



**ADVISORY OPINION 20-05 ON IMPLEMENTING *ALLINA*
DECEMBER 3, 2020**

The Office of the General Counsel (“OGC”) has received questions regarding the steps the Department of Health and Human Services (“HHS” or “the Department”) is taking to comply with the Supreme Court’s decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019) that the Department must use notice-and-comment rulemaking in certain circumstances where the Administrative Procedure Act (“APA”) does not require such rulemaking. In this Advisory Opinion, OGC clarifies what the public can expect the Center for Medicare to do in order to satisfy *Allina*’s requirements regarding notice-and-comment rulemaking.

This advisory opinion sets forth the current views of the Office of the General Counsel.¹ It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.

I. Meaning of “Substantive Legal Standard”

The Supreme Court in *Allina* held that under Social Security Act Section 1871, any Medicare issuance that establishes or changes a “substantive legal standard” governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, must go through notice-and-comment rulemaking. *See also* Social Security Act § 1871(a)(2). The Court declined to define the term “substantive legal standard,” other than to conclude it is not coterminous with the APA term “substantive rule.” *See* 139 S. Ct. at 1814. However, the Supreme Court made clear that Congress has imposed more stringent procedural requirements for certain Medicare issuances than the framework that otherwise would apply under Section 4 of the APA, even with the Richardson Waiver. *See* 36 Fed. Reg. 2,532 (Feb. 5, 1971). Thus, some statements of policy that would not need to go through notice-and-comment rulemaking under the APA may be required to do so by Section 1871(a).

OGC interprets the phrase “substantive legal standard” in Section 1871(a)(2) 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 by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and 3) sets forth a requirement not otherwise mandated by statute

¹ *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”).

or regulation. *See, e.g., Select Specialty Hosp.-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53 (D.D.C. 2019). A broadly-worded statute or regulation can be interpreted in a variety of ways, and where HHS unilaterally issues discrete, binding criteria purporting to explain statutory or regulatory requirements, that statement of policy will usually be viewed as creating a new norm, in contravention of the Department’s rulemaking obligations as interpreted in *Allina*. But, for example, where a statute or regulation is drafted narrowly enough to create the relevant norm, the agency can provide additional clarity through guidance without creating a new non-statutory or non-regulatory norm.

II. *Allina*’s Effect on HHS Enforcement Actions

Where HHS or the Centers for Medicare & Medