What Gets Measured Gets Managed: The Case for Bypassing Notice-and-Comment Rulemaking for Measure Maintenance

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INTRODUCTION

Suppose that Aaron is an ophthalmologist who lives and works in the San Francisco Bay Area. In his flourishing private practice, Aaron mostly performs routine cataract surgeries. This is perhaps unsurprising, as cataract extractions are some of the most commonly performed surgical procedures.[1] For every cataract surgery, Aaron always follows a detailed checklist[2] and has at least one assisting staff member.

Now, suppose that Daniel is another ophthalmologist who lives in relatively rural Amherst, Massachusetts. Daniel does not employ any nurses or anesthesiologists; he operates alone. Also, because Daniel performs cataract surgeries significantly less often than Aaron, he has no standardized operating procedures.

Aaron and Daniel both make a living by performing the same twenty-minute cataract extraction procedure, but they vary dramatically in how they do so. Similar variation occurs among cataract surgeons across the country

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1. *See* Tommaso Rossi et al., *Cataract Surgery Practice Patterns Worldwide: A Survey*, 6 BMJ OPEN OPHTHALMOLOGY 1, 1 (2021) ("Cataract extraction is the most prevalent surgical procedure of all medical specialties . . . ."); Suzann Pershing et al., *Cataract Surgery Complications and Revisit Rates Among Three States*, 171 AM. J. OPHTHALMOLOGY 130, 130 (2016) ("Cataract surgery is . . . . the largest single source of Medicare expenditures . . . .").

2. To view examples of safety checklist components for cataract surgery, see *Surgical Safety Checklist*, AM. ACAD. OPHTHALMOLOGY, https://www.aao.org/asset.axd?id=ba210a8b-68ac-4911-b537-f5d8ae53c16a [https://perma.cc/266A-6JUU].

and the rest of the world.[3] For such a prevalent operation, there is a serious lack of consensus on what surgical procedures should be followed.[4]

This lack of consensus appears to stem, at least in part, from the relationship between the quality and cost of care.[5] While quality and cost are often complementary,[6] they can also be at tension. For example, in the context of cataract surgery, the presence of additional surgeons, anesthesiologists, and nurses plausibly improves patient safety.[7] The effect of additional staff on costs, however, is both certain and large.[8] With the introduction of a second surgeon and dedicated anesthesiologist, the cost of a twenty-minute, uncomplicated surgery more than doubles.[9]

As Medicare rapidly evolved to become the nation's second-largest social insurance program,[10] both quality and cost of care came under stress.[11]

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3. A worldwide survey revealed that cataract surgeons vary greatly in their administration of "preoperative and postoperative care, diagnostics, surgical setting, precautions, and follow-up" practice patterns. Rossi et al., *supra* note 1, at 1–2. This variation is attributable to many factors, including surgeons' individual preferences and habits. *Id.*

4. A survey revealed a lack of consensus on many key issues in perioperative procedures, including staffing: 40% of cataract surgery operating rooms have only one surgeon present, 30% use a resident as a second surgeon, and only 30% have a dedicated anesthesiologist. Rossi et al., *supra* note 1, at 6. Another area of variation was surgeons' rate of surgical materials exchange: 92% changed phaco tip, 80% changed handpiece, 71% changed phaco tray dripping, and 69% changed all tubing. *Id.* at 8. There is "no question" that these four materials contaminate during surgery. *Id.*

5. *See generally* Clark C. Havighurst & James F. Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSROs*, 70 NW. U. L. REV. 6 (1975).

6. Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 523 n.12 (2013) ("In most markets, quality improvements are costly. That's not always, or even usually, true in medicine.").

7. Rossi et al., *supra* note 1, at 6.

8. *Id.*

9. *Id.* (reporting cost per surgery of $46 for single surgeon and available anesthesiologist, compared to $120 for two surgeons and dedicated anesthesiologist).

10. *Trustees Report & Trust Funds*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 6, 2023, 4:57 PM), https://www.cms.gov/OACT/TR#:~:text=The%20Medicare%20Program%20is%20the,actuarial%20status%20of%20the%20program [https://perma.cc/4NUU-QPWN].

11. As Professor Nicholas Bagley puts it:

> Explanations for Medicare's lackluster performance when it comes to cost and quality are commonplace. Congress is loath to curb payments to powerful hospital and physician groups. Warring partisan ideologies on charged healthcare issues bedevil political reform. Cultural infatuation with medical technology and antipathy toward rationing spur the rapid adoption of expensive new treatments, even those of uncertain value. And Medicare's popularity makes the public, especially politically active elderly citizens, resistant to reform.

Medicare's reimbursement system contained a fundamental design flaw: it incentivized physicians to bill for higher volumes of items and services irrespective of their cost.[12] By the 1980s, physician payments began ballooning out of control.[13] At the same time, providers lacked coherent standards for care quality, leading to systemic disparities in care.[14] At times, patient outcomes could only be described as egregious: by 2010, "avoidable hospital errors appear[ed] to contribute to the deaths of [approximately] fifteen thousand Medicare beneficiaries *each month*."[15]

Reflecting a recognition of these problems, the Centers for Medicare and Medicaid Services ("CMS") began to transition to "value-based" programs, or programs that attempted to shift the focus of care from volume to value.[16] The Merit-Based Incentive Payment System ("MIPS") represents one iteration of these programs.[17]

Like all value-based programs, MIPS relies on "measures" to assess provider performance.[18] Just as exams score the academic performance of students, measures score providers in how they render care.[19] Measures are based on rich discussions regarding how best to assess value through empirical data.[20] Throughout the development of a given measure, the measure's developer facilitates continuous conversations with their stakeholders, including through multiple periods of public comment.[21] When CMS finally implements the fully-developed measure into its program, the

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Bagley, *supra* note 6, at 521.

12. When Medicare began in 1965, Congress excluded from coverage medical care deemed "not reasonable and necessary for the diagnosis or treatment of illness or injury." Bagley, *supra* note 6, at 526. But this exclusion left physicians with "nearly untrammeled discretion to determine medical necessity." *Id.*

13. As physicians continued to bill Medicare for their reasonable charges, physician payments began increasing by an average of sixteen percent per year between 1978 and 1987. Bagley, *supra* note 6, at 540 n.99. While Congress has since attempted to address escalating costs by implementing a reformed fee schedule for physician payments, physicians continue to maximize their reimbursements by increasing the volume and intensity of care that they provide, *id.* at 540–43, particularly by adopting expensive new technologies, *id.* at 542.

14. *See infra* notes 37–40 and accompanying text.

15. Bagley, *supra* note 6, at 522 (citing OFFICE INSPECTOR GEN., DEP'T HEALTH & HUMAN SERVS., OEI-06-09-00090, ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES, at ii (2010), https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf [https://perma.cc/E9C9-CM6Y]).

16. *See infra* note 43.

17. *See infra* note 46 and accompanying text.

18. *See infra* Section I.A.

19. *See infra* text accompanying notes 55–56.

20. *See infra* Section I.B.

21. *Id.*

measure's "life cycle" still does not end.[22] Instead, the measure undergoes maintenance processes to ensure that it is continuing to further the goals of the MIPS program.[23]

One ongoing source of difficulty, however, is the extent to which notice-and-comment rulemaking applies to measure maintenance. CMS has made a longstanding assumption that *new* measures need to undergo notice-and-comment procedures before CMS implements them into programs like MIPS.[24] But when do *changes* to existing measures need to undergo notice-and-comment?

In seeking to comply with the Supreme Court's decision in *Azar v. Allina Health Services* (*Allina II*), measure maintenance processes currently suffer from delay.[25] This Comment argues that the existing legal framework can and should be interpreted to permit measure maintenance to bypass the delay of the notice-and-comment process. Given the robust public comment opportunities that exist throughout measure development and maintenance, this would not deprive the public of the opportunity for participation. Rather, removing measure maintenance from the rulemaking process merely removes a redundant layer of formality and allows measures to reflect the most current clinical best practices. Given that measures exist to incentivize the best possible care, this Comment argues that this change is not only legally feasible but medically and fiscally necessary.

This Comment proceeds in four Parts. Part I provides the relevant policy background, including the MIPS scoring system and the life cycle of a typical measure. Part II explores the legal framework governing the notice-and-comment requirement under the Medicare Act. Part III argues that measure maintenance processes can and ought to bypass the notice-and-comment requirement. Part IV concludes.

I. POLICY BACKGROUND

The guiding inspiration of Medicare's value-based programs is captured by a simple phrase: "What gets measured gets managed."[26] At its founding, Medicare purposefully lacked mechanisms for measuring performance of

22. *See infra* text accompanying notes 69–74.

23. *Id.*

24. *See infra* text accompanying note 172.

25. *See* Azar v. Allina Health Servs. (*Allina II*), 139 S. Ct. 1804 (2019).

