictionary to define the phrase as follows: "A 'substantive legal standard' at a minimum includes a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'"[117] From this definition, it concluded that the interpretive rule at issue in the case changed the duties of the parties by defining a term used to calculate Medicare payments.[118]

This is a good place to start the analysis, but it is far from clear that an interpretive rule can have such an effect. After all, the dominant approach taken by courts in distinguishing between

---

Geo Wash L Rev at 930–31 (cited in note 28) ("[L]egislative rules have the distinctive capacity to bind with the force of statutes."). However, that same dictionary also defines a "regulation" as a "[r]ule of order prescribed by superior or competent authority relating to an action of those under its control." *Black's Law Dictionary* 1156–57 (West 5th ed 1979).

113 42 USC § 1395hh(a)(2).

114 42 USC § 1395hh(a)(2).

115 42 USC § 1395hh(a)(2).

116 *Allina Health Services*, 863 F3d at 943.

117 Id.

118 Id.

legislative and interpretive rules has been to ask whether they bind with the "force of law" or have "legal effects." Legislative rules act with the force of law, but interpretive rules do not.[119] And an interpretive rule does not impose legal obligations on its own; rather, its "force derives from the *existing legal duty* inherent in the existing legislative rule or statute."[120] To determine whether a rule is legislative, courts traditionally look to "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."[121] The interpretive rule in *Allina Health Services*, for example, does not independently create or modify a legal duty or change a legal standard. The legal duty is created by the Medicare Act, which requires that patients "entitled to benefits under Part A" be included in the Medicare fraction for calculating hospital reimbursement.[122] The agency's interpretive rule merely *clarifies* or *describes* an existing legal duty created by statute.[123]

The phrase "substantive legal standard" is best understood as codifying the legal effects test in the Medicare Act. Only a rule that creates or modifies the legal obligations of parties can be said to "establish or change a substantive legal standard." Such a rule is a legislative rule. Therefore, interpretive rules fall outside of the scope provision and are not "regulations" subject to the notice-and-comment requirement.

One way to argue for a broader meaning of the term—one that *does* encompass some interpretive rules—would be to focus

---

[119] See *National Latino Media Coalition v Federal Communications Commission*, 816 F2d 785, 788 (DC Cir 1987) ("An 'interpretative' rule, by contrast [to a legislative rule], does not contain new substance of its own but merely expresses the agency's understanding of a congressional statute. . . . Thus an interpretative rule does not have the force of law."). See also *National Mining Association v McCarthy*, 758 F3d 243, 251–52 (DC Cir 2014):

> An agency action that sets forth legally binding requirements for a private party to obtain a permit or license is a legislative rule. (As to interpretive rules, an agency action that merely interprets a prior statute or regulation, and does not itself purport to impose new obligations or prohibitions or requirements on regulated parties, is an interpretive rule.)

[120] Jacob E. Gersen, *Legislative Rules Revisited*, 74 U Chi L Rev 1705, 1711 n 42 (2007) (emphasis added), citing *General Motors v Ruckelshaus*, 742 F2d 1561, 1565 (DC Cir 1984). See also *National Latino Media Coalition*, 816 F2d at 788.

[121] *American Mining Congress*, 995 F2d at 1112.

[122] *Allina Health Services*, 863 F3d at 939, quoting 42 USC § 1395ww(d)(5)(F)(vi)(I). The Medicare fraction is a component of the formula used to calculate reimbursements made to "hospitals that treat a disproportionately high number of low-income patients." *Allina Health Services*, 863 F3d at 938.

[123] See notes 27–35 and accompanying text.

on the word "standard" in "substantive legal standard." Interpretive rules can certainly articulate standards by which regulated parties' conduct will be evaluated. And while such rules may not constitute "substantive law" in any strict sense of the term, it has been argued that interpretive rules are functionally similar to substantive law when they are used to bind parties.[124] So if "substantive legal standard" is given its broadest possible meaning, it could conceivably encompass some interpretive rules, namely, those interpretive rules that put forward binding standards drawn from statutes or legislative rules.

