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AGENDIA, INC. V. BECERRA: IMPOSING A DANGEROUS ASSUMPTION OF UNWORTHINESS TO LOCAL COVERAGE DETERMINATION

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INTRODUCTION

In *Agendia, Inc. v. Becerra*, the Court of Appeals for the Ninth Circuit addressed whether 42 U.S.C. § 1395hh of the Medicare Act requires that a local coverage determination (LCD) undergo a notice-and-comment process before being adopted.[1] More specifically, the issue was whether the LCDs establish or change a "substantive legal standard" under 42 USC § 1395hh(a)(2).[2] The court ruled in favor of the Department of Health and Human Services, holding that § 1395hh's notice-and-comment requirement does not apply to LCDs because such determinations do not establish or change a substantive legal standard.[3] The dissent disagreed, arguing that the majority's selective use of dictionaries and abstract analysis of the Medicare statute's structure "elevates form over substance." [4] This note argues, in line with the dissent, that the majority erred in its holding and imposed a dangerous assumption of unworthiness to LCDs.

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1. Agendia, Inc. v. Becerra, 4 F.4th 896, 898-99 (9th Cir. 2021). Agendia also argued that the portions of the Medicare Act and its implementing regulations that authorize MACs to issue LCD unconditionally delegate regulatory authority to private entities. *Id.*

2. *Id.* at 900.

3. *Id*. The court also rejected Agendia's alternative theory that contractor's ability to issue LCDs reflects an unconstitutional delegation of regulatory power to private entities, holding that the Constitution permits contractors to issue such determinations. *Id.* at 902-03.

4. *Id.* at 904 (Block, J., dissenting).

Part I summarizes the factual and procedural background behind the court's opinion.[5] Part II explores the notice-and-comment requirement under the Medicare Act,[6] courts' interpretation of "substantive legal standard,"[7] and the mechanisms to promote consistency in Medicare claims adjudications.[8] Part III explains the reasoning underlying the court's decision.[9]

Finally, Part IV (1) asserts that the court's flawed reasoning ignored the fact that the standard prescribed in an enabling statute does not preclude administrative agencies from establishing additional requirements in furtherance of that statute;[10] (2) contends that the court's erroneous holding imposed a dangerous assumption that LCDs are not substantial in the Medicare Program and deprived the public of a transparent and competent process to establish LCDs;[11] (3) maintains that the court should have followed Supreme Court jurisprudence and distinguished the phrase "substantive legal standard" in § 1395hh from other statutes including the Administrative Procedure Act (APA);[12] and (4) argues that the court should have affirmed the district court's decision using proper statutory interpretation principles and opened the door for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment process.[13]

I. THE CASE

"Agendia is a clinical laboratory that furnishes molecular diagnostic tests for doctors treating breast cancer patients".[14] In 2012 and 2013, Agendia filed claims with the Medicare Administrative Contractor (MAC) to seek reimbursement from the Department of Health and Human Services (HHS).[15]

5. *See infra* Section I.

6. *See infra* Section II.A.

7. Section II.B.

8. *See infra* Section II.C.

9. *See infra* Section III.

10. *See infra* Section IV.A.

11. *See infra* Section IV.B.

12. *See infra* Section IV.C.

13. *See infra* Section IV.D.

14. Agendia, Inc. v. Becerra, 4 F.4th 896, 898 (9th Cir. 2021). Agendia has three genomic diagnostic products. MammaPrint is the first and only FDA-cleared IVDMIA breast cancer recurrence assay. BluePrint is a molecular subtyping assay. TargetPrint is an ER/PR/HER2 expression assay. The tests use genomic molecular diagnostics to identify sub-types of breast cancer and other information that can be used to evaluate treatment options. *Agendia Genomic Tests (MammaPrint, BluePrint & TargetPrint) Among Highlights of San Antonio Breast Cancer Symposium,* AGENDIA, (Dec. 23, 2013) https://agendia.com/agendia-genomic-tests-mammaprint-blueprint-targetprint-among-highlights-of-san-antonio-breast-cancer-symposium/.

15. During that time, Agendia provided BluePrint and TargetPrint tests to oncologists for eighty-six Medicare beneficiaries. *Agendia*, 4 F.4th at 898.

The MAC denied payment based on an LCD that the MAC previously issued,[16] concluding that the claims did not meet the statutory "reasonable and necessary" standard for Medicare reimbursement.[17] After the MAC denied the payment, Agendia requested reconsideration from a Qualified Independent Contractor (QIC), a separate Medicare contractor.[18] The QIC denied the payment after determining that there was insufficient evidence to support the required clinical utility for the tests.[19] In 2014, after the QIC's denial, Agendia requested a hearing before an Administrative Law Judge (ALJ) .[20] The ALJ issued a fully favorable decision for Agendia in 2018.[21] Nevertheless, a second QIC wrote to the Medicare Appeals Council to challenge the ALJ's decision.[22] In 2019, the Council, on its own motion, reversed the ALJ's decision and concluded that the tests were not reasonable and necessary.[23]

Agendia filed a complaint in the Central District of California suing the Secretary of HHS.[24] The complaint asked the court to consider whether 42 U.S.C. § 1395hh of the Medicare Act requires an LCD undergo a notice-and-comment process before adoption.[25] More specifically, the argument centered on whether the LCDs establish or change a "substantive legal standard."[26] The district court ruled in favor of Agendia, holding that the notice-and-comment process is a statutory requirement for LCDs.[27] The Secretary appealed to the Court of Appeals for the Ninth Circuit.[28]

16. *Id.* The payment denial was on the grounds that the tests were not covered by Medicare based on LCD L32288 and lack of Molecular Diagnostic Services (MoIDX) program approval. *Agendia,* 420 F. Supp. 3d 985, 989 (C.D. Cal. 2019). LCD L32288 confirmed non-coverage of all molecular diagnostic tests unless expressly announced otherwise. *Id.* MoIDX is a program to identify and establish coverage for molecular diagnostic tests based on clinical information. *Id.*

17. *Agendia*, 4 F.4th at 898.

18. *Agendia,* 420 F. Supp. 3d at 989.

19. *Id.*

20. *Id.*

21. *See id.* (finding that both tests were medically reasonable and necessary).

22. *Id.* at 990.

23. *Id.*; *Agendia*, 4 F.4th at 898. The council also explained that there was "no reason not to apply substantial deference" to the relevant LCD or to question the MoIDX program's findings*." Agendia*, 4 F.4th at 898; *Agendia*, 420 F. Supp. 3d at 990.

24. *Agendia*, 420 F. Supp. 3d at 990.

25. *Agendia*, 4 F.4th at 898—99. *See supra* text accompanying note 1.

26. *Agendia,* 420 F. Supp. 3d at 997.

27. *Agendia*, 4 F.4th at 899. *See supra* text accompanying note 3.

28. *Agendia*, 4 F.4th at 899.

II. LEGAL BACKGROUND

A. The notice-and-comment requirement under the Medicare Act

Congress amended the Medicare Act in 1986 and again in 1987 to codify a requirement that certain Medicare rules go through a notice-and-comment process.[29] The final statutory provision states:

> "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under [42 USC § 1395hh(a)(1)]." 42 USC § 1395hh(a)(2).