26. Angela L. Winegar et al., *Value-Based Healthcare: Measuring What Matters—Engaging Surgeons To Make Measures Meaningful and Improve Clinical Practice*, 476 CLINICAL ORTHOPAEDICS & RELATED RSCH. 1704, 1704 (2018) (discussing strategy to develop effective measures for assessment of orthopedic surgeons).

health care providers.[27] But in recent decades, Medicare has increasingly brought quality, cost, and other dimensions of care under control through measurement.[28] To be sure, this transformation aimed to improve the quality of care rendered to Medicare beneficiaries.[29] But CMS also had an existential motivation: the financial viability of the Medicare program was at stake.[30]

When Congress created Medicare in 1965, it expressly committed to reimbursing the costs of care while "interfering as little as possible with the practice of medicine."[31] Medicare's chief architect would later explain that "[t]he sponsors of Medicare, including myself, had to concede . . . that there would be no real controls over hospitals and physicians. I was required to promise . . . that the Federal agency would exercise no control."[32] Accordingly, the original Medicare relied entirely on physicians to certify the medical necessity of care.[33] It could not refuse to pay for treatments on the grounds that they were unreasonable or unnecessary.[34] The resulting system "inherently reward[ed] the provision of services," whether needed or not, and paid the same amount whether or not the service was of acceptable quality.[35]

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27. *See* Bagley, *supra* note 6, at 526.

28. *See* Cheryl L. Damberg et al., *Measuring Success in Health Care Value-Based Purchasing Programs*, 4 RAND HEALTH Q. 9, 9 (2014). *See generally* Rishi K. Wadhera et al., *Quality Measure Development and Associated Spending by the Centers for Medicare & Medicaid Services*, 323 JAMA 1614 (2020) (examining spending on quality measure development from 2008 to 2018); Reena Duseja et al., *Development of Episode-Based Cost Measures for the US Medicare Merit-Based Incentive Payment System*, JAMA HEALTH F. (May 14, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2779946 [https://perma.cc/Y7NY-KFB9] (summarizing development of cost measures since 2015).

29. *See, e.g.*, Damberg et al., *supra* note 28.

30. Over the past couple decades, there has been persistent and growing concern over the fiscal sustainability of the Medicare program. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFF., COMPTROLLER GENERAL'S FORUM ON HEALTH CARE: UNSUSTAINABLE TRENDS NECESSITATE COMPREHENSIVE AND FUNDAMENTAL REFORMS TO CONTROL SPENDING AND IMPROVE VALUE 3 (2004); *see also infra* note 41 (providing cost statistics as of 2021).

31. Bagley, *supra* note 6, at 521.

32. *Id.* at 526 (quoting RICK MAYES & ROBERT A. BERENSON, MEDICARE PROSPECTIVE PAYMENT AND THE SHAPING OF U.S. HEALTH CARE 17 (2006) (quoting Wilbur Cohen, one of the creators of Medicare)).

33. *Id.* (citing Social Security Amendments of 1965, Pub. L. No. 89–97, sec. 102(a), §§ 1814(a)(2), 1835(a)(2)(B), 79 Stat. 303).

34. As enacted in 1965, the Medicare Act prohibited the program from "exercis[ing] any supervision or control over the practice of medicine, [or] the manner in which medical services are provided." *Id.* at 521 (quoting Social Security Amendments of 1965, Pub. L. No. 89–97, sec. 102(a), § 1801, 79 Stat. 291 (codified at 42 U.S.C. § 1395 (2006)).

35. Robert A. Berenson & Paul B. Ginsburg, *Improving the Medicare Physician Fee Schedule: Make It Part of Value-Based Payment*, 38 HEALTH AFFS. 246, 246–47 (2019) (reviewing the historical development of the Medicare Physician Fee Schedule and concluding the revised program suffers from many of the same inherent issues as the original).

In the ensuing decades, Medicare adopted a number of new programs to manage spending and encourage providers to operate more efficiently.[36] But forty years after beginning this series of major reforms, Medicare continues to suffer in both quality and cost. Medicare beneficiaries continue to experience disparities in quality of care across race,[37] gender,[38] geography,[39] and other social dimensions.[40] At the same time, costs have grown into an existential threat to the program: the Medicare Trustees predict that the Medicare Part A trust fund—which accounts for about forty percent of Medicare's total spending[41]—will be depleted by 2028.[42]

To address these ongoing problems with quality and cost, CMS began to experiment with value-based programs, which linked providers' reimbursements to their provision of low-cost, high-quality care.[43] Section

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36. *See* Bagley, *supra* note 6, at 534–54 (explaining the four "most ambitious" efforts to reform Medicare); Eric Lopez et al., *How Much More than Medicare Do Private Insurers Pay? A Review of the Literature*, KAISER FAM. FOUND. (Apr. 15, 2020), https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/ [https://perma.cc/5E9V-8J46] (describing the adoption of a prospective payment system for hospital services in 1983, which helped slow growth in costs by setting payment rates for hospitals in advance based on categories of services); Berenson & Ginsburg, *supra* note 35, at 246–47 (describing the development of the Medicare Physician Fee Schedule in 1992, which set payment rates based on the relative resource costs of each service rather than historical charges).

37. *See, e.g.*, Arnold M. Epstein et al., *Race and Gender Disparities in Rates of Cardiac Revascularization: Do They Reflect Appropriate Use of Procedures or Problems in Quality of Care?*, 41 MED. CARE 1240, 1240 (2003); Julie C. Lauffenburger et al., *Racial/Ethnic and Gender Gaps in the Use of and Adherence to Evidence-Based Preventive Therapies Among Elderly Medicare Part D Beneficiaries After Acute Myocardial Infarction*, 129 CIRCULATION 754, 754 (2014).

38. *See, e.g.*, Ann F. Chou et al., *Gender and Racial Disparities in the Management of Diabetes Mellitus Among Medicare Patients*, 17 WOMEN'S HEALTH ISSUES 150, 150 (2007).

39. *See, e.g.*, Avi Dor & John Holahan, *Urban-Rural Differences in Medicare Physician Expenditures*, 27 INQUIRY 307, 307 (1990); *see also* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 30, at 10–11.

40. *See, e.g.*, Tomi Akinyemiju et al., *Race/Ethnicity and Socio-Economic Differences in Colorectal Cancer Surgery Outcomes: Analysis of the Nationwide Inpatient Sample*, 16 BMC CANCER 1, 2 (2016).

41. In 2021, Medicare Part A benefits represented thirty-nine percent of total Medicare spending. *See* Juliette Cubanski & Tricia Newman, *What To Know About Medicare Spending and Financing*, KAISER FAM. FOUND. (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/#:~:text=Growth%20in%20Per%20Capita%20Medicare,Parts%20A%2C%20B%2C%20and%20D&text=For%20example%2C%20the%20average%20annual,7.0%25%20between%202000%20and%202010 [https://perma.cc/8AMQ-87VG].

42. *Id.*

43. The concept of using financial incentives to drive improvements in care dates as far back as the early 1990s. *See* Damberg et al., *supra* note 28. In 2010, the Patient Protection and

I.A reviews the Merit-Based Incentive Payment System ("MIPS"), which is just one of many value-based programs employed by CMS today.[44]

A. Under MIPS and Other Value-Based Programs, Providers of Care Are Paid Based on Performance

In 2015, the bipartisan Medicare Access and CHIP Reauthorization Act ("MACRA") gave birth to MIPS.[45] As with other value-based programs, the premise of MIPS is linking financial incentives to the performance of healthcare providers on certain measures.[46] Traditionally,[47] MIPS assesses providers[48] in four performance categories: quality, cost, promoting interoperability, and improvement.[49] Table 1 lists these four performance categories.

Affordable Care Act significantly expanded these experiments by requiring the Medicare program to develop, test, and implement performance-based payment strategies across various providers and care settings. *See generally* Patient Protection and Affordable Care Act of 2010 §§ 3001, 3006–07 (codified as amended in scattered sections of 42 U.S.C.).

44. *See* Damberg et al., *supra* note 28 (discussing other examples of value-based programs).

45. Medicare Access and CHIP Reauthorization Act of 2015 § 101(b)–(c), 42 U.S.C. § 1395w-4(q). The MACRA established separate participation tracks for organizations and individuals. *See* Duseja et al., *supra* note 28, at 1–2. MIPS represents the participation track available to individual clinicians and clinician groups. *Id.*

46. *See, e.g.*, Damberg et al., *supra* note 28 (discussing other examples of value-based programs).

47. "Traditional MIPS" refers to CMS's original reporting option, implemented beginning in 2016. *Traditional MIPS Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://qpp.cms.gov/mips/traditional-mips [https://perma.cc/A5SM-S6TS]. While Traditional MIPS is still available as a reporting option as of 2023, CMS has announced plans to sunset Traditional MIPS in the future. *See MIPS Value Pathways (MVPs)*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://qpp.cms.gov/mips/mips-value-pathways [https://perma.cc/QY8V-Z6MC]. To limit the scope of this discussion, this Comment focuses on the Traditional MIPS reporting option only.

48. MIPS-eligible clinicians include physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthesiologists. 81 Fed. Reg. 77008, 77014 (Nov. 4, 2016). A clinician may elect to participate in MIPS either as an individual or as part of a clinician group. *Id.* Here, the term "provider" technically refers to both types of participating entities. For convenience, this Comment refers to "providers" with singular pronouns.

49. The MACRA established four performance categories: quality, resource use, clinical practice improvement activities, and meaningful use of certified EHR technology. 42 U.S.C. § 1395w-4(q)(2)(A). In the first year that MIPS went into effect, these performance categories were titled "quality," "cost," "advancing care information," and "improvement." *See* 81 Fed. Reg. 77008, 77016 (Nov. 4, 2016). Beginning in 2020, the "advancing care information" performance category was replaced with "promoting interoperability." *Compare Merit-Based Incentive Payment System*, HEALTHIT, https://www.healthit.gov/topic/federal-incentive-programs/MACRA/merit-based-incentive-payment-system [https://perma.cc/6BZ8-XTZA], *with*

Table 1. MIPS Performance Categories (2023)[50]

Category	Category Description
Quality	Measures healthcare processes, outcomes, and patient experience.
Cost	Assesses cost of patient care provided.
Promoting Interoperability	Requires use of an Electronic Health Record system that meets certain certification criteria.
Improvement Activities	Assesses improvement in care processes, enhancement of patient engagement, and increased access to care.