But such a broad meaning does not seem likely given courts' formalistic understanding of what constitutes substantive law for purposes of administrative procedure. While the Medicare Act is not subject to the APA's rulemaking requirement, it still uses much of the language associated with the APA's distinction between substantive and interpretive rules. Given that the APA defines terms that are widely used in administrative law, it makes sense to start with the assumption that those terms are being used similarly in other statutes pertaining to administrative procedure. Absent compelling evidence to the contrary, "substantive legal standard" should be read narrowly to exclude interpretive rules from the definition of "regulation" presented in the scope provision and therefore from the notice-and-comment requirement. Nevertheless, it is necessary to look to the statute as a whole and to legislative history to determine the meaning of the scope provision.

2. The rest of the text of the scope provision does not clarify its meaning.

One possible argument in favor of the broad construction of the scope provision can be drawn from its inclusion of "requirement[s]" and "other statement[s] of policy" in addition to "rule[s]." This language could suggest that agency actions beyond "rules" must be promulgated as regulations subject to the notice-and-

---

[124] See Gersen, 74 U Chi L Rev at 1711 (cited in note 120) (citation omitted):

> But at least one pocket of scholarship suggests that . . . valid interpretive rules are binding to the extent that they "merely interpret" already existing legal duties.
>
> Rules that should have been issued using notice and comment procedures but were not are known as spurious rules or, equivalently, procedurally-deficient legislative rules.

comment requirement. It is a widely accepted principle of statutory interpretation that all words of a statute should be given effect when possible.[125] One could argue that the terms "requirement" and "other statement of policy" would be superfluous if they did not expand the scope of the provision beyond legislative rules and subject *some* other agency actions to promulgation through notice and comment.

There is an alternative explanation, however, that is consistent with the narrower interpretation of the scope provision. This language could also be read as simply clarifying that all agency actions, regardless of their *designations* by agencies, will be subject to notice and comment if they change substantive legal standards. The reference to "other statement[s] of policy" could simply mean that any agency action, even if it is *nominally* a statement of policy, must be promulgated "by regulation" and through notice and comment if it establishes or changes a "substantive legal standard"[126]—that is, if it is in fact a legislative rule incorrectly presented by the agency. In this way, the expansive language at the beginning of the provision could simply be expressing the familiar idea that the *content* of the agency action and not its formal designation is what determines the proper mode of promulgation. This is an equally valid reading of the provision that gives each term meaning, so no compelling inference can be drawn in either direction.

Even if one were to reject this explanation and take the expansive language as evidence that some properly designated statements of policy must be promulgated as regulations subject to notice and comment, the argument in favor of the broader interpretation of the scope provision is by no means dispositive. The presumption against superfluity is just that: a presumption. It is one of many competing concerns that plays a role in determining the best meaning of a statutory provision.[127] Canons of statutory interpretation are tools that can help us understand how an ordinary reader of English would understand the text, but a single canon cannot on its own dictate the meaning of a statute.[128] And

---

125 See, for example, *Leocal v Ashcroft*, 543 US 1, 12 (2004).

126 42 USC § 1395hh(a)(2).

127 See *United States v Atlantic Research Corp*, 551 US 128, 137 (2007) ("[O]ur hesitancy to construe statutes to render language superfluous does not require us to avoid surplusage at all costs.").

128 For criticism of substantive canons of interpretation, see generally Karl N. Llewellyn, *Remarks on the Theory of Appellate Decision and the Rules or Canons about*

the evidence provided by the rest of the statute favors a narrow reading of the scope provision.

3. The whole act suggests that interpretive rules are not "regulations" subject to notice and comment.

Considering the context provided by the whole text of a statute can help a reader determine the ordinary meaning of a word or phrase within a given provision.[129] The Supreme Court has held that "[t]he plainness or ambiguity of statutory language is determined [not only] by reference to the language itself, [but as well by] the specific context in which the language is used, and the broader context of the statute as a whole."[130]

In this case, the broader context of the statute indicates that "regulations" and "interpretive rules" are separate categories; this distinction also applies within the scope provision. Section 1395hh(e)(1)—the "retroactivity provision"—states that, absent certain circumstances, "[a] substantive change in *regulations*, manual instructions, *interpretative rules*, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change."[131] The provision clearly contemplates "regulations" and "interpretative rules" as distinct categories. The term "regulation" should be understood to have the same meaning in the rest of the statute, including the scope provision and the notice-and-comment provision.[132] And if "regulations" and "interpretive

How Statutes Are to Be Construed, 3 Vand L Rev 395 (1950); William N. Eskridge Jr, Book Review, *The New Textualism and Normative Canons*, 113 Colum L Rev 531 (2013).