The § 1395hh notice-and-comment requirement under the Medicare Act has distinct framing language from the notice-and-comment requirement under the Administrative Procedure Act (APA).[30] Under the APA, an agency seeking to adopt a new administrative rule should first give notice of the proposed rule and subject it to a period of public comment.[31] While the APA specifies which rules are *exempt* from notice-and-comment,[32] the Medicare Act specifies which rules are *subject* to the notice-and-comment process.[33] Table 1 compares the key features of the notice-and-comment requirements under the APA and the Medicare Act § 1395hh.[34]

Despite the framing differences, for decades, courts agreed that the term "substantive legal standard" in the Medicare Act involved the same scope as

29. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99—509 § 9321(e)(1), 100 Stat. 1874, 201718 (codified at 42 U.S.C. § 1395hh(b)(1)); Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203 § 4035(b)(2), 101 Stat. 1330—77, 1330—78 (codified at 42 U.S.C. § 1395hh(a)(2)).

30. *See infra* Table 1.

31. Administrative Procedure Act § 1, 5 U.S.C. § 553.

32. *Id.* § 553(b)(A), (B). The APA makes exceptions to its notice-and-comment requirement for interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice, as well as when there is a good cause to deviate from notice-and-comment procedures. *Id.*

33. 42 U.S.C. § 1395hh(a)(2). Substantive legal standards are subject to the notice-and-comment requirement under the Medicare Act. *Id.*

34. *See infra* Table 1.

legislative rules under the APA.[35] However, in 2019, the Supreme Court decided *Azar v. Allina Health Services* (*Allina II*).[36] The Court disagreed with the alignment between the Medicare Act and the APA,[37] and held that the Medicare Act's notice-and-comment requirements are broader and more extensive than the APA's requirements.[38] For example, certain policy statements are exempt as "interpretative rules" under the APA.[39] However, if they "establish or change" a "substantive legal standard" that governs payment for services, the scope of benefits, or eligibility for services or benefits, the notice-and-comment rulemaking pursuant to the Medicare Act is still required for these policy statements.[40]

In *Allina II*, the CMS policy at issue allowed Medicare Part C patients to be included in the disproportionate share hospital payment calculation, which considerably reduced the hospitals' payments.[41] The Court concluded that the CMS policy established or changed a "substantive legal standard."[42] However, the Court did not specifically define "substantive legal standard" or describe its core attributes.[43] Consequently, the decision left CMS with no guidance as to which policies must undergo notice-and-comment requirements.[44]

B. Courts' approach to "substantive legal standard" after Allina II

The D.C. Circuit has relied on a dictionary approach to resolve "substantive legal standard" issues.[45] According to the court, a "substantive legal standard" is "at [] minimum… a standard that creates, defines, and regulates the rights, duties,

35. Josh Armstrong, *Necessary "Procedures": Making Sense of the Medicare Act's Notice-and-Comment Requirement*, 87 U. CHI. L. REV. 2175, 2186 (2020).

36. Azar v. Allina Health Servs. (Allina II), 139 S. Ct. 1804 (2019).

37. *Id*. at 1815.

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

39. Administrative Procedure Act § 1, 5 U.S.C. § 553.

40. *See supra* note 38.

41. 139 S. Ct. at 1809. The reason behind this is that Medicare program offers additional payments to institutions that serve a disproportionate number of low-income patients and Medicare Part C patients tend to be wealthier. *Id.*

42. *Id.* at 1813.

43. Armstrong, *supra* note 35, at 2177–78.

44. *Id.*

45. Allina Health Servs. v. Price (Allina I), 863 F.3d 937, 943 (D.C. Cir. 2017).

and powers of parties."[46] Lower district courts generally follow the D.C. Circuit's approach when faced with an issue related to § 1395hh.

In 2019, the D.C. District Court decided *Select Specialty Hospital-Denver, Inc. v Azar*.[47] In that case, CMS required providers to obtain a certain form through qualifying providers in order to receive reimbursement.[48] The court held that the rule altered a substantive legal standard because the rule "essentially changed the eligibility criteria for reimbursement."[49] In its opinion denying HHS's motion for reconsideration, the court further explained that under the D.C. Circuit's interpretation, § 1395hh(a)(2) "'distinguish[es] a substantive from a *procedural* legal standard,' and requires that CMS conduct notice and comment rulemaking for changes to the former but not to the latter type of standard."[50]

The Eastern District of Pennsylvania adopted the D.C. Circuit's dictionary approach in *Polansky v. Executive Health Resources, Inc*.[51] In *Polansky*, CMS implemented a time-based reimbursement policy to determine inpatient status.[52] For example, the policy instructed that twenty-four hours be used as a benchmark to determine inpatient status.[53] The court held that the policy is a "substantive legal standard" because it affected a hospital's right to payment.[54] Relying on the D.C. Circuit's interpretation, the court reasoned that "if a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a 'substantive legal standard,'" and "if a policy does not affect the authority of CMS, but simply provides instructions for enforcement, it is more likely not to be characterized as a 'substantive legal standard.'"[55]

The Central District of California also agreed with the D.C. Circuit's dictionary approach.[56] The court in *Agendia, Inc. v. Azar* held that the LCD is a "substantive legal standard" that warrants the § 1395hh(a)(2) notice-and-

46. *Id.* The DC Circuit also decided in *Clarian Health West, LLC v. Hargan* that the new guidance concerning when to apply an old reimbursement formula did not alter a substantive legal standard because it simply changed the procedures for processing that reimbursement. 878 F.3d 346, 354-56 (D.C. Cir. 2017). Only these two cases in the DC Circuit implicate the Medicare Act's notice-and-comment requirement before the Supreme Court decided *Allina Health Servs.*

47. 391 F. Supp. 3d 53 (D.D.C. 2019).

48. *Id.* 58–60.

49. *Id.* at 69.

50. Select Specialty Hosp.-Denver, Inc. v. Azar, No. CV 10-1356, 2019 WL 5697076, at *3 (D.D.C. Nov. 4, 2019).

51. 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019).

52. *Id.* at 933.

53. *Id.*

54. *Id.* at 935.

55. *Id.* at 934–35.

56. Allina Health Servs. v. Price (Allina I), 863 F.3d 937, 943 (D.C. Cir. 2017).

comment process.[57] Although the case at issue later overruled the decision on the same ground, the court's reasoning is worth mentioning.[58] The court concluded that the LCD established a "substantive legal standard," because it defined Agendia's right to payment throughout the administrative process.[59]

The District of Connecticut confronted § 1395hh(a)(2) in *Yale New Haven Hospital v. Azar*.[60] The case involved HHS's policy concerning Disproportionate Share Hospital (DSH) payments to merged hospitals.[61] The DSH adjustment provides additional Medicare reimbursement to hospitals that treat a disproportionately large number of low-income patients.[62] Although the court did not express an opinion on the interpretation of the term "substantive legal standard," the court considered it "undisputed" that the policy was a "substantive legal standard" because it governs the payment for services.[63]

In summary, because the D.C. Circuit offered one interpretation of "substantive legal standard" in *Allina I,* and the Supreme Court in *Allina II* neither endorsed nor rejected the D.C. Circuit's interpretation of § 1395hh(a)(2), other courts can either choose to adopt the D.C. Circuit's interpretation or "accept the invitation to innovate."[64] However, lower courts are more likely to adopt D.C. Circuit's dictionary approach when deciding on § 1395hh(a)(2).[65]

C. Mechanisms to promote consistency in Medicare claims adjudications

The significance of the Medicare program is undisputed. Medicare spends approximately $700 billion annually to provide health care for over sixty million aged or disabled Americans, nearly one-fifth of the Nation's population.[66] Even seemingly modest modifications to the program can affect millions of lives.[67] Therefore, consistency in adjudication is vital.

57. 420 F. Supp. 3d 985, 997 (C.D. Cal. 2019) *overruled by* Agendia, Inc. v. Becerra, 4 F.4th 896, 897 (9th Cir. 2021).

58. Agendia, Inc. v. Becerra, 4 F.4th 896, 897 (9th Cir. 2021).

59. *See Agendia*, 420 F. Supp. 3d 985 at 997 (finding the standard substantive during the entire administrative process because it is binding on the private contractors and is entitled to substantial deference in the administrative process).