Based on a provider's scores in each category, she receives a MIPS final score.[51] A percentage weight corresponds to each category,[52] so some categories weigh more heavily in the final score than others. For example, for the 2023 MIPS performance year, the cost category has twice the weight of the improvement activities category.[53] Figure 1 lists the four performance categories and their respective weights for each performance year.

Promoting Interoperability: Traditional MIPS Requirements, QUALITY PAYMENT PROGRAM, https://qpp.cms.gov/mips/promoting-interoperability [https://perma.cc/BH5Z-77QK].

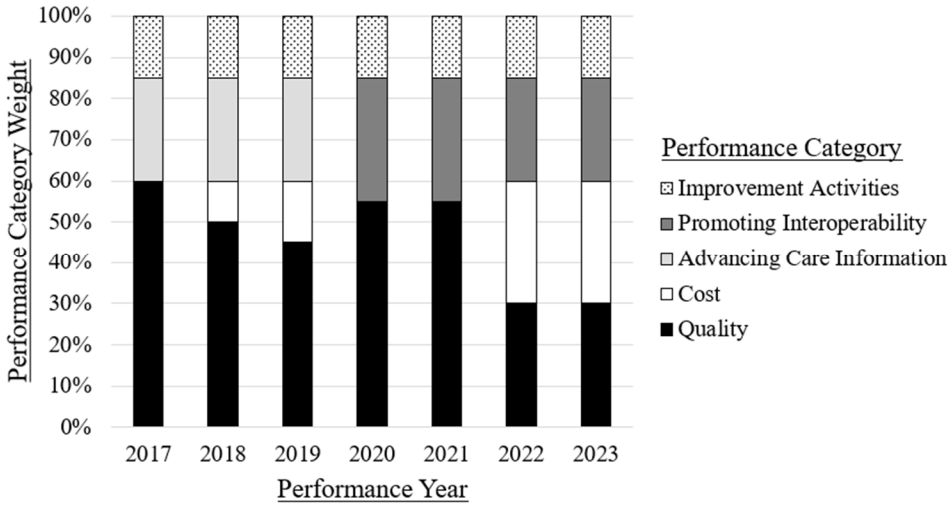
50. *Traditional MIPS Overview*, *supra* note 47.

51. *See* 81 Fed. Reg. 77008, 77016 (Nov. 4, 2016) (summarizing the scoring methodology under MIPS for the 2017 performance year).

52. *See* 42 U.S.C.§ 1395w-4(q)(5)(E) (establishing minimum and maximum weights for performance categories and authorizing Secretary to adjust certain weights).

53. *Compare* 42 U.S.C. § 1395w-4(q)(5)(E)(i)(II), *with* 42 U.S.C. § 1395w-4(q)(5)(E)(i)(III).

Figure 1. MIPS Performance Category Weights (2017–2023)



A provider has good reason to pay attention to her MIPS final score because her score affects how much CMS pays her in the future. To illustrate, suppose that Daniel's MIPS final score in 2022 was an unfortunate 18 out of 100 points. Because he scored poorly, CMS penalizes him by reducing his Medicare reimbursements in a future year. Thus, for every Part B service that he provides in 2024, CMS reduces his reimbursements by nine percent. This means if Daniel provides a $100 service, he receives only $91 in reimbursement.

Table 2 lists the payment adjustments for the 2022 performance year.

Table 2. MIPS Payment Adjustment: 2022 Performance Year (2024 Payment Year)[54]

MIPS Final Score	MIPS Payment Adjustment
0.00–18.75 points	-9% payment adjustment
18.76–74.99 points	Negative payment adjustment (greater than -9% and less than 0%)
75.00 points	Neutral payment adjustment (0%)
75.01–88.99 points	Positive payment adjustment
89.00–100.00 points	Positive payment adjustment and exceptional performance bonus

54. *See* 86 Fed. Reg. 64996, 65536 (Nov. 19, 2021).

A provider's score in each performance category is determined by her performance on one or more "measures" in that category.[55] Measures vary broadly in design. For example, they can be pass-fail. Or, like a test graded on a curve, they can score a provider based on her performance relative to peers. All measures have one thing in common, however: They generate a score using data.[56]

A measure's specifications simply describe how to calculate a measure based on the available data, without revealing the rationale for the measure's design.[57] In reality, much lies below the surface: measures rely on a robust foundation of conceptualization, development, testing, and reevaluation activities.[58] Section I.B describes these activities for an illustrative measure.

B. Public Participation Is Invited Throughout the Measure Life Cycle

Consider *Routine Cataract Removal with Intraocular Lens (IOL) Implantation* (the "Cataract cost measure"), which measures the cost of routine cataract surgeries performed by clinicians like Aaron and Daniel.[59] By statute, the developer of this measure is required to ask for stakeholder feedback.[60]

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55. *See* 81 Fed. Reg. 77008, 77011 (Nov. 4, 2016).

56. *See id.* (summarizing clinician reporting options for several performance categories). The source of data depends on the performance category. *Id.* For certain categories, a provider must submit her own data. *Id.* at 77014–15. In contrast, for the cost category, a provider does not have to do any additional work; her score automatically generates based on the claims she already submitted to receive reimbursement. *Id.* at 77015.

57. For an example of measure specifications, see *About Cost Measures & Development Process*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 3, 2023, 1:39 PM), https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about [https://perma.cc/B5WF-H9CG] (select and download cost measure methodology ZIP files).

58. From fiscal years 2009 through 2018, the amount of funds obligated to CMS-contracted organizations for quality measurement activities totaled over $350 million. U.S. GOV'T ACCOUNTABILITY OFF., CMS COULD MORE EFFECTIVELY ENSURE ITS QUALITY MEASUREMENT ACTIVITIES PROMOTE ITS OBJECTIVES 29–30 (2019), https://www.gao.gov/assets/710/701755.pdf [https://perma.cc/YLV9-V8PN]. Some measures are developed by CMS-contracted organizations; others are developed by professional groups, such as medical specialty societies. *See, e.g.*, Gregary T. Bocsi et al., *Developing Pathology Measures for the Quality Payment Program—Part I: A Quest for Meaningful Measures*, 144 ARCHIVES PATHOLOGY LAB'Y MED. 686, 686–87 (2020) (describing quality measure development process used by a subcommittee of College of American Pathologists).

59. *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS): ROUTINE CATARACT REMOVAL WITH INTRAOCULAR LENS (IOL) IMPLANTATION MEASURE 1 (2021), https://qpp.cms.gov/docs/cost_specifications/2021-12-13-mif-ebcm-cataract.pdf [https://perma.cc/LPM6-CWLZ].

60. 42 U.S.C. § 1395w–4(q)(12)(A).

Over the course of a year, a clinical subcommittee, represented by various geographies, clinical specialties, training backgrounds, and practice types,[61] provided input on the measure's specifications to a CMS-contracted measure developer.[62] Once the developer produced draft measure specifications, it distributed confidential reports to all clinicians who were eligible to be scored under the measure.[63] These reports showed clinicians what their scores would look like and invited them to share further feedback on the measure.[64]

Next came the "pre-rulemaking" process, which created two opportunities for public comment before actual rulemaking.[65] The first comment period opened when CMS posted the measure on its Measures Under Consideration ("MUC") list.[66] The second comment period commenced with evaluation by the Measure Applications Partnership ("MAP").[67] The MAP evaluation concluded with a recommendation to finalize the measure through rulemaking.[68]

Following rulemaking and final implementation, the public still had an opportunity to comment during the endorsement process conducted by a

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61. *See* Duseja et al., *supra* note 28, at 2–3. Specifically, the clinical subcommittee was comprised of ten members representing eleven affiliated specialty societies. CTRS. FOR MEDICARE & MEDICAID SERVS., EPISODE-BASED COST MEASURE FIELD TESTING MEASURE DEVELOPMENT PROCESS: OCTOBER 2018 FIELD TESTING 8 (2018), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf [https://perma.cc/79JP-KALV].

62. *See* 83 Fed. Reg. 35704, 35903 (July 27, 2018); Duseja et al., *supra* note 28, at 2–3.

63. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 61, at 4.

64. *Id.*

65. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., PRE-RULEMAKING AND MEASURES UNDER CONSIDERATION 2022 FREQUENTLY ASKED QUESTIONS 1–2 (2022) [hereinafter PRE-RULEMAKING FAQ], https://www.cms.gov/files/document/pre-rulemaking-faq-2022-01102022-508.pdf [https://perma.cc/SFA3-ZMPS]; CTRS. FOR MEDICARE & MEDICAID SERVS., 2019 PRE-RULEMAKING KICKOFF: MEASURES UNDER CONSIDERATION AND MEASURE APPLICATION PARTNERSHIP OVERVIEWS 54 (2019) [hereinafter PRE-RULEMAKING KICKOFF], https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/MUC2019_KickOff_notes-508.pptx [https://perma.cc/4M69-Y7KX].