[129] See William N. Eskridge Jr, *Interpreting Law: A Primer on How to Read Statutes and the Constitution* 86 (Foundation 2016), citing *United Savings Association of Texas v Timbers of Inwood Forest Associate, Ltd*, 484 US 365, 371 (1988) ("Statutory construction [ ] is a holistic endeavor. A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law."); Scalia and Garner, *Reading Law* at 167–69, 180–82 (cited in note 89).

[130] *Yates v United States*, 135 S Ct 1074, 1081–82 (2015) (alterations in original), quoting *Robinson v Shell Oil Co*, 519 US 337, 341 (1997) (quotation marks omitted). See also Eskridge, *Interpreting Law* at 87 (cited in note 129) ("Especially where the ordinary meaning of the statutory provision on point is open to more than one interpretation, the whole act can help us understand what the ordinary meaning of a statutory provision might be.").

[131] 42 USC § 1395hh(e)(1) (emphasis added).

[132] See Eskridge, *Interpreting Law* at 108 (cited in note 129) ("In our legal system, interpreters traditionally assume that 'identical words used in different parts of the same act are intended to have the same meaning.'"), quoting *Sullivan v Stroop*, 496 US 478, 484 (1990).

rules" are separate categories, then interpretive rules are not subject to the notice-and-comment requirement. This provision provides compelling evidence in favor of a narrow construction of the scope provision that excludes interpretive rules.

One could also look to the alternative publication provision as a source of meaning, but this provision is, unfortunately, of limited probative value. The inclusion of a provision prescribing an alternative mode of publication means that HHS must be able to promulgate interpretive rules outside the province of § 1395hh(a). But this still leaves the question of *which* interpretive rules fall outside the scope of § 1395hh(a).

Section 1395hh(a)(1)(3)(A) clearly contemplates that regulations "prescribed" under § 1395hh(a)(1) will be published.[133] So the alternative publication provision—which requires the publication of interpretive rules in the Federal Register—would be redundant if interpretive rules were completely covered by the "regulations" subject to promulgation through notice and comment. The alternative publication provision could be read, then, to apply to *all* interpretive rules. The provision is, however, also consistent with only *some* interpretive rules being subject to publication under the promulgation-power provision. In the latter reading, the provision would provide an alternative mode of publication only for those interpretive rules that are not covered by the scope provision.

Neither interpretation is superior, so this provision provides no help in determining the scope of the notice-and-comment provision.

4. The title of the scope provision strongly suggests that only legislative rules are "regulations" subject to the notice-and-comment requirement.

The title of § 1395hh(a)—"Authority to prescribe regulations; *ineffectiveness of substantive rules not promulgated by regulation*"[134]—provides further evidence that the scope provision applies specifically to legislative rules. The Supreme Court has repeatedly held that "the title of a statute or section can aid in resolving an ambiguity in the legislation's text."[135] The meaning

---

[133] "The Secretary . . . shall establish and publish a regular timeline for the publication of final regulations." 42 USC § 1395hh(a)(1)(3)(A).

[134] 42 USC § 1395hh(a) (emphasis added).

[135] *Immigration and Naturalization Service v National Center for Immigrants' Rights, Inc*, 502 US 183, 189 (1991), citing *Mead Corp v Tilley*, 490 US 714, 723 (1989); *Federal Trade Commission v Mandel Brothers, Inc*, 359 US 385, 388–89 (1959). See also *Yates*, 135 S Ct at 1083 (looking to the title of a statute to interpret a statutory term). In *Yates*, each

of the scope provision is ambiguous, so consideration of the provision's title is clearly appropriate.