60. 457 F. Supp. 3d 93, 108 n.10 (D. Conn. 2020).

61. *Id.* at 96.

62. *Id.*

63. *Id.* at 108 n. 10.

64. Armstrong, *supra* note 35, at 2190.

65. In a plain meaning approach to statutory interpretation, dictionaries are good sources of common understanding of words. *Looking It Up: Dictionaries and Statutory Interpretation*, 107 HARV. L. REV. 1437, 1442 (1994).

66. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1808 (2019).

67. *Id.*

1. Medicare administrative contractors (MACs)

Under the Medicare Prescription Drug Improvement, and Modernization Act (MMA) of 2003, MACs are hired to reduce administrative burdens and modernize the claims and appeals processing system.[68] A MAC is a private entity that processes claims in a geographic jurisdiction assigned by HHS.[69] MACs perform a variety of activities including processing Medicare claims, handling provider reimbursement services, reviewing medical records for selected claims, and establishing LCDs.[70]

A four-step appeals process helps to promote consistency in medical claim adjudication.[71] First, if a provider disagrees with the initial determination of a MAC, the provider may seek a redetermination by the MAC that denied the claim.[72] Second, the provider may seek a review by a different contractor, known as a qualified independent contractor (QIC).[73] Third, the provider may request a hearing before an Administrative Law Judge (ALJ).[74] Finally, if the ALJ rejects the claim, the provider may seek review by the Medicare Appeals Council.[75] Final decisions by the Medicare Appeals Council may be appealed to federal court if the amount in controversy requirements are met.[76]

2. The "reasonable and necessary" standard

Through Medicare, HHS reimburses medical providers for the cost of items and services that are "reasonable and necessary for the diagnosis or treatment of

68. Baum, J.. B., *How Do Medicare Contractors Help with Appeals?* EHEALTH MEDICARE, https://www.ehealthmedicare.com/blog/medicare-tips/how-do-medicare-contractors-help-with-appeals/ (July 7, 2021).

69. *What's a MAC*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC (last updated Jan. 26, 2023).

70. *Id.* There are 12 Medicare Part A and B MACs that assist with original Medicare claims, four of which also process home health and hospice claims. There are also four durable medical equipment (DME) MACs. Lisa Eramo, *Medicare Administrative Contractors (MAC),* HELPADVISOR (Sept. 10, 2021), https://www.helpadvisor.com/medicare/medicare-administrative-contractor-mac.

71. 42 C.F.R. § 405.904 (2022).

72. *See id.* 42 C.F.R. § 405.904(a)(2).

73. *Id.* The reconsideration at the second stage is an independent review of the administrative record by a QIC. U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/ReconsiderationbyaQualifiedIndependentContractor (last visited Jan. 23, 2023).

74. 42 C.F.R. § 405.904(b) (2022).

75. *See id.* § 405.904(a).

76. U.S. DEP'T OF HEALTH & HUM. SERVS. *Appeals to the Medicare Appeals Council (Council),* https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-council/index.html (last reviewed Oct. 30, 2017).

illness or injury or to improve the functioning of a malformed body member."[77] The CMS and its contractors determine whether items and services are "reasonable and necessary" either through a case-by-case review of the clinical appropriateness of claims, or through local and national coverage policies.[78] In January 2021, CMS published a final rule to define the reasonable and necessary standard.[79] Under the current framework, an item or service is reasonable and necessary if it is (1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients. [80]

3. National coverage determination (NCD)

An NCD is a nationwide determination of whether Medicare will pay for an item or service.[81] NCDs are made through an evidence-based process.[82] The development of an NCD generally begins with CMS reviewing the scientific literature to evaluate an issue, which may lead to CMS commissioning an assessment by an external contractor and referring the issue to the Medicare Evidence Development and Coverage Advisory Committee.[83] The NCD has a stringent notice-and-comment process, required by the Medicare Act, which provides opportunities for public participation.[84] Specifically, the Secretary of HHS must publish a draft version of the NCD online and allow a thirty day public comment period.[85] Once an NCD is finalized and published, its coverage guidelines are binding nationwide.[86] In the absence of an NCD, an item or service may still be covered at the discretion of the Medicare contractors based on a LCD.[87]

77. 42 U.S.C. § 1395y(a)(1)(A).

78. Elizabeth Halpern et al., *CMS Finalizes "Reasonable and Necessary" Definition, Expedited Breakthrough Device Coverage Process,* HOGAN LOVELLS (Jan. 18, 2021),

https://www.jdsupra.com/legalnews/cms-finalizes-reasonable-and-necessary-7634854/.

79. 42 C.F.R. § 405.201.

80. *Id.* The final rule further clarified when an item or service would be "appropriate for Medicare patients" under element (3).

81. 42 C.F.R. § 405.1060(a)(1) (2022).

82. *Medicare Coverage Determination Process*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Coverage/DeterminationProcess (last updated Mar. 3, 2022).

83. *Analysis of National & Local Coverage Determinations,* RHEUMATOLOGIST (Apr. 15, 2020), https://www.the-rheumatologist.org/article/analysis-of-national-local-coverage-determinations/.

84. 42 U.S.C. § 1395y(I)(3).

85. *Id*.

86. 42 C.F.R. § 405.1060(a)(4) (2022); *see also Medicare Coverage Determination Process,* U.S. CTRS. FOR MEDICARE & MEDICAID SERVICES [CMS] (Mar. 3, 2022), https://www.cms.gov/Medicare/Coverage/DeterminationProcess#:~:text=In%20the%20absence%20of%20a,local%20coverage%20determination%20(LCD).

87. *Medicare National Coverage Determinations,* KAISER PERMANENTE (Jan. 3, 2023), https://healthy.kaiserpermanente.org/washington/support/medicare-health-plans-2023.

4. Local coverage determination (LCD)

MACs may develop LCDs in the absence of an NCD or as a supplement to an NCD, so long as the LCD does not conflict with an NCD.[88] LCDs play a critical role in the Medicare program because the vast majority of Medicare coverage decisions are made through LCDs.[89] For example, a one-week study found that LCDs defined coverage for fifty-nine percent of the 75,000 unique procedure codes billed to Medicare Part B.[90] According to the CMS Medicare Coverage Database, there are 349 NCDs and 1,103 LCDs.[91] LCDs can exist where there is no related NCD.[92] For example, there are 49 LCDs but no NCD policy for the molecular pathology test.[93] The data suggests LCDs supplement NCD coverage, potentially offering more options for patients during diagnosis and treatment.[94]

LCDs were originally created to allow MACs to adopt local medical practice standards.[95] However, as evidence-based medicine evolves, LCDs are now focused on consistency in coverage rather than variation. But there is still incredible variation across the states, depending on the MAC responsible and the geographic boundaries.[96] A 2020 study found that significant inconsistencies in

88. Rafael Díaz Treviño, An Analysis of the Differences between National and Local Coverage Determinations of Medical Procedures in the U.S. (Sept. 2010) (Master's Thesis, Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology) (On File with the Massachusetts Institute of Technology Libraries).

89. U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., OEI-01-11-00500, LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE (2014) [hereinafter DHHS].

90. *Id.*

91. *National Coverage NCD Report Results*, U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS. [CMS], https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title (last visited April. 18, 2023); *Final LCDs Alphabetical Report Results*, U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS. [CMS], https://www.cms.gov/medicare-coverage-database/reports/local-coverage-final-lcds-alphabetical-report.aspx?lcdStatus=all (last visited April. 18, 2023).