66. PRE-RULEMAKING FAQ, *supra* note 65, at 1; PRE-RULEMAKING KICKOFF, *supra* note 65.

67. The Measure Applications Partnership ("MAP") is a stakeholder group convened by the National Quality Forum, *see infra* note 69, which provides recommendations for selecting measures for performance programs such as MIPS. *See MAP Final Reports*, NAT'L QUALITY F., https://www.qualityforum.org/setting_priorities/partnership/map_final_reports.aspx#:~:text=The%20Measure%20Applications%20Partnership%20is,the%20selection%20of%20performance%20measures [https://perma.cc/A47J-Q2HX].

68. *See* 83 Fed. Reg. 35704, 35903 (July 27, 2018).

consensus-based entity ("CBE").[69] This began with an expert panel meeting,[70] followed by a committee meeting to finalize the evaluation and grant endorsement. The committee meeting occurred within a four-month public comment period.[71]

Even after endorsement, opportunity for public comment persisted through a process called comprehensive measure reevaluation.[72] The reevaluation process opened in early 2022, with a comment period spanning four months.[73] A public survey followed in February 2023.[74]

As summarized in Figure 2, the life cycle of the Cataract cost measure features periodic opportunities for public comment. Indeed, the sixty-day public comment period during rulemaking is a relatively brief moment in the life of the measure.

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69. At the time, this consensus-based entity was the National Quality Forum ("NQF"), a not-for-profit, membership-based organization. *About Us*, NAT'L QUALITY F., https://www.qualityforum.org/About_NQF/ [https://perma.cc/DU8M-XAPK]; *NQF's History*, NAT'L QUALITY F., https://www.qualityforum.org/about_nqf/history/ [https://perma.cc/WA8G-PMFY].

70. NAT'L QUALITY F., COST AND EFFICIENCY, SPRING 2019 REVIEW CYCLE: CDP REPORT 5 (2020), https://www.qualityforum.org/Publications/2020/02/Cost_and_Efficiency_Final_Technical_Report_-_Spring_2019_Cycle.aspx [https://perma.cc/3E8H-A24S].

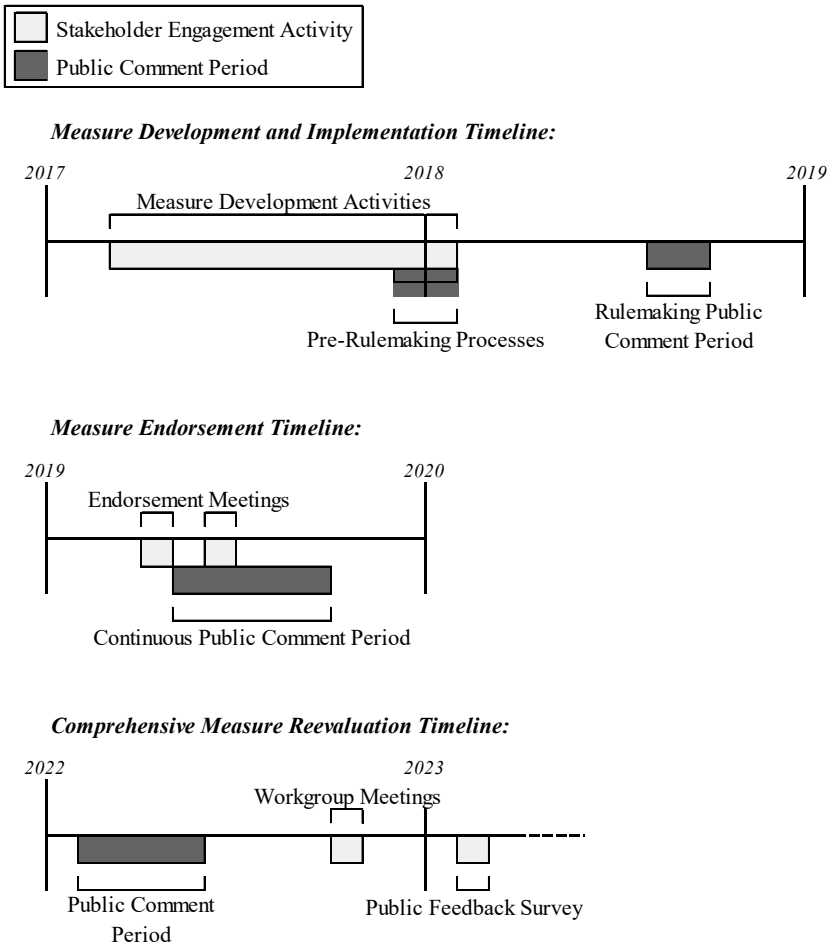
71. *Id.*

72. *See* ACUMEN, LLC, MACRA EPISODE-BASED COST MEASURES: COMPREHENSIVE REEVALUATION PUBLIC COMMENT SUMMARY REPORT 4 (2022), https://www.cms.gov/files/document/wave-one-public-comment-summary-report.pdf [https://perma.cc/WL79-3398].

73. *Prior Cost Measure Development and Input*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 3, 2023, 1:47 PM), https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior [https://perma.cc/QW4H-BK4M] (navigate to "Wave 1 cost measure comprehensive reevaluation (2022-2023)").

74. *Id*.

Figure 2. Timelines of Development, Endorsement, and Maintenance for the Cataract Cost Measure[75]



75. *See* 83 Fed. Reg. 35704, 35903 (July 27, 2018) (describing stakeholder input collection processes, including clinical subcommittee meetings and field test reports, and proposing implementation of the measure); PRE-RULEMAKING FAQ, *supra* note 65, at 1–2 (describing Measures Under Consideration ("MUC") list and Measure Applications Partnership ("MAP") evaluation); PRE-RULEMAKING KICKOFF, *supra* note 65, at 54 (describing general timelines for public commenting on MUC list and MAP deliberations); NAT'L QUAL. F., *supra* note 70, at 5 (detailing NQF measure evaluation processes and accompanying public comment period); ACUMEN, *supra* note 72, at 4 (describing initial public comment period for comprehensive measure reevaluation); CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 57 (describing October 2022 stakeholder meeting and February 2023 public survey requesting additional measure input).

The Cataract cost measure is one of hundreds of measures used in CMS value-based programs.[76] Each measure hinges on unique clinical considerations, calling for adjustments and changes of varying degrees past the implementation stage. The volume and complexity of measures enhances the need for a clear answer as to what subsequent changes, if any, must undergo notice-and-comment rulemaking. As Part II reviews, the existing case law and regulations fail to provide this much-desired answer.

II. LEGAL BACKGROUND

Generally, agencies seeking to adopt new rules must provide notice of the proposed rule and subject it to a period of public comment.[77] The purpose of this notice-and-comment procedure is to give parties fair warning of potential changes in agency regulations and an opportunity to be heard on those changes.[78]

When distinguishing between rules that require notice-and-comment and those that do not, the boundary line is not always clear. This is true under the Administrative Procedure Act ("APA"),[79] and even truer under the Medicare Act.[80] As Sections II.A and II.B explain, the Supreme Court's attempt in 2019 to rectify the Medicare Act's notice-and-comment standard did little to illuminate the boundary line. Instead, by upending the Medicare Act's previously assumed alignment with the APA, the Supreme Court left both

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76. As of 2023, the MIPS program uses 180 quality measures, 25 cost measures, 29 promoting interoperability measures, and 104 improvement activities. *See Explore Measures & Activities*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://qpp.cms.gov/mips/explore-measures [https://perma.cc/5WSG-FDA9] (filter to "Performance Year 2023" and navigate to "Quality Measures," "Promoting Interoperability," "Improvement Activities," and "Cost Measures" tabs).

77. *See* 5 U.S.C. § 553.

78. *See, e.g.*, *Allina II*, 139 S. Ct. 1804, 1816 (2019) (citing RICHARD J. PIERCE & KRISTIN E. HICKMAN, ADMINISTRATIVE LAW TREATISE § 4.8 (6th ed. 2019)); *see also* United States v. Reynolds, 710 F.3d 498, 517 (3d Cir. 2013).

79. Various types of rules, including "interpretive rules," are exempted from the APA's notice-and-comment requirements. Elizabeth Williams, Annotation, *What Constitutes "Interpretative Rule" of Agency so as To Exempt Such Action from Notice Requirements of Administrative Procedure Acts (5 U.S.C.A. § 553(b)(3)(A))*, 126 A.L.R. Fed. Art. 1 § 2[a], at 347 (2015). But the APA does not define "interpretive," nor does its legislative history offer any insight. *Id.* Thus, courts and commentators have described the distinction between rules requiring notice-and-comment and those that do not as "fuzzy," "tenuous," "blurred," "baffling," and "enshrouded in considerable smog." *Id.*

80. *See infra* Section II.B; *see also* Agendia, Inc. v. Becerra, 4 F.4th 896, 910 (9th Cir. 2021) (Block, J., dissenting) (urging Supreme Court to address "important and unresolved issue" of defining Medicare Act's legal standard for notice-and-comment requirement).

courts and regulators scrambling to determine the Medicare Act's new standard.