In general, legal terms of art bear their widely understood meaning absent compelling evidence to the contrary.[136] So the term "substantive rules" ought to have the same meaning in the title of § 1395hh(a) as it does in other administrative law contexts. "Substantive rules" should be synonymous with the APA's legislative rules, which are, in contrast to interpretive rules, subject to notice and comment. And because the term "substantive rules" is used in the title in the same way that the phrase "rule[ ] . . . that establishes or changes a substantive legal standard" is used in the text of § 1395hh(a)(2), the two should be equated. This is particularly true given that "substantive rules" could easily be defined as rules that "establish[ ] or change a substantive legal standard."[137] This is simply one piece of evidence supporting a narrower interpretation of the statute. But it seems more likely that Congress used superfluous language[138] than that it implicitly gave a term with a widely understood meaning in the context of administrative law an entirely new meaning.

---

opinion included some endorsement of the use of titles in statutory interpretation, but the dissent criticized the plurality by arguing that titles can often be underinclusive. See id at 1094 (Kagan dissenting), citing *Lawson v FMR LLC*, 134 S Ct 1158, 1169 (2014). Courts, therefore, should be careful when using titles in statutory interpretation to avoid narrowing the law simply because a title is necessarily abridged. *Yates*, 135 S Ct at 1094 (Kagan dissenting). There is no such risk in the interpretation of § 1395hh(a)(2) because the title uses a specific term of art that clarifies the meaning of a single ambiguous phrase within the text of the statute.

136 See *Morissette v United States*, 342 US 246, 263 (1952):

> [W]here Congress borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them.

While the meaning of "substantive rule" has not been established by "centuries of practice," the term has been used widely in administrative law for most of the existence of the modern administrative state.

137 See Part III.B.1.

138 See notes 125–38 and accompanying text.

5. Legislative history suggests that the language of the scope provision was chosen to reflect the distinction between legislative and interpretive rules.

Legislative history also suggests that the scope provision draws a distinction between legislative rules and interpretive rules, confirming that only the former are subject to notice and comment. The conference committee report for the amendment noted that "[t]he conference agreement includes the House Provision, with an amendment to clarify that *only* policies establishing or changing a substantive legal standard governing benefits, payment, or eligibility must be promulgated as regulations." The conferees note that this language reflects recent court rulings."[139]

The "House Provision" to which the conference committee refers would have implemented a "significant effect" test.[140] Congress deliberately opted to change the language from "significant effect" to "substantive legal standard." The significant impact (or substantial impact) test was widely used before the rise of the "legal effects" test to determine whether a rule was substantive: if a rule had a substantial impact, it was found to be substantive rather than interpretive.[141] During the mid-1980s, around the time that the relevant amendment to the Medicare Act was passed, courts began abandoning the "substantial impact" test and instead started asking whether the rule carried the force of law or was legally binding.[142] In *General Motors Corp v Ruckelshaus*,[143] for example, the DC Circuit held that "if by its action [an] agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule."[144] The fact that Congress initially included language associated with the substantive/interpretive rule distinction and then changed the language to "reflect[ ] recent court rulings"[145] suggests that Congress used the term "substantive legal standard" in a narrower sense that encompasses only legislative rules. A "rule . . . that establishes or changes a substantive legal standard" is simply a rule with legal effects. In other words, such a rule is a legislative rule.

---

139 *Omnibus Budget Reconciliation Act of 1987*, HR Rep No 100-495, 100th Cong, 1st Sess 566 (1987), reprinted in 1987 USCCAN 2313-1245, 2313-1312 (emphasis added).

140 Id at 563.

141 See William Funk, *A Primer on Nonlegislative Rules*, 53 Admin L Rev 1321, 1326 (2001).

142 See id.

143 742 F2d 1561 (DC Cir 1984).

144 Id at 1565.

145 HR Rep No 100-495 at 566 (cited in note 139).

On a related note, one could ask why Congress would have adopted language in the Medicare Act that differs so significantly from that of the APA if it did not intend to create a significantly different regime. In other words, the difference in statutory language could indicate that Congress intended the statute to substantively differ. But there is an alternative explanation for the divergence. The Medicare Act's rulemaking section was amended *repeatedly*, and piecemeal construction could naturally lead to a unique structure.[146] It initially consisted solely of an authorization to promulgate "regulations." Starting from and building upon this unique place, the two major amendments to the statute implemented and defined the scope of the notice-and-comment requirement.[147] The notice-and-comment provision was added first, and the scope provision seems to have been added to clarify it.[148] It makes sense that the scope provision, inserted to clarify existing law, would look different from the functionally equivalent portion of the APA, which was part of the statutory scheme from the beginning.