92. *Medicare Center Database,* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS. [CMS], https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=molecular%20pathology&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,F,P&contractOption=all&sortBy=relevance (search in search bar "molecular pathology") (last visited Feb. 18, 2023).

93. *Id.*

94. TREVINO, *supra* note 88, at 7.

95. *Id.* at 40 (interviewing a Contractor Medical Director who was responsible for making the final LCD policy).

96. David C. Chan & Maria Polyakova, *The Impact of Local Coverage Determinations on Costs and Patient Outcomes,* NAT'L BUREAU ECONOMIC RSCH. (2020), https://www.nber.org/programs-projects/projects-and-centers/center-aging-and-health-research/6910-impact-local-coverage-determinations-costs-and-patient-outcomes?page=1&perPage=50.

LCDs arise when a MAC's geographic jurisdiction changes over time, when MACs have different coverage, and when MACs have different denial rates.[97]

An LCD determination, as required by the statute, is based on medical necessity at the time of service.[98] Although LCDs only bind the issuing MAC, the Qualified Independent Contractor, an Administrative Law Judge, and the Council at the higher levels all "owe substantial deference" to the relevant LCDs.[99]

LCDs were traditionally established through internal policies, not promulgated by regulation, subjecting them to less scrutiny.[100] HHS issued a Program Integrity Manual (PIM), which is a compilation of guidelines to instruct the MACs on how to conduct a medical review of Medicare claims submitted by providers and suppliers for payment.[101] According to the PIM, the establishment of a new LCD requires justification by peer-reviewed evidence that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service.[102] For example, after Agendia's MammaPrint's clinical significance was published in 2016,[103] the MAC for Florida, Puerto Rico, and the Virgin Islands region revised the LCD to include the testing assay for use in the management of breast cancer treatment.[104]

A series of government actions added procedural requirements to LCDs, with the goal of increasing transparency.[105] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) imposed a new

97. *Id.*

98. 42 U.S.C. § 1395y(a)(1)(A).

99. 42 C.F.R. §§ 405.968(b)(2)-(3), 405.1062(a)-(b) (2022).

100. Agendia, Inc. v. Azar, 420 F. Supp. 3d 985, 989 (C.D. Cal. 2019).

101. Erringer v. Thompson, 371 F.3d 625, 628 (9th Cir. 2004).

102. *Local Coverage Determinations,* U.S. CTRS. FOR MEDICARE & MEDICAID SERVICES (Feb. 14, 2019), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10901.pdf.

103. Fatima Cardoso et al., *70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer,* 375 NEW ENG. J. MED. 717, 717 (2016); Laurence Slembrouck et al., *Decentralization of Next-Generation RNA Sequencing-Based MammaPrint®, and BluePrint® Kit at University Hospitals Leuven and Curie Institute Paris,* 12 TRANSLATIONAL ONCOLOGY, 1557, 1558 (2019).

104. *Agendia's MammaPrint Now Included in First Coast Coverage for Medicare Breast Cancer Patients in Florida, Puerto Rico and the Virgin Islands,* AGENDIA (May 2, 2017), https://agendia.com/agendias-mammaprint-now-included-in-first-coast-coverage/. However, CMS later retired that LCD and Agendia's MammaPrint is not in the current Medicare Coverage Database. *Medicare Coverage Database,* U.S. CTRS. FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/medicare-coverage-database (searched in search bar "mammaprint") (last visited Feb. 27, 2023). The BluePrint test is still considered a statutorily excluded test. *Billing and Coding: MoIDX: BluePrint® Test*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/medicare-coverage database/view/article.aspx?articleId=55146 (last visited Feb. 27, 2023).

105. H.R. REP. NO. 114-190, at 127 (2015).

consultation requirement for the development of LCDs.[106] Section 731 of the MMA called for a plan to evaluate new LCDs, determine which LCDs should be adopted nationally, and establish greater consistency among LCDs.[107] In 2016, Congress amended the Medicare Act by adding a separate, public notice requirement specifically for LCDs.[108] For each LCD developed, the new mandate requires the MACs to publish: (1) the determination, (2) where and when it was first made public, (3) links to the proposed LCD and responses to public comments, (4) a summary of the evidence and a list of sources, and (5) an explanation of the MAC's reasoning.[109] This information is published at least forty-five days before the effective date on both the MAC's website and on the CMS website.[110]

In 2018, the House Ways and Means Health Subcommittee introduced the Local Coverage Determination Clarification Act.[111] The bill reflected congressional concern about the lack of transparency, certainty, and consistency of LCDs.[112] To ensure a thorough evidentiary review of LCDs, the bill requires MACs to establish an open process for developing LCDs, including instituting a notice-and-comment process.[113] The Senate read the bill twice and referred it to the Committee on Finance.[114]

It is unclear whether an LCD that is established before the 2016 Amendment needs to go through § 1395hh notice-and-comment process.[115] Although a 1986 congressional report suggested that § 1395hh would not apply

106. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731, 117 Stat. 2066.

107. DHHS*, supra* note 89. In 2014, the HHS's Office of Inspector General published a report revealing that LCDs create inconsistency in Medicare Coverage. The report calls for a need to increase consistency among existing LCDs and a plan to evaluate new LCD topics for national coverage. *Id.*

108. 42 U.S.C. § 1395y(l)(5); 21st Century Cures Act, Pub. L. No. 114-255, § 4009, 130 Stat. 1185 (2016).

109. 42 U.S.C. § 1395y(l)(5)(D).

110. *Id.* Because the amendment does not have retroactive effect, it does not govern the LCDs challenged by Agendia in the case at issue.

111. H.R. REP. NO. 115-933, pt. 1, at 1 (2018).

112. H.R. REP. NO. 115-933, pt. 1, at 6 (2018).

113. *Id.* at 6. The requirement includes publicly posting online proposed LCDs and the rationale and evidence relied on for making such determinations; convene open public meetings; solicit input from the public; and establish a public comment period for development draft policies and posting responses to comment received. *Id.*

114. *H.R. 3645 - Local Coverage Determination Clarification Act of 2018*, U.S. CONGRESS (Sept. 17, 2018), https://www.congress.gov/bill/115th-congress/house-bill/3635/all-actions?q=%7B%22search%22%3A%5B%22%5C%22LOCAL+COVERAGE+DETERMINATION+CLARIFICATION+ACT+OF+2018%5C%22%22%5D%7D&s=5&r=1.

115. Azar v. Allina Health Servs.*,* 139 S. Ct. 1804, 1814 (2019) (noting that the legislative history of § 1395hh is "ambiguous at best.").

to LCDs,[116] Congress amended the statute and issued another congressional report in 1987 suggesting that LCDs fall under the scope of § 1395hh.[117] Because LCDs have never gone through the § 1395hh notice-and-comment process, the Ninth Circuit, in the present case, is the first court of appeals to weigh in on whether § 1395hh notice-and-comment is required for LCDs established before the 2016 Amendment.[118]

III. THE COURT'S REASONING

In *Agendia, Inc. v. Becerra,* the crux of the issue before the court was whether LCDs require the § 1395hh notice-and-comment process.[119] The court provided both definitional reasoning and structural reasoning for whether an LCD establishes or changes a substantive legal standard. The majority ruled in favor of the Secretary, holding that LCDs do not require notice-and-comment under 42 U.S.C. § 1395hh because such determinations do not establish or change a substantive legal standard.[120]

The court refused to define the outer boundaries of what constitutes a substantive legal standard. Rather, the court determined that the only substantive legal standard involved in this case was the "reasonable and necessary" standard under § 1395y(a)(1)(A).[121] The court looked at the dictionary meaning of the key statutory terms "establish" and "change."[122] According to these definitions, an LCD does not "make or form," or "replace or substitute" the legal standard.[123] The court found further support from its holding in *Erringer v. Thompson*, which concluded that the reasonable and necessary standard would remain unaltered if LCDs ceased to exist.[124] Therefore, the court found the LCDs to be a simple application of the "reasonable and necessary" standard to a particular claim.[125]

116. H.R. REP. NO. 99-1012, pt.1, at 311 (1986) (Conf. Rep.).

117. H.R. REP. NO. 100-391, pt.1, at 429–30 (1987).

118. Agendia, Inc. v. Becerra, 4 F.4th 896, 900 (9th Cir. 2021).

119. Because denial of Agendia's claims for reimbursement is based on MAC's LCD that did not undergo "the § 1395hh notice-and-comment process[,]" Agendia maintained that the denial was improper. *Agendia,* F.4th at 899-900.