A. The Statutory Framework for Notice-and-Comment Rulemaking

The starting point of the notice-and-comment requirement is § 553 of the APA.[81] It declares that agencies "shall" publish general notices of proposed rules, providing "interested persons" an opportunity to participate in the rulemaking process.[82] After articulating the general rule, the APA proceeds to carve out exemptions.[83] Unless a statute says otherwise, notice-and-comment is not required for certain types of rules, including "interpretive rules" and "general statements of policy."[84] Further, an agency can skip the procedure for "good cause"—that is, if it finds that notice-and-comment would be "impracticable, unnecessary, or contrary to the public interest."[85]

While § 553 of the APA applies to many agencies, it does not apply to public benefit programs like Medicare.[86] Instead, the notice-and-comment requirements for the Medicare program appear in a separate, Medicare-specific statute.[87] The Medicare Act requires CMS to provide the public with advance notice and an opportunity to comment before adopting a "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard."[88] This requirement applies to CMS regulations that impact the following areas: "scope of benefits," "payment for services," or "eligibility" for furnishing or receiving services or benefits.[89] Notably, the Medicare Act explicitly cross-references the APA's "good cause" exemption.[90]

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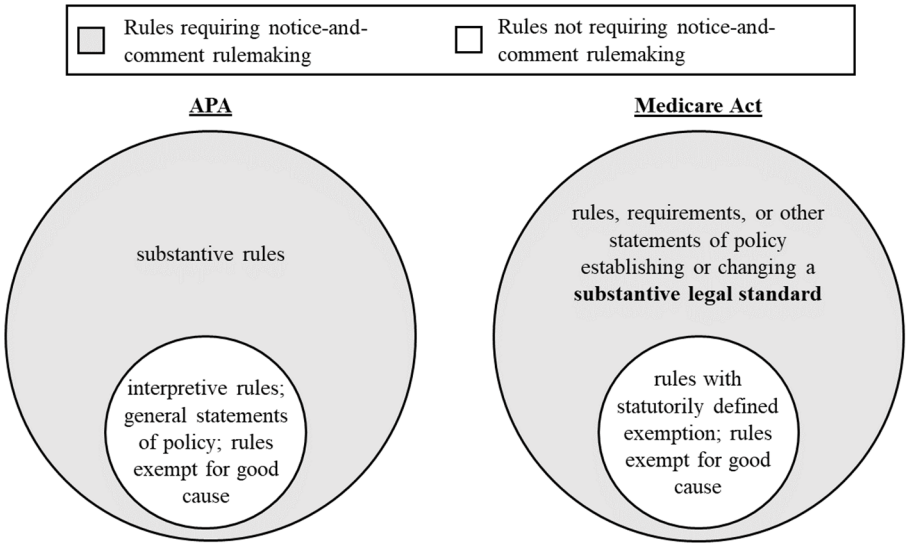
81. *See* § 553.
82. § 553(b)-(c).
83. § 553(b)(3).
84. § 553(b)(3)(A).
85. § 553(b)(3)(B).
86. § 553(a)(2).
87. *See* 42 U.S.C. § 1395hh. When Congress enacted the Medicare Act in 1965, it initially did not address procedures for public input. *Allina II*, 139 S. Ct. 1804, 1808 (2019). However, CMS volunteered to follow the informal notice-and-comment rulemaking procedures under the APA. *See id.* (citing Clarian Health W., LLC v. Hargan, 878 F.3d 346, 356–57 (D.C. Cir. 2017)). By the 1980s, the burgeoning scope of Medicare and heightening scrutiny over public comment procedures led Congress to enact amendments to the Medicare Act that specifically provided for notice-and-comment. *See id.* at 1808–09 (citing § 9321(e)(1), 100 Stat. 2017; § 4035(b), 101 Stat. 1330–78).
88. § 1395hh(a)(2).
89. *Id.*
90. § 1395hh(b)(2)(C).

Notwithstanding the inapplicability of the APA to the Medicare program, courts for decades have relied on the APA when defining and interpreting the standard in the Medicare Act.[91] Various courts of appeals have held that rules affecting a "substantive legal standard" under the Medicare Act are coterminous with the scope of "substantive rules" under the APA.[92]

The differing language between the APA and the Medicare Act makes this interpretation problematic. As an initial observation, the basic structures of the two statutes simply do not align. The APA declares a broad category of "substantive rules," then carves out exemptions: "interpretive rules," "general statements of policy," and rules exempt for "good cause." In contrast, the Medicare Act states upfront that the notice-and-comment requirement only applies to a limited set. Figure 3 lists the key phrases defining the respective boundary lines under the APA and the Medicare Act.

Figure 3. Comparing the APA and the Medicare Act



These structural differences suggest that the APA's "substantive rule" does not mean the same thing as the Medicare Act's "substantive legal

91. Josh Armstrong, *Necessary "Procedures": Making Sense of the Medicare Act's Notice-and-Comment Requirement*, 87 U. CHI. L. REV. 2175, 2186 (2020). Note that Armstrong refers to rules requiring notice-and-comment under the APA as "legislative" rules rather than "substantive" rules. *Id.* at 2180.

92. *Id.* at 2186.

standard." These legal standards could still be interpreted as coterminous, however, if the two statutes were consistent in how they divide between regulations that need notice-and-comment and those that do not. Unfortunately, no such consistency exists.

Consider, for example, the statutes' use of the phrase "statement of policy." The APA explicitly defines "*general* statements of policy" as a carve-out: such statements do not require notice-and-comment.[93] But the corresponding Medicare Act provision begins with the phrase "rule, requirement, or *other* statement of policy,"[94] suggesting that *all* "rules" and "requirements" in fact belong to a broader category of "statements of policy." So then, a "statement of policy" under the APA is exempt from notice-and-comment as long as it is "general." But under the Medicare Act, a "statement of policy"—which apparently encompasses the universe of rules and requirements promulgated by CMS—could well be subject to notice-and-comment if it affects a "substantive legal standard."[95]

Speaking of "substantive legal standard," what does that phrase even mean? It is a "novel and enigmatic"[96] phrase that does not appear anywhere else in the entire United States Code.[97] The APA uses temptingly similar language in its delayed-effective date provision.[98] For any "substantive rule," the APA declares, there must be at least thirty days' delay between the date of publication and the date that the final rule becomes effective.[99]

While courts of appeals were previously content to gloss over these textual inconsistencies by equating the APA's "substantive rule" to the Medicare Act's "substantive legal standard,"[100] the Supreme Court would soon jolt the two phrases into misalignment in *Allina II*.

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93. 5 U.S.C. § 553(b)(A) (emphasis added).

94. § 1395hh(a)(2) (emphasis added).

95. In *Azar v. Allina Health Services*, both the majority and the dissent analyzed the "statement of policy" phrase as a key piece of textual evidence. 139 S. Ct. 1804, 1811, 1819 (2019).

96. *Id.* at 1813.

97. *Id.* at 1810; *see also* UNITED STATES CODE, OFF. L. REVISION COUNS., https://uscode.house.gov/advancedSearch.xhtml [https://perma.cc/L8LT-MK87] (enter quoted phrase "substantive legal standard" in "General Search Terms" field).

98. *See* § 553(d).

99. *See id.* This general pronouncement is subject to a series of carve-outs. First, there need not be a delay, even for a "substantive rule," if the regulation "grants or recognizes an exemption or relieves a restriction." *See* § 553(d)(1). Second, "interpretive rules and statements of policy" are exempt. *See* § 553(d)(2). Third, an agency may avoid delay for "good cause." *See* § 553(d)(3).

100. *See supra* notes 91–92 and accompanying text.

B. The Uncertain Landscape Created by Allina II

"When courts can 'interpret statutes to be coherent and internally consistent,' they should."[101] But in *Allina II*, the Supreme Court departed from this guiding principle in favor of a more textually faithful interpretation.[102] By explicitly acknowledging the textual incongruities between the Medicare Act and the APA, *Allina II* managed to pull courts' heads out of the sand. It did little, however, to orient courts to their new reality.

Because *Allina II* declined to offer any further guidance regarding the legal standard governing the Medicare Act's notice-and-comment requirement, subsequent court decisions have trailblazed their own approaches. While some courts supported the broad applicability of notice-and-comment procedures, others acknowledged the practical necessity of limiting the breadth of the requirement.

1. In *Allina II*, the Supreme Court Leaves Hanging the Meaning of "Substantive Legal Standard."

Allina II dealt with a new Medicare payment formula that substantially reduced payments to certain hospitals.[103] Instead of promulgating the new formula through notice-and-comment, CMS implemented the formula in the form of a spreadsheet published on its website.[104] In a 7–1 decision, the Supreme Court affirmed the D.C. Circuit's invalidation of the formula (*Allina I*), holding that CMS's failure to subject the formula to notice-and-comment was fatal.[105]

The Supreme Court's holding, however, was narrow.[106] After evaluating the textual inconsistencies between the APA and the Medicare Act, the Supreme Court concluded that the phrase "substantive legal standard" under the Medicare Act could not have the same meaning as the phrase "substantive rule" under the APA.[107] But the Supreme Court stopped short of providing any further guidance regarding the meaning of "substantive legal

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101. Silverado Hospice, Inc. v. Becerra, 42 F.4th 1112, 1120 (2022) (citing Freeman v. Gonzales, 444 F.3d 1031, 1039 (9th Cir. 2006)).

102. *See Allina II*, 139 S. Ct. at 1811.

103. *Id.* at 1808.

104. *Id.* at 1810.

105. *Id.* at 1817.

106. *Id.* at 1814 ("Other questions about the statute's meaning can await other cases . . . we follow the well-worn path of declining 'to issue a sweeping ruling when a narrow one will do.'" (quoting McWilliams v. Dunn, 582 U.S. 183, 197 (2017))).

107. *Id.* at 1806, 1813.

standard."[108] Indeed, it explicitly declined to either affirm or reject the definition of "substantive legal standard" set forth by the D.C. Circuit.[109] In the aftermath of *Allina II*, courts had no choice but to supply their own interpretations of the standard.