* * *

The text of the scope provision strongly suggests that interpretive rules are not "regulations" subject to notice and comment. While the key phrase "substantive legal standard" is somewhat ambiguous in isolation, the whole act, title of the key provision, and legislative history all support the conclusion that "regulations" and "interpretive rules" are separate categories within the Medicare Act. The latter need not go through notice and comment.

C. Implications of the Narrow Meaning of "Regulations": Rebutting the DC Circuit's *Expressio Unius* Argument

Under the narrow reading of the statute advocated by this Comment, interpretive rules are entirely outside the scope of the notice-and-comment provision because they are not "regulations" as defined in the scope provision. This interpretation of the statute rebuts the DC Circuit's *expressio unius* argument. If the notice-and-comment provision applies only to regulations—that

---

[146] See Part I.D.2.

[147] See Omnibus Budget Reconciliation Act of 1986 § 9321, 100 Stat at 2016; Omnibus Budget Reconciliation Act of 1987 § 4035, 101 Stat at 1330–77.

[148] See Omnibus Budget Reconciliation Act of 1986 § 9321, 100 Stat at 2016; Omnibus Budget Reconciliation Act of 1987 § 4035, 101 Stat at 1330–77.

is, to the legislative rules identified in the scope provision—then it was entirely unnecessary for Congress to provide a separate exception to the rule. Providing an explicit good cause exception *is* necessary because that exception can apply to legislative rules. The DC Circuit's application of *expressio unius* was inapposite because interpretive rules are entirely outside the scope of the requirement.

The Medicare Act and the APA get to the same point regarding interpretive rules but do so in different ways. Whereas the APA has a broad notice-and-comment requirement that it restricts by way of an exception for interpretive rules, the Medicare Act has a narrower notice-and-comment requirement that excludes interpretive rules by definition.

D. The Importance of Flexible Interpretive Rulemaking

All of the justifications for exempting interpretive rules from notice and comment in administrative law apply with equal force to the Medicare Act. Continued use of interpretive rulemaking can help address the ossification problem if used in cases in which the value of public participation is not particularly great. This may be what courts are implicitly doing when they apply the legal effects test. If one accepts the position that the legislative/interpretive line is not a clear line between discrete categories, but rather a judgment about how much policymaking discretion we want to give agencies before restricting their autonomy, the distinction is made simply to balance the competing interests of administrative efficiency and public participation. Reforming the notice-and-comment process might be the best solution to the problem of ossification, but it is likely that exempting interpretive rulemaking from notice and comment leads to more efficient rulemaking while imposing only limited burdens on the public.

There are two significant benefits of the interpretive rule exception. First, interpretive rules are valuable because they allow agencies to quickly notify the public of how the agency interprets existing law.[149] Interpretive rules are, in other words, an effective means of clarifying ambiguities and uncertainties in the law. If interpretive rules were required to go through notice and comment, such uncertainty would increase. Second, notice and comment imposes extra costs on agencies. Exempting interpretive rules from notice and comment allows agencies to spend their

[149] See Franklin, 120 Yale L J at 303 (cited in note 5).

scarce resources in more productive ways.[150] Such costs might be justified if notice and comment conferred significant social benefits, but it seems unlikely to do so in the context of interpretive rules.

The justifications for notice and comment lack some of their salience in the context of interpretive rules. Notice and comment is valuable in large part because it encourages public participation in rulemaking such that parties who may be affected by new regulations have a voice in the crafting of policy.[151] This is particularly valuable because such parties likely have information at their disposal that is unavailable to the agency. If a proposed rule may come at a greater cost than anticipated, it would be valuable for the agency to have access to information that would allow it to more accurately gauge the costs of the rule and update its cost-benefit analysis.