120. *Id.*

121. *Id*. at 900.

122. *Id*.

123. *Id.*

124. Although finding support in *Erringer*, the court acknowledged the distinction between it and the present case. *Id.* In *Erringer*, the issue was whether the HHS's manual providing criteria to MACs for denial of payment based on LCDs requires notice-and-comment under the APA, and the court did not interpret § 1395hh under the Medicare Act. Erringer v. Thompson, 371 F.3d 625, 627, 633 (9th Cir. 2004).

125. *Agendia*, 4 F.4th at 900. Specifically, the local determination reflects a MAC's view of what qualifies as reasonable and necessary. *Id.*

The court also compared the statutory structure of § 1395hh to the notice-and-comment process for NCDs.[126] First, unlike its national counterpart, an LCD is not binding at the higher levels of administrative review,[127] thus, the court rejected Agendia's argument that the LCDs must undergo a more "arduous" notice-and-comment process under § 1395hh.[128] Second, the court reasoned that the explicit exemption in § 1395hh for the NCDs implies the congressional intent that LCDs do not establish or change a substantive legal standard. Therefore, the statutory language does not warrant an express exemption for LCDs.[129] Third, the court rejected Agendia's argument that the Supreme Court's holding in *Azar v. Allina Health Services* applies to the present case.[130] From *Allina*'s holding, an interpretative rule, which is exempt from the APA notice-and-comment requirement, may still be subject to § 1395hh notice-and-comment process.[131] Because the Court in *Allina* did not expressly explain whether the policy at issue established or changed "a substantive legal standard," Agendia's reliance on *Allina* is considered "misplaced."[132]

In the dissent, Judge Block argued that the LCDs should be subject to § 1395hh notice-and-comment process, because they "establish" a standard at the initial stage of review and "change" the standards applied on appellate review.[133] Judge Block disagreed with the majority's selective dictionary readings and abstract statutory analysis.[134] Instead, he offered broad and flexible dictionary definitions.[135] Based on alternative meanings of "change," a standard can "'change' even if it is not replaced root and branch."[136] Because the majority did

126. *Id.*

127. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. §§ 405.968(b)(2)-(3), 405.1062(a)-(b).

128. *Id.* NCD is exempt from 13955hh but not from 1395y. 1395hh process consists of notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment, while 1395y process requires a draft be posted online with thirty days for public comment. NCD is exempt from 13955hh but not from 1395y. Therefore, the court held that it would make little sense to subject non-binding LCDs to a formal rule-making process but not their national, binding counterparts. The notice-and-comment requirement of 1395hh is more stringent than the requirement of 1395y. *Id.*

129. *Id.* at 902.

130. *Id.* at 901–02. The issue in *Azar v. Allina Health Services* is whether a Medicare reimbursement policy adopted by HHS was exempt from the § 1395hh notice-and-comment process. Allina Health Servs., 139 S. Ct. at 1809.

131. *Allina,* 139 S. Ct. at 1817.

132. *Agendia*, 4 F.4th at 902.

133. *Id.* at 904 (Block, J., dissenting).

134. *Id.*

135. *Id.* at 905–06. In addition to the single dictionary source used by the majority, the dissenting opinion looked at alternative definitions from at least four additional sources.

136. *Id.* at 906.

not offer a compelling reason to favor its selective interpretations, the dissent found the majority's definitional analysis deficient.[137]

Because the phrase "substantive legal standard" appears nowhere else in the U.S. Code,[138] the dissent looked at the legislative history and the structure of the statute. First, the dissent relied on the absence of the phrase "and LCDs" in the § 1395hh notice-and-comment exemption.[139] Second, the dissent found the legislative history of § 1395hh(a)(2) ambiguous.[140] Acknowledging that some portions of the congressional record favor the majority's decision, the dissent nevertheless reasoned that Congress intended to give § 1395hh's rulemaking provisions the broadest possible scope.[141] Third, the dissent examined the recent changes to the Medicare statute.[142] The 2016 amendment did not add notice-and-comment requirements for LCDs, but rather loosened the existing rules. This reflects the congressional intent to subject LCDs to § 1395hh(a)(2) notice-and-comment provisions.[143]

IV. ANALYSIS

In *Agendia, Inc. v. Becerra,* the court ruled in favor of the Secretary, holding that § 1395hh's notice-and-comment requirement does not apply to LCDs because such determinations do not establish or change a substantive legal standard.[144] The court's flawed reasoning ignores the fact that the standard prescribed in an enabling statute does not preclude administrative agencies from establishing additional requirements in furtherance of that statute.[145] The court's erroneous holding imposed a dangerous assumption that LCDs are not a substantial part of Medicare and deprived the public a transparent and competent process to establish LCDs.[146] The court should have instead followed Supreme Court jurisprudence and distinguished the phrase "substantive legal standard" in § 1395hh from other statutes, including the APA.[147] The court should have affirmed the district court's decision using proper statutory interpretation

137. *Id.*

138. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1814 (2019).

139. *Agendia*, 4 F.4th at 906 (Block, J., dissenting).

140. *Id.* at 907 (Block, J. dissenting).

141. *Id.* at 907–08 (Block, J., dissenting).

142. *Id.*

143. *Id.* at 908–9 (Block, J., dissenting).

144. *See id.* at 900, 903 (finding that Agendia's alternative theory that contractor's ability to issue LCDs reflects an unconstitutional delegation of regulatory power to private entities, holding that the Constitution permits contractors to issue such determinations).

145. *See infra* Section IV.A.

146. *See infra* Section IV.B.

147. *See infra* Section IV.C.

principles and opened the door for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment process.[148]

A. The court's flawed reasoning ignored the fact that the standard prescribed in an enabling statute does not preclude administrative agencies from establishing additional requirements in furtherance of that statute.

The court held that an LCD itself is not a "substantive legal standard" because the legal standard at issue is "reasonable and necessary".[149] Indeed, the "reasonable and necessary" standard is necessary in the statute as "an intelligible principle" under the delegation doctrine.[150] However, the court failed to recognize that the application of a statutory standard can still establish a legal standard in furtherance of that statute.

An example of this is found in the Food and Drug Administration's (FDA) application of the Federal Food, Drug, and Cosmetic Act (FFDCA) provisions authorizing the Agency to regulate pre-market approval of new drugs under the statutory standard of safety and efficacy.[151] FDA promulgates regulations to determine the kind and quantity of data in a submission package for a specific new drug to meet the statutory standards.[152] The FFDCA also authorizes FDA to regulate certain nonprescription drugs under the legal standard of "generally recognized as safe and effective," or GRASE.[153] Accordingly, the FDA, through a notice-and-comment process in 1972, established the over-the-counter (OTC) drug monograph.[154] To meet the statutory standard of GRASE, the nonprescription drugs must meet the requirements outlined in the OTC drug monograph for each therapeutic category.[155] In both examples, the FDA established additional rules and requirements in furtherance of the statutory standards.[156]

148. *See infra* Section IV.D.