2. District Courts Revert to the D.C. Circuit's Definition of a "Substantive Legal Standard."

In *Allina I*, the D.C. Circuit adhered to the following definition of a "substantive legal standard":[110] "[A]t a minimum[, a 'substantive legal standard'] includes a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'"[111] The D.C. Circuit grounded this proposal in the dictionary definition of "substantive law," which it defined in contrast to "procedural law."[112]

In the absence of further guidance from *Allina II*, several courts simply reverted to the D.C. Circuit's definition.[113] These courts suggested that a broad set of Medicare policies—namely, all policies affecting provider reimbursements—could implicate a "substantive legal standard."

a. Select Specialty Hospital-Denver Inc. v. Azar

Select Specialty was the first case after *Allina II* to apply the new meaning of "substantive legal standard."[114] In this case, the D.C. District Court considered a policy change that impacted over seventy long-term care hospitals across roughly two dozen states.[115] Up to 2007, CMS had reimbursed these hospitals for the unpaid co-insurance and deductible obligations, or "bad debts," of patients who were dually enrolled in Medicare

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108. *Id.* at 1814.

109. *Id.* ("We need not, however, go so far as to say that the hospitals' interpretation, adopted by the [D.C. Circuit], is correct in every particular.").

110. The D.C. Circuit initially set forth this definition in *Clarian Health West, L.L.C. v. Hargan*, 878 F.3d 346, 354 (D.C. Cir. 2017).

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

112. *Id.* ("'Substantive law' is the part of the law that 'creates, defines, and regulates the rights, duties, and powers of parties.'"). "We may say that the substantive law defines the remedy and the right, while the law of procedure defines the modes and conditions of the application of the one to the other." Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F. Supp. 3d 53, 68 (D.D.C 2019) (quoting JOHN SALMOND, JURISPRUDENCE 476 (Glanville L. Williams ed., 10th ed. 1947)).

113. *See Select Specialty*, 391 F. Supp. 3d at 68; Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019).

114. 391 F. Supp. 3d at 67.

115. *Id.* at 55.

and Medicaid.[116] But in 2007, without undergoing notice-and-comment procedures, CMS abruptly began denying these reimbursements to the hospitals unless they had first billed their state Medicaid programs and secured appropriate documentation.[117] Unfortunately, some hospitals were not enrolled in their respective state Medicaid programs and, therefore, could not bill them.[118] Some hospitals were entirely unable to enroll; those that did found that it was impossible to obtain reimbursements for prior years.[119] Combined, the hospitals sued CMS for over twenty million dollars in retroactive reimbursements.[120]

Notwithstanding the Supreme Court's hesitation to endorse the D.C. Circuit's "substantive legal standard" definition, the D.C. District Court concluded that it was bound to apply it.[121] The District Court acknowledged that the policy was ostensibly procedural because it merely required the hospitals to follow a new filing procedure, which did not change the hospitals' entitlement to a fixed sum of money.[122] However, the District Court found that the policy was ultimately substantive because it forced the hospitals to participate in state Medicaid programs, which changed the eligibility criteria for reimbursement by requiring hospitals to enter into new contracts with third parties.[123] This contracting requirement, according to the D.C. District Court, made the policy substantive rather than procedural in nature.[124] Because the policy had thus changed a "substantive legal standard" without undergoing notice-and-comment rulemaking, the policy was invalid.[125]

b. Polansky v. Executive Health Resources, Inc.

A few months later, a District Court in Pennsylvania followed suit in adopting the D.C. Circuit's "substantive legal standard definition."[126] In *Polansky*, the District Court considered a False Claims Act *qui tam* action.[127] The relator alleged that the defendant had knowingly advised its client

116. *Id.*
117. *Id.*
118. *Id.*
119. *Id.*
120. *Id.*
121. *Id.* at 68.
122. *Id.*
123. *Id.* at 69.
124. *Id.*
125. *Id.* at 70.
126. Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019).
127. *Id.* at 918.

hospitals to improperly classify hundreds of thousands of claims as inpatient stays rather than outpatient visits.[128] Since inpatient stays are reimbursed at a higher rate than outpatient visits, the relator alleged that the defendant had fraudulently advised its clients to bill at the higher inpatient rate.[129] This violated the Medicare Act's direction to submit claims only for services that were "reasonable and necessary" for medical treatment.[130]

Before determining whether the defendant was liable under the False Claims Act, the District Court examined the policy governing the classification of hospital visits as inpatient or outpatient.[131] CMS had conveyed this policy through a series of manuals, but it had never subjected the policy to notice-and-comment.[132] The District Court reasoned that before the defendant could be found liable, the underlying policy must be held valid.[133] And this could only be so if the policy had neither established nor changed a "substantive legal standard."[134]

After surveying the three preexisting cases[135] that applied the D.C. Circuit's definition of "substantive legal standard," the District Court synthesized the following rule: a policy is more likely to be considered a "substantive legal standard" if it changes a right to reimbursement or the amount of reimbursement.[136] Here, the policy affected the amount of reimbursement because it determined eligibility for inpatient classification, which in turn determined eligibility for a higher reimbursement rate.[137] Accordingly, the District Court found that the policy implicated a "substantive legal standard" and invalidated the policy for failure to undergo notice-and-comment.[138]

Select Specialty and *Polansky* indicated that a Medicare policy is more likely to be considered a "substantive legal standard" when the policy impacts an amount of money or the right to receive that money. *Select Specialty* and *Polansky* struck down policies that affected considerable sums of money—

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128. *Id.*
129. *Id.* at 919.
130. *See id.* at 932 (citing 42 U.S.C. § 1395y(a)(1)(A)).
131. *Id.* at 932–36.
132. *Id.* at 932–33.
133. *See id.* at 931.
134. *See id.* at 932.
135. *Id.* at 934–35 (surveying Clarian Health W., L.L.C. v. Hargan, 878 F.3d 346 (D.C. Cir. 2017), *Allina I*, 863 F.3d 937 (D.C. Cir. 2017), and Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F. Supp. 3d 53 (2019)).
136. *Id.*
137. *Id.* at 935.
138. *Id.* at 936.

over twenty million in claimed reimbursements[139] and hundreds of thousands of claims.[140] Nothing in *Select Specialty* or *Polansky* suggests, however, that a policy becomes less substantive in nature when it affects a smaller amount of money.

Consider a routine update to the Cataract cost measure that causes Aaron's MIPS score to shift by one percentile rank, increasing his MIPS bonus by a nearly imperceptible amount. However slight, this update affects Aaron's amount of reimbursement. *Select Specialty* and *Polansky* suggest that this measure update should still undergo notice-and-comment rulemaking. But if CMS must undertake notice-and-comment for the Cataract cost measure alongside hundreds of other measures each year, it may well experience an "unnecessary and potentially severe burden"[141] on its administration.

In subsequent cases implicating reimbursement, the Ninth Circuit implicitly appeared to recognize this practical motivation for limiting the scope of the notice-and-comment requirement.

3. The Ninth Circuit Sidesteps the "Substantive Legal Standard."

While *Allina II* invalidated the government's payment formula for failure to undergo notice-and-comment, it explicitly left open an escape hatch for future cases. It suggested that under different facts, CMS could argue that "the policy at issue . . . didn't 'establis[h] or chang[e]' a substantive legal standard . . . because the *statute* itself" provided the relevant standard.[142] In *Allina II*, this hatch was left firmly closed by the facts, as CMS had made no suggestion that a statute had mandated the policy change at issue.[143] In the following cases, however, the Ninth Circuit opened the hatch and explored its contours by upholding two CMS policies that were implemented pursuant to statutory directives.

a. Agendia, Inc. v. Becerra

Local coverage determinations ("LCDs") are regional determinations as to whether a medical item or service is "reasonable and necessary" for

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139. *See supra* text accompanying note 120.

140. *See supra* text accompanying note 128.

141. *See Allina II*, 139 S. Ct. 1804, 1823 (2019) (Breyer, J., dissenting) (discussing the possibility that tens of thousands of pages of Medicare guidance documents could be required to undergo notice-and-comment as a consequence of the *Allina II* ruling).

142. *Id.* at 1816.