But while interpretive rules certainly reflect policy decisions to some extent, they are first and foremost authoritative agency interpretations of existing law. In *Allina Health Services*, for example, HHS simply decided that Medicare Part C recipients were also "entitled to benefits under Part A" for purposes of calculating hospitals' reimbursement for Medicare enrollees.[152] Such matters of interpretation are less likely to benefit from notice and comment. The job of the HHS in such a case is simply to determine what "entitled to" means in the context of the Medicare Act.[153] If the agency is acting as a faithful agent of Congress, trying to interpret the statute to carry out the law, the notice-and-comment process would likely be of limited value in arriving at the correct interpretive outcome.

One would expect lawyers working within federal agencies to be more expert in statutory interpretation than potential commentators. Agency lawyers responsible for drafting rules will have expert knowledge of the authorizing statute and the relevant background law. Interpretive input from, for example, regulated parties will at best be redundant. In legislative rulemaking, outside parties will have key information at their disposal that is not available to the agency. But in interpretive rulemaking, there

---

150 See id at 304 (collecting sources).

151 See id at 305.

152 *Allina Health Services*, 863 F3d at 939 (quotation marks omitted).

153 It might seem strange to draw such a clear line between determining underlying meaning—which certainly requires some discretion—and creating law. But interpretation is generally understood within administrative procedure to *not* create substantive law. This understanding should apply with equal force in the context of Medicare.

is no information asymmetry that would make outside input helpful. Moreover, that input would almost certainly be dictated by the underlying financial interests of regulated parties. This is also true of legislative rulemaking, of course. But in interpretive rulemaking, there are no benefits that might justify the *requirement* that agencies consider obviously self-serving input.

This does not mean, however, that the agency is unchecked. If the interpretive rule provides an unreasonable interpretation of the statute or goes beyond the acceptable bounds of interpretation, the rule can be challenged in court and struck down. To some extent, this is a matter of institutional (or public) competency. For legislative rules, notice and comment provides a necessary opportunity for parties to bring relevant information to agencies. For interpretive rules, however, agencies and courts are experts in statutory interpretation, and they can be expected to get to the right outcome without having to respond to potentially thousands of public comments. And there is no reason to think that this applies any less in the Medicare context then in the rest of administrative law.

CONCLUSION

Section 1395hh presents a difficult puzzle of statutory interpretation—it resembles a *very* familiar statute but differs in key ways: its scope is dictated by a term whose ordinary meaning in context is not entirely clear, and the statute as a whole contains a number of contradictory signals. Nevertheless, the text of the scope provision, the larger statutory context, and the relevant legislative history are clear when read together: interpretive rules are not "regulations" subject to notice and comment.

This interpretation of § 1395hh can resolve the circuit split created by the DC Circuit in *Allina Health Services*. It suggests that the Medicare Act did not reproduce the APA's requirements as clearly as the First, Sixth, Eighth, and Ninth Circuits found. But the 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. A more thorough interpretation of the statute shows that interpretive rules are not "regulations" subject to notice and comment under the Medicare Act.

Furthermore, this interpretation of § 1395hh raises issues relevant to courts constructing the rulemaking provisions of statutes that fall outside the scope of the APA and, more generally, to

anyone engaging in statutory interpretation. First, it suggests that courts should not be too quick to assume that procedures created outside the context of the APA are identical to those of the APA. In drafting § 1395hh, Congress deviated significantly in several respects from the procedural requirements set out in the APA; those differences should be respected, and courts should be careful before concluding that the requirements are equivalent. In this case, the scope of the Medicare Act's notice-and-comment provision is fundamentally different from that of the APA in that it implicitly excludes interpretive rules. While this leaves the Medicare Act's effects functionally equivalent to those of the APA, there may be other statutes in which this is not the case.

Second, it illustrates a problematic application of the *expressio unius* canon that might be widespread and that courts should be wary of when engaging in statutory interpretation. If the scope of a rule is not completely clear, courts should carefully examine the scope before invoking the *expressio unius* canon to reject an implicit exception. The case of § 1395hh illustrates that "implicit exceptions" might not be improperly categorized, but instead might fall fundamentally outside the scope of the rule.