149. *Agendia*, 4 F.4th at 900.

150. J.W. Hampton, Jr. & Co. v. U.S., 276 U.S. 394, 409 (1928).

151. 21 U.S.C. § 355(a)-(b).

152. 21 C.F.R. § 314.105 (2022).

153. 21 U.S.C. § 355h.

154. *Over-the-Counter (OTC) Drug Monograph Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process (May 29, 2020); *see also Monograph Reform is Here!*, U.S. FOOD & DRUG ADMIN., at 7, https://www.fda.gov/media/139503/download (last visited March 10, 2023) (discussing how the over-the-counter drug review process began in 1972 to evaluate the drugs' safety and effectiveness).

155. 21 C.F.R. § 330.1 (2016) (providing GRASE *requirement*).

156. 21 U.S.C. § 355h (2020); *see also* 21 C.F.R. § 330.1 (2016) (providing GRASE *requirement*).

The requirements the FDA established in furtherance of FFDCA standards have the force of law and can be contested in courts.[157] For example, the Medical Device Amendments of 1976 authorized the FDA to establish various levels of oversight for medical devices.[158] Specifically, for a new device to be exempt from the premarket approval process, it must meet the statutory standard of being "substantially equivalent," to another device already on the market.[159] The FDA establishes device review process to determine the substantial equivalence, known as the § 510(k) process.[160] Courts have held that the § 510(k) process establishes federal requirements and has force of law.[161]

The determination of LCDs by MACs has similar social and economic impacts as the FDA's premarket review process.[162] Both processes affect the availability of medical treatments or services to certain patients.[163] While only new drugs that receive FDA approval can be marketed to reach patients, only treatments and services that are covered by LCDs can be reimbursed and offered to patients. Additionally, both processes affect how manufacturers or providers make their products or services for patients. While FDA's drug review process determines what evaluation studies a drug company needs to conduct before reaching the patient, LCDs impact whether providers can seek reimbursement after reaching patients. The economic impact to the providers and the unmet medical needs of the patients indicate that the notice-and-comment of LCDs cannot be "short-circuited".[164]

The determination of LCDs by MACs is also procedurally similar to the FDA's premarket review process. Both processes require the assessment of scientific data based on medical evidence, meriting deference from reviewing courts. While the FDA's scientific judgment receives deference from the

157. *See infra* note 149 and accompanying text.

158. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

159. 21 U.S.C. § 360c.

160. *Premarket Notification 510(k),* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#se (last updated Oct. 3, 2022).

161. *See, e.g.*, Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996) (discussing how § 510(k) requires a "premarket notification" process); Cytori Therapeutics, Inc. v. Food & Drug Admin., 715 F.3d 922, 927 (D.C. Cir. 2013) (describing when the FDA concluded a product did not meet § 510(k)'s substantial evidence criteria).

162. *See supra* note *165.*

163. *See Premarket Notification 510(k),* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#se (describing when a 510(k) is an is not required for distributing a medical device) (last visited March 16, 2022).

164. Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 87 (D.C. Cir. 2014) (reclassifying device requires FDA to undergo notice-and-comment process).

court,[165] LCDs merit substantial deference from higher levels in the appeal process.[166] Additionally, both processes require local offices across the country to apply uniform standards. While the FDA pre-approval inspections are often conducted by local staff across the county under the same good manufacturing practices standards,[167] the LCDs are determined by MACs in each jurisdiction under the same "reasonable and necessary" standards.[168]

The fact that a legal standard is defined in the statute does not mean that it is the only standard an agency can apply. Instead, the statuary standard should be considered an overarching standard, one that harbors sub-standards relevant to more specific categories. Specifically for LCDs, the statutory standard of "reasonable and necessary," does not preclude the development of additional standards for a specific coverage category. Therefore, the court's holding that the case only concerns one "reasonable and necessary" standard lacked justification because it ignored the fact that the standard prescribed in an enabling statute does not preclude administrative agencies from establishing additional requirements in furtherance of that statute.

B. The court's erroneous holding imposed a dangerous assumption that LCDs are not substantial in the Medicare Program and deprived and public of a transparent and competent process to establish LCDs.

By erroneously holding that LCDs should not be subject to a more demanding procedure, the court imposed a dangerous assumption that LCDs are not as salient as their national counterparts.[169] LCDs are binding at the MAC level and owed "substantial deference" during the administrative appeal process.[170] Therefore, LCDs are equally impactful as NCDs to affect providers' right to reimbursement and Medicare beneficiaries' right to access treatment. The court failed to acknowledge the key distinction between LCDs and NCDs.[171] Unlike NCDs, LCDs are intrinsically inconsistent because LCDs limit coverage

165. ViroPharma, Inc. v. Hamburg, 898 F. Supp. 2d 1, 23 (D.D.C. 2012) (deferring to FDA's decision regarding bioequivalence determination).

166. *See supra* note 99 and accompanying text.

167. *Text Description: Map Showing FDA Offices across the Country,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/jobs-and-training-fda/text-description-map-showing-fda-offices-across-country (last visited March 17, 2022).

168. 42 U.S.C. § 1395y(a)(1)(A).

169. Agendia, Inc. v. Becerra, 4 F.4th 896, 900 (9th Cir. 2021) ("[S]ubjecting local coverage determination, which are not binding, to a more demanding procedure than their national, binding counterparts would make little sense.").

170. *Id.* at 898.

171. *See supra* Section II.C.a.

for certain medical procedures differently across states.[172] Additionally, LCDs from different MACs define similar clinical topics.[173] Therefore, because the LCDs can create undesired inconsistency, it makes *more* sense to subject LCDs to a more stringent § 1395hh notice-and-comment process.[174]

The court's assumption of insubstantiality also undermines the integrity of LCDs. The notice-and-comment process acts as a safeguard to ensure that LCDs are reviewed by MACs using a risk- and science-based approach.[175] In the current era of real-world evidence, where benefits or risks of a drug are derived from sources other than traditional clinical trials,[176] the health care community is using more complex and dynamic data to support coverage decisions.[177] In the absence of a public comment process the public does not have an opportunity to be heard before changes are made, and it is unclear whether the evidentiary review conducted by MACs is comprehensive and up to date. Therefore, subjecting the LCDs to the notice-and-comment requirement is essential to establish transparency and confidence throughout the process.[178] By erroneously holding that LCDs should not be subject to a more demanding procedure, the court not only imposed a dangerous assumption that LCDs are not substantial in Medicare, but also ignored the intrinsic inconsistency among the LCDs. As a result, the court's holding deprived the public of a transparent and competent process to establish LCDs.

Finally, the court could have avoided leaving LCDs in an awkward and neglected position by considering the practical consequences of its interpretation. The Court usually does not consider practical consequences or policy implications of interpretation when the statutory language "speaks for itself."[179] However, when the text is unclear, information leaned from considering practical consequences is relevant and important.[180] Particularly, considering negative practical consequences can reveal that a particular interpretation is

172. *Id.*

173. *Id.*

174. *See supra* notes 174–76 and accompanying text (discussing inconsistency of LCD coverage).

175. Abbe R. Gluck & Anne Joseph O'Connell, *Argument Preview: Requiring Notice and Comment under the Medicare Statute*, SCOTUSBLOG.COM, https://www.scotusblog.com/2019/01/argument-preview-requiring-notice-and-comment-under-the-medicare-statute/ (Jan. 8, 2019).

176. 21 U.S.C. § 355g(b).

177. *Real-World Evidence*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence (last visited Mar. 18, 2022).