143. *Id.* at 1816–17.

beneficiary treatment.[144] They are issued by regional Medicare administrative contractors ("MACs") and are not binding at higher levels of administrative review.[145]

In *Agendia*, a MAC denied a laboratory's reimbursement claim for molecular diagnostic tests based on a previously issued LCD.[146] The laboratory challenged the denial, arguing that the LCD was invalid because it had been issued without opportunity for notice-and-comment.[147]

A majority of the Ninth Circuit upheld the LCD because it did not "establish[] or change[]" the controlling legal standard—the Medicare statute's "reasonable and necessary" requirement did.[148] The LCD merely reflected the MAC's view of what items and services qualified under the standard.[149] The majority noted that prior cases had specifically described LCDs as independent from the Medicare Act's "reasonable and necessary" standard.[150] These cases had recognized that even if LCDs ceased to exist, the Medicare Act's "reasonable and necessary" standard would remain unaltered.[151] Based on this independence, LCDs could not have "establish[ed] or chang[ed]" the "reasonable and necessary" standard.[152]

Sitting by designation, a District Judge from the Eastern District of New York dissented.[153] The dissent began by pointing out that an administrative law judge ("ALJ") had initially issued a favorable decision to the laboratory, which the Medicare Appeals Council later reversed based on the previously-issued LCD.[154] This demonstrated that even if LCDs purported to be non-binding, they were in fact binding at initial stages of claim adjudication and could compel reversal of ALJ decisions.[155] Thus, LCDs "defin[ed] and regulate[d] the rights" of parties, even as they also "guide[d]" the application of a statutory standard.[156] Because the LCDs "'establish[ed]' a standard at the initial stage of review and 'change[d]' the standards" upon appellate review, the dissent maintained that LCDs ought to require notice-and-comment.[157]

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144. Agendia, Inc. v. Becerra, 4 F.4th 896, 897–98 (9th Cir. 2021).
145. *Id.* at 897.
146. *Id.* at 898.
147. *Id.* at 898–99.
148. *Id.* at 900.
149. *Id.*
150. *Id.*
151. *Id.* (citing Erringer v. Thompson, 371 F.3d 625, 631 (9th Cir. 2004)).
152. *Id.*
153. *Id.* at 904.
154. *Id.* at 903–04.
155. *Id.* at 904.
156. *Id.*
157. *Id.*

The dissent also proposed a new definition of "substantive legal standard" as one that would include all "'rules' and 'statements of policy' that decide Medicare claims, impact the rights of parties in the Medicare adjudicative process, or otherwise have a 'significant effect' on stakeholders in the Medicare system."[158] Finally, the dissent chided the majority for "miss[ing an] opportunity" to offer a "realistic" definition and invited the Supreme Court to take up this "important and unresolved" issue.[159]

b. Silverado Hospice, Inc. v. Becerra

In *Silverado Hospice*, the Ninth Circuit considered another policy that CMS implemented pursuant to a statutory directive.[160] *Silverado Hospice* concerned the Budget Control Act, which required CMS to implement across-the-board spending cuts upon the occurrence of certain conditions.[161] These conditions occurred in 2013, triggering the Budget Control Act's spending cuts and forcing CMS to find a way to implement a two percent spending reduction consistent with the Medicare statute and regulations.[162] CMS eventually issued a letter explaining its methodology for cutting hospice reimbursements.[163] Certain hospices sued, alleging that CMS had failed to undertake notice-and-comment procedures when implementing the methodology update.[164]

The Ninth Circuit held that CMS had not established or changed a "substantive legal standard" by issuing the letter.[165] Instead, CMS had merely implemented the controlling legal standard found in the Budget Control Act.[166] By implementing the spending reduction, CMS had "simply abided by congressional and presidential directives."[167] Accordingly, the policy was not subject to the Medicare Act's notice-and-comment requirement.[168]

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158. *Id.* at 910.
159. *Id.*
160. *See* Silverado Hospice, Inc. v. Becerra, 42 F.4th 1112, 1113 (9th Cir. 2022).
161. *Id.* at 1113–14.
162. *Id.* at 1115–16.
163. *Id.*
164. *Id.* at 1122.
165. *Id.*
166. *Id.*
167. *Id.*
168. *Id.* at 1123.

4. *Allina II*'s Progeny Diverges.

In *Agendia* and *Silverado Hospice*, the Ninth Circuit held that CMS did not establish or change a "substantive legal standard" when it implemented an explicit statutory directive.[169] In doing so, the Ninth Circuit acknowledged that certain Medicare policies could bypass notice-and-comment, even if such policies affected reimbursements.

Arguably, *Agendia* and *Silverado Hospice* have limited significance due to their facts. *Agendia*'s reasoning depends on the unique status of LCDs: because LCDs are independent from the Medicare Act's "reasonable and necessary" provision, the majority concluded that LCDs could not have established or changed the controlling legal standard. On the other hand, *Silverado* featured the rather unusual circumstance of a Medicare regulation born out of a non-Medicare statute. The Ninth Circuit allowed this regulation to escape from the Medicare Act's notice-and-comment requirement only because the regulation did not technically derive from the Medicare Act.

The fact that the Ninth Circuit chose to uphold these policies at all, however, indicates that it understood *Allina II* differently from the *Select Specialty* and *Polansky* courts. Given that *Agendia* and *Silverado Hospice* dealt with claims for reimbursement, the Ninth Circuit could readily have found that the policies altered a "substantive legal standard" because they affected rights to payment. By declining to do so, the Ninth Circuit seemed to recognize—even if only implicitly—that such a rule would create practical difficulties. Since Medicare is, at its core, a reimbursement program, such an interpretation of "substantive legal standard" would expand the scope of the notice-and-comment requirement to include virtually everything that Medicare touches.

Thus, the progeny of *Allina II* falls into two camps. The first camp, represented by *Select Specialty*, *Polansky*, and the *Agendia* dissent, construes the Medicare Act's notice-and-comment requirement more broadly. The second camp, comprised of *Agendia*'s majority and *Silverado Hospice*, is inclined to allow Medicare policies to bypass the notice-and-comment requirement so long as CMS can point to a clear statutory basis for doing so.

a. The Regulatory Approach: Navigating the Notice-and-Comment Requirement for Measure Maintenance Issues

Both leading up to and following the *Allina II* decision, CMS's approach to the notice-and-comment requirement for measure maintenance was

169. *Id.*; Agendia, Inc. v. Becerra, 4 F.4th 896, 902 (9th Cir. 2021).

understandably cautious, noncommittal, and vague. This approach, however, provided inadequate guidance as to which maintenance changes are "substantive" enough to require notice-and-comment.

Prior to *Allina II* in 2019, CMS employed a cautious tone when navigating the notice-and-comment requirement for its measures. When it initially introduced quality measures to the MIPS program, CMS defined "substantive" changes to measures simply by contrasting them to "maintenance" changes.[170] CMS listed a handful of examples of such changes, stressing that these lists were non-exhaustive.[171] In 2018, CMS reiterated this approach for its MIPS cost measures.[172]

For a separate value-based program, CMS defined "substantive" changes even more vaguely by contrasting them only to "nonsubstantive" changes.[173] Again employing noncommittal language, CMS stated that "substantive" changes "might" include those that are so significant that "the measure is no longer the same measure" or cause a standard of performance to become more stringent.[174]

Following *Allina II*, the Health and Human Services Office of the General Counsel ("HHS-OGC") issued an Advisory Opinion that provided its interpretation of the case.[175] While the Advisory Opinion was nonbinding and lacked the force of law, it provided HHS-OGC's current views on how *Allina II* should be implemented.[176]

Citing *Select Specialty*, HHS-OGC's Advisory Opinion interpreted the phrase "substantive legal standard" to mean:

> Any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any *legal right or obligation* relating to the scope of Medicare benefits, payment[s] . . . or eligibility . . . *and* 3) sets forth a requirement *not otherwise mandated by* statute or regulation.[177]

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170. 81 Fed. Reg. 77008, 77037 (Nov. 4, 2016) (describing measure maintenance approach for quality measures used in MIPS program).

171. CMS declared that "substantive" changes could concern measure specifications, measure titles, and domain modifications, while "maintenance" changes could include changes to diagnosis and procedure codes, definitions, and changes to population exclusions. 81 Fed. Reg. 77008, 77137 (Nov. 4, 2016).

172. *See* 83 Fed. Reg. 35704, 35901–02 (July 27, 2018).

173. 42 C.F.R. § 416.325(a).

174. 83 Fed. Reg. 41144, 41475 (Aug. 17, 2018) (describing measure maintenance approach for HAC Reduction Program).

175. Dep't of Health & Human Servs., Advisory Opinion 20-05 on Implementing *Allina* (Dec. 3, 2020), at 1.

176. *Id.*

177. *Id.* at 1–2 (emphasis added).

HHS-OGC's interpretation appeared to hinge the notice-and-comment requirement on the concept of a "norm." HHS-OGC opined that notice-and-comment is required when the agency "unilaterally issues discrete, binding criteria" that are "usually . . . viewed as creating a new norm."[178] This is true even when such statements "purport[]" to merely explain statutory or regulatory requirements.[179] However, when an existing statute or regulation is "drafted narrowly enough" to create the "norm," additional guidance does not need notice-and-comment.[180]

In the context of enforcement actions based on sub-regulatory guidance, HHS-OGC further reiterated its reliance on the "norm" inquiry. The "critical question," HHS-OGC said, is whether a violation of a Medicare rule can be shown in the absence of a sub-regulatory guidance document.[181] Otherwise, the guidance establishes a "norm" and is valid only if it was issued through notice-and-comment rulemaking.[182]

In its current regulations, CMS again draws a distinction between "substantive" and "nonsubstantive" changes.[183] While "substantive" changes must undergo notice-and-comment procedures, "nonsubstantive" changes can occur through less formal channels—for example, through website posting or email announcement.[184] The regulations do not say much more about how the distinction is made. For certain value-based programs, CMS determines whether a change to a measure is "substantive" based on the following criteria:

> Non-substantive measure specification updates include those that –
>
> (i) Narrow the denominator or population covered by the measure;
>
> (ii) Do not meaningfully impact the numerator or denominator of the measure;

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178. *Id.* at 2.
179. *Id.*
180. *Id.*
181. *Id.*
182. *Id.*
183. *See* 42 C.F.R. § 416.325 (relating to Ambulatory Surgical Center Quality Reporting (ASCQR) program); § 412.24(d)(1) (relating to PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) program); § 422.164(d) (relating to Part C Star Ratings program); § 423.184(d) (relating to Part D Star Ratings program).
184. *See* § 416.325(c) (providing for notification of sub-regulatory maintenance on CMS website and online program manual); § 412.24(d)(1) (providing that "technical measure specification updates" are shared through CMS website and email announcements).

> (iii) Update the clinical codes with no change in the target population or the intent of the measure;
>
> (iv) Provide additional clarifications:
>
> (A) Adding additional tests that would meet the numerator requirements;
>
> (B) Clarifying documentation requirements;
>
> (C) Adding additional instructions to identify services or procedures; or
>
> (v) Add alternative data sources.[185]

For other programs, CMS specifies only that it makes the determination on a case-by-case basis.[186]

Because CMS largely avoided defining when measure changes require notice-and-comment and when they do not, CMS effectively handed off the decision to its individual programs. As Part III explains, this approach was unideal from a clinical standpoint.

III. THE SOLUTION: CASTING OFF THE NOTICE-AND-COMMENT REQUIREMENT

CMS relies on a broad portfolio of measures, each with unique maintenance needs. For such a diverse set of measures, maintenance changes are ill-suited to binary classification as either "substantive" or "nonsubstantive." Some types of maintenance do not alter the intent of the measure; for example, they might simply narrow the population of clinicians under measurement. Other types of maintenance, however, could have a greater effect on the purpose of the measure. A rigid classification fails to account for the reality that maintenance changes occur on a spectrum of substantiveness.

Regardless of its intent, any maintenance change will shift the resulting distribution of measure scores. By design, a shift in measure scores leads to a shift in provider reimbursements. And as *Allina II* and its progeny suggest, any change to provider reimbursements is potentially enough to trigger the notice-and-comment requirement.[187]

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185. § 422.164(d)(1) (relating to Part C Star Ratings program); *see also* § 423.184(d)(1) (providing similar language for Part D Star Ratings Program).

186. *See* § 416.325(a) (describing measure maintenance procedures for ASCQR program).

187. *See supra* Section II.B.4.

Naturally, CMS regulations align with the case law in leaving open the possibility that certain maintenance changes require notice-and-comment. In doing so, however, the regulations fail to interpret the Medicare Act's notice-and-comment standard with adequate precision. Only for two quality programs does CMS provide criteria for determining the substantiveness of a maintenance change.[188] For the vast universe of remaining measures, CMS largely leaves its individual programs to determine the substantiveness of a change on a "case-by-case" basis.[189]

Rather than leaving its programs to cope with such uncertainty, CMS should amend its regulations to establish that once it implements a measure into a program, any subsequent measure revisions will not require notice-and-comment. In other words, CMS should create a clean divide between the implementation and maintenance phases in the measure life cycle: implementation requires notice-and-comment, but maintenance does not. Such a clear statement would empower developers to continue engaging the public in maintenance discussions without incurring the delay inherent to rulemaking.

The legal justification for this approach readily appears in the Medicare statute. While the Medicare Act's "substantive legal standard" is distinct from the APA's "substantive rule," the Medicare Act still explicitly cross-references the good-cause exemption in the APA. Thus, the Medicare Act's good-cause exemption is exactly the same as the good-cause exemption under the APA. So regardless of whether a policy implicates a "substantive legal standard," the Medicare Act allows the policy to bypass notice-and-comment if doing otherwise would be "impracticable, unnecessary, or contrary to the public interest"[190] pursuant to § 553 of the APA.

The APA's good-cause provision lends two viable justifications for exempting measure maintenance from notice-and-comment. First, notice-and-comment is "unnecessary" because it is redundant; the measure maintenance process is already replete with opportunities for public comment. Second, notice-and-comment causes delay that is "contrary to the public interest" in the context of medical care. By delaying the implementation of clinically meaningful changes, notice-and-comment hinders measures from properly incentivizing providers to improve.

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188. *See supra* note 185.
189. *See supra* note 186.
190. 5 U.S.C. § 553(b)(3)(B).

A. In Light of Existing Opportunities for Public Engagement, Notice-and-Comment Rulemaking Is Unnecessary

As illustrated by the Cataract cost measure, there are robust opportunities for public engagement throughout the measure life cycle. Beginning in 2017, the developer of the Cataract cost measure began soliciting stakeholder input by convening groups of experts.[191] The developer then distributed reports to all clinicians who would be scored under the measure and invited their feedback. After soliciting public comment through pre-rulemaking and rulemaking, CMS implemented the measure for use in the 2019 performance year.

Following implementation, the developer continued to solicit public engagement through two additional processes: measure endorsement and comprehensive reevaluation. The endorsement process included a four-month public comment period. The comprehensive measure reevaluation process opened with yet another four-month public comment period, followed by a public survey in early 2023.

Through these activities, the measure life cycle already satisfies the core goals of notice-and-comment by providing the public with notice of changes and an opportunity to be heard. The only practical effect of additional notice-and-comment procedures is the addition of sixty days for public comment on top of the cumulative eight months already provided by endorsement and comprehensive reevaluation. In those eight months, interested members of the public have ample opportunity to share feedback on the measure. The additional sixty-day public comment period is more formal than functional; it effectively invites members of the public to reiterate their feedback.

B. The Delay Caused by Notice-and-Comment Is Contrary to the Public Interest

In their quest to comply with the existing regulations, measure developers tend to err on the side of caution by opting into rulemaking, even when the substantiveness of the anticipated measure changes is debatable.[192] This means if a stakeholder suggested changes to the measure in 2022, they would need to wait for pre-rulemaking and rulemaking processes to take place during 2023 and 2024. In effect, the stakeholder must wait as long as three years to see their suggestions come to fruition.

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191. *See supra* Section I.B.

192. *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 57.

Such a multi-year delay has adverse impacts on the clinical relevance of the measure. Delaying a measure's incorporation of meaningful updates forces the measure to evaluate present-day performance with dated specifications. This hampers the ability of the measure to account for nascent advancements in care, such as new technologies or best practices. This could unwittingly penalize providers for adopting new medical technologies or practices that result in better patient care. Alternatively, a measure could evolve unfavorably over the course of a multi-year delay. For example, once a critical mass of providers learns how to achieve maximum scores, the measure is no longer capable of incentivizing improvements in care. The delay of rulemaking only prolongs the measure's inefficacy.

Without having to undergo notice-and-comment rulemaking, measure updates could proceed at a much quicker pace. For example, CMS could adopt an annual cycle: it could solicit public input in early 2022, finalize and announce changes in late 2022, and adopt those changes in the 2023 performance year. Compared to the multi-year cycle necessitated by notice-and-comment, an annual update would better ensure the measure's clinical relevance. In turn, this would improve the measure's efficacy by better capturing the dimensions of present-day care.

C. Addressing Counterarguments

Critics of the modern regulatory state often argue that rulemaking-induced delay is both intentional and beneficial; it facilitates more deliberative agency decisions, which ultimately benefits stakeholders by resulting in more well-considered policies.[193] In the context of measure maintenance, however, the potential harms of delay may well outweigh the supposed benefits. When notice-and-comment rulemaking delays meaningful changes, it hurts CMS's ability to accurately assess provider performance. And when CMS cannot appropriately measure clinicians, it misses out on an opportunity to

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193. As John Geilman writes:

> In the long run, the Supreme Court's decision [in *Allina II*] to require more rules to go through the notice-and-comment procedure will be useful for the healthcare industry. It may sacrifice some speed . . . but the greater industry input will lead to more tailored rules. More tailored rules will lead to decreased healthcare costs . . . [and] will lead to greater ossification of CMS policy, which will create more stability in the market.

John Geilman, *Implications of* Azar v. Allina Health Services *on Rulemaking: How To Know When Notice and Comment Is Required Under the Medicare Act*, 36 BYU J. PUB. L. 157, 173 (2022).

incentivize improvements in care. Ultimately, patients bear the consequences of this lost opportunity.

With respect to the measure maintenance process, critics may also point out that measure specifications are technically in flux during the public comment periods offered by endorsement and comprehensive reevaluation. Such critics may then argue that the public should have an opportunity to comment on the measure's "final" specifications through rulemaking. However, such a perspective fundamentally misconstrues the nature and purpose of measures. At no point is a measure truly final; a measure evolves continuously through back-and-forth exchanges between the developer and the public. Waiting for a measure to be "final" is akin to putting a bow on the measure at an arbitrary point in time. Once the developer revises a measure based on public comment, the public will always have a future opportunity to provide input on the measure. And of course, public comment can always take place through channels other than the Federal Register.

IV. CONCLUSION

This Comment contributes to the discussion of the Medicare Act's notice-and-comment requirement in three ways: it (1) reviews the updated jurisprudence interpreting *Allina II*, (2) summarizes CMS's approach to the notice-and-comment requirement in the context of measures, and (3) proposes two statutory justifications for resolving the uncertainty of notice-and-comment for measure maintenance changes.

To deploy measures as effectively as possible, CMS can and should amend its regulations to allow measure maintenance to bypass the notice-and-comment requirement. To justify this approach, CMS needs to look no further than the Medicare Act. By cross-referencing the APA, the Medicare Act allows certain rules to bypass notice-and-comment for good cause. On these grounds, CMS could find that notice-and-comment for measure maintenance is at least unnecessary, if not also contrary to the public interest.

While measures are just one of the many tools wielded by Medicare's complex bureaucracy, their continued relevance is difficult to overstate. Measures represent an increasingly important key strategy in managing quality and controlling costs. As CMS continues to address persistent problems in both areas, it will continue to rely on measures in its efforts to hold providers accountable. Given that nearly half of Medicare's trust fund faces depletion within the next five years, measures must evolve—and they must evolve quickly.