178. H.R. REP. No. 115-933, at 5 (2018).

179. Carcieri v. Salazar*,* 555 U.S. 379, 392 (2009).

180. William Baude & Ryan D. Doerfler, *The (Not So) Plain Meaning Rule*, 84 U. CHI. L. REV. 539, 553 (2017).

implausible.[181] Here, because the statutory text's "substantive legal standard" is unclear,[182] the court could have avoided its flawed reasoning by considering the practical consequences of neglecting LCDs. Instead, the court ignored the practical consequences, imposed a dangerous assumption that LCDs are not substantial in Medicare, and deprived the public of a transparent and competent process to establish LCDs.

C. The court should have followed Supreme Court jurisprudence and distinguished the phrase "substantive legal standard" in § 1395hh from other statutes including the APA.

The court should have followed recent Supreme Court jurisprudence and distinguished the §1395hh notice-and-comment from that under the APA. Congress expressly borrowed APA's good cause exemption by cross-referencing it in the Medicare Act.[183] However, Congress did not cross-reference APA's exemption for interpretative rules and policy statements.[184] As the majority in *Allina II* pointed out, Congress cross-referenced both APA exceptions in the Clean Air Act, but not in the Medicare Act.[185] As Justice Sotomayor emphasized in the oral argument for *Allina II*, Congress's express choice to use a different articulation of the standard suggests different meanings.[186] The meaningful variation rule also suggests that Congress intended to give the phrase "substantive legal standard" a different scope as compared to the term "substantive rule" under the APA.[187] In addition, the court should not confuse the LCDs with the interpretative rules under the APA because the phrase "interpretative rules" is used almost exclusively in the context of APA.[188] Although the majority did not expressly state that LCDs are interpretative rules, it considered LCDs as guidance for the application of the legal standard.[189] The court should not confuse LCDs with any guidance documents that are interpretative rules exempted from APA's notice-and-comment requirement.

181. *Id.*; U.S. v X-Citement Video, Inc., 513 U.S. 64, 69-70 (1994) (rejecting one interpretation to avoid absurd results).

182. *See infra* Section IV.D.

183. 42 U.S.C. § 1395hh(b)(2)(C).

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

185. *Id.*

186. Transcript of Oral Argument at 6-7, Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019) (No. 17-1484), https://www.supremecourt.gov/oral_arguments/argument_transcripts/2018/17-1484_8o6a.pdf.

187. WILLIAM N. ESKRIDGE JR. ET AL., CASES AND MATERIALS ON LEGISLATION AND REGULATION: STATUTES AND THE CREATION OF PUBLIC POLICY 623 (6th ed. 2019).

188. A search of the U.S. Code found that, among 65 hits of phrase "interpretative rules", 59 are in the context of APA.

189. Agendia, Inc. v. Becerra, 4 F.4th 896, 900 (9th Cir. 2021).

Even if LCDs were interpretative rules under APA, the court should have followed the recent Supreme Court jurisprudence and held that LCDs require notice-and-comment under the Medicare Act, just like the policy statement in *Allina II*.[190] Therefore, the court should have held that LCDs are subject to the §1395hh notice-and-comment requirement, regardless of whether they are interpretative rules exempted from APA's notice-and-comment requirement.

The court should have given the phrase "substantive legal standard" a unique scope under the Medicare Act because the phrase "substantive legal standard" appears nowhere else in the U.S. Code other than in § 1395hh(a)(2).[191] The meaning of a phrase used by Congress may be determined by looking to other statutes under the whole code rule.[192] Justices in the modern Supreme Court regularly compare or analogize statues that contain similar words or phrases.[193] Among the 532 majority/plurality opinions between 2005 and 2017, 144 (27.1%) opinions used the whole code rule for interpretation.[194] Relatedly, when Congress uses a unique phrase in a statute that appears nowhere else in the entire U.S. Code, the rule of meaningful variation suggests that "a change of wording denotes a change in meaning."[195] Here, a search of the U.S. Code for several terms in which the word "substantive" appears reveals the following:

"substantive law": 417 hits

"substantive rule": 138 hits

"substantive legal standard": 7 hits (all in Medicare context)

It is apparent from the search results that Congress intentionally and purposely used "substantive legal standard" in the Medicare context to give the phrase a different scope from any other statutes. Therefore, the court should have distinguished § 1395hh's notice-and-comment from the APA's notice-and-comment requirement. In addition, the court should have considered the whole code rule and given the phrase "substantive legal standard" a unique scope in the Medicare context.

190. *See supra* Section II.A. Among the 532 majority/plurality opinions from the Supreme Court between 2005 and 2017, 367 (69%) opinions used Supreme Court precedent for statutory interpretation. Anita S. Krishnakumar, *Cracking the Whole Code Rule*, 96 N.Y.U. L. REV. 76, 97 (2021).

191. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1814 (2019).

192. W. Virginia Univ. Hosps., Inc. v. Casey, 499 U.S. 83, 89 (1991) (examining the U.S. Code and finding at least 34 statutes showing that expert witness fees are distinct expense from attorney's fees).

193. Krishnakumar, *supra* note 190 at 82-83.

194. *Id.* at 96.

195. Eskridge, *supra* note 194 at 623; *see* Epic Sys. Corp. v. Lewis, 138 S. Ct. 1612, 1625-26 (2018) (using a meaningful variation and whole code comparison for the enforceability of the Federal Arbitration Act).

D. The court should have affirmed the district court's decision using proper statutory interpretation principles and opened the door for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment process.

The court should have acknowledged that legislative history is not a plausible interpretative tool in this specific case because the legislative history of § 1395hh is ambiguous. Courts generally examine legislative documents because the formal history of a statute's evolution is relevant to its interpretation.[196] For example, in *Blanchard v. Bergeron*, the Supreme Court relied on congressional committee reports to determine the legislature's intent.[197] However, there are limitations to using committee reports because they can be "as ambiguous as the statute[,]…[and] may even be misleading".[198] Here, as pointed out in the dissent, some portions of the congressional records support the holding that the LCDs are exempt from notice-and-comment, but other portions suggested otherwise.[199] Because the legislative history of § 1395 is "ambiguous at best,"[200] the majority should not have cherry-picked portions to support its holding.[201] Instead, the court should have simply acknowledged that legislative history is not a helpful tool for interpretation in this case.

A plausible interpretation of the phrase "substantive legal standard" has two steps. The first step is to find the scope of "legal standard" in the Medicare context, and the second step is to identify the plain meaning of the word "substantive."[202] The first step is aligned with the Whole Act Rule, which assumes that the legislature drafted the statute as an internally consistent document.[203] Here, neighboring provisions of § 1395hh(a)(2) hint at the scope of legal standards in the Medicare context.[204] Specifically, the scope of a legal standard under the Act should include regulations, manual instructions, interpretative rules, statements of policy, or guidelines.[205] The second step of the proposed interpretation is to look at the plain meaning of the word "substantive,"

196. Eskridge, *supra* note 194 at 727.

197. 489 U.S. 87, 95 (1989).

198. Eskridge, *supra* note 194 at 750.

199. Agendia, Inc. v. Becerra, 4 F.4th 896, 907 (9th Cir. 2021) (Block, J., dissenting); Azar v. Allina Health Servs., 139 S. Ct. 1804, 1813–15 (2019).

200. *Azar,* 139 S. Ct. at 1814.

201. *Id.* at 1815.

202. *See infra* text accompanying notes 208–212.

203. *See supra* notes 190 and accompanying text.

204. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (providing insight into the Secretary's authority to carry out the Medicare programs).

205. 42 U.S.C § 1395hh(c)(1).

which is consistent with the modern Supreme Court's practice.[206] An ordinary meaning of the word "substantive" is anything that creates or changes "rights and duties."[207] This interpretation is consistent with the D.C. Circuit's dictionary approach that the word "substantive" relates to "rights, duties, and powers of parties."[208] Under this approach, any regulations, manual instructions, interpretative rules, statements of policy, or guidelines that create and define rights and duties should be subject to the § 1395hh notice-and-comment requirement.

The proposed interpretation follows the recent Supreme Court jurisprudence in *Azar* that the § 1395hh notice-and-comment should be broader than the APA's.[209] Because the policy in *Azar* is a statement that changes how hospitals receive payments, it is a "substantive legal standard." The proposed interpretation is also consistent with all prior district court cases where courts resolve issues on "substantive legal standard."[210] The change of procedure in *Select Specialty Hospital-Denver*, the time-based reimbursement policy in *Polansky*, and the adjustment policy in *Yale New Haven* are all "substantive legal standards" because they fall under the scope of legal standards, and they alter rights to receive reimbursement.

The proposed interpretation does not conflict with other interpretative approaches such as intent and purpose.[211] Although the legislative intent is difficult to infer based on ambiguous legislative history, Congress has the functional equivalent of intent by acting through its sequential procedures.[212] Under the theory of functional equivalent of intent, Congress, acting as a group, "plan[s] by using internal sequential procedures allowing them to project their collective actions forward in time."[213] Here, the series of sequential actions to add procedural requirements to LCDs' acts is functionally equivalent of intent, which is to increase transparency of LCDs.[214] Specifically, the public notice

206. The Court frequently used text/plaining meaning approach. Krishnakumar, *supra* note 197, at 97–98. Almost half (49.8%) of the majority/plurality opinions between 2005 and 2017 used the plain meaning approach. *Id.*

207. *Substantive,* MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/substantive (last visited Mar. 9, 2022)

208. Allina Health Servs. v. Price*,* 863 F.3d 937, 943 (D.C. Cir. 2017).

209. *See supra* note 36 and accompanying text.

210. *See supra* Section II.B.

211. Among the 532 majority/plurality opinions from the Supreme Court between 2005 and 2017, 152 (28.6%) opinions used purpose approach and 58 (10.9%) opinions used intent approach. Krishnakumar, s*upra* note 197, at 97–98.

212. Victoria F. Nourse, *Elementary Statutory Interpretation: Rethinking Legislative Intent and History, 55* BOS. COLL. L. REV., 1613, 1625 (2014).

213. *Id.* at 1613.

214. *See supra* Section II.C.d.

mandate amended in 2016 further confirmed Congress's intent to subject LCDs to notice-and-comment under the Medicare Act.[215]

Finally, the proposed interpretation does not conflict with the purpose of the Medicare Act. When the Medicare Act was enacted in 1965, the goal was to provide a hospital insurance program to increase benefits and improve certain existing programs.[216] Subsequent amendments to increase LCD transparency aligns with this goal because the public has an opportunity to comment on coverage and reimbursement before they happen.[217] Therefore, the proposed interpretation does not contradict with other interpretative approaches such as intent and purpose.

The Court of Appeals for the Ninth Circuit should have affirmed the district court's decision and opened the door for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment process. The Court in *Azar* refused to define a "substantive legal standard," but acknowledged the possibility of defining it in future cases.[218] Considering the significance of Medicare, it is imperative for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment requirement. Doing so will provide the administrators of Medicare with much-needed guidance as to which rules they must subject to notice-and-comment. Considering the significance of LCDs,[219] the case at issue is a great opportunity for the Supreme Court to clarify the "substantive legal standard." By ruling that LCDs should be subject to the notice-and-comment requirement, the case could have opened the door for the Supreme Court to address this long-awaited clarification.

V. CONCLUSION

In *Agendia, Inc. v. Becerra*, the court held that § 1395hh's notice-and-comment requirement does not apply to LCDs because such determinations do not establish or change a substantive legal standard.[220] The court's flawed reasoning ignored the fact that the standard prescribed in an enabling statute does not preclude administrative agencies from establishing additional requirements in furtherance of that statute.[221] The court's erroneous holding imposed a dangerous assumption that LCDs are not substantial in Medicare and deprived

215. 21st Century Cures Act, Pub. L. No. 114-255, § 4009, 130 Stat. 1185 (2016).

216. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286.

217. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1809 (2019).

218. *Id.* at 1814.

219. *See supra* Section II.C.d.

220. 4 F.4th 896, 900 (9th Cir. 2021).

221. *See supra* Section IV.A.

the public of a transparent and competent process to establish LCDs.[222] The court should have followed Supreme Court jurisprudence and distinguished the phrase "substantive legal standard" in §1395hh of the Medicare Act from other statutes including the APA.[223] The court should have affirmed the district court's decision using proper statutory interpretation principles and opened the door for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment process.[224] Considering the significance of Medicare, it is imperative for the Supreme Court to clarify the reach of the Medicare Act's notice-and-comment requirement, which will provide the administrators of the Medicare system with much-needed guidance as to which rules they must subject to notice-and-comment.

222. *See supra* Section IV.B

223. *See supra* Section IV.C

224. *See supra* Section IV.D

Table 1 Comparison of notice-and-comment requirements under the Administrative Procedural Act (APA) and the Medicare Act § 1395hh

	APA	Medicare
Coverage	Any rulemaking by a federal government agency.[225]	Any rule, requirement, or other statement of policy that establishes or changes a substantive legal standard.[226]
Exception	Interpretative rules, general statements of policy, or rules of agency organization, procedure.[227] Good cause exception.[228]	National coverage determination.[229] Good cause exception.[230]
Minimum public comment period	Not specified in the statute. 30 day requirement in the Federal Register's guidelines.[231]	60 days with exceptions listed in the statute. [232]
Minimum duration between final rule publication and its effective date	30 days.[233]	Not specified in the statute.
Maximum duration between the	N/A	No more than 3 years in general.[234]

225. *See generally* Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1710 (2007) (noting that scholars often refer to this as "legislative rules" or "substantive rules").

226. 42 U.S.C. § 1395hh (a)(2).

227. 5 U.S.C. § 553(b)(A).

228. 5 U.S.C. § 553(b)(B).

229. 42 U.S.C. § 1395hh(a)(2) (2003). The national coverage determination has its own stringent notice-and-comment requirement. 42 U.S.C. § 1395y(I)(3) (2021).

230. 42 U.S.C. § 1395hh(b)(2)(C) (cross-referencing APA's good cause exception).

231. OFFICE OF THE FED. REGISTER, *A Guide to the Rulemaking Process,* https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf (last reviewed Jan. 2011).

232. 42 U.S.C. § 1395hh(b)(1).

233. There are exceptions to the 30-day requirement in the A.P.A. for: (1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy, and (3) as otherwise provided by the agency for good cause. 5 U.S.C. § 553(d).

234. 42 U.S.C. § 1395hh(a)(3)(B).

publication of proposed regulation and final regulation		
Test for final regulation	Not specified in the statute. Courts developed a logical outgrowth test.[235]	Logical outgrowth test.[236]
Retroactivity effects	Not provided in the statute. Courts determined permissible retroactivity.[237]	No retroactivity effect.[238]

235. Chocolate Mfrs. Ass'n of U.S. v. Block, 755 F.2d 1098, 1105 (4th Cir. 1985) (holding that the final rule has to be consistent with the original proposed rule and a logical outgrowth of the notice and comments already given).

236. 42 U.S.C. § 1395hh(a)(4).

237. *See* William V. Luneburg, *Retroactivity and Administrative Rulemaking*, 1991 DUKE L. REV. J. 106, 109–10 (1991) (analyzing the precedent asserted in *Bowen v. Georgetown University Hospital*, which allowed retroactive application of a statute).

238. 42 U.S.C. § 1395hh(a)(3)(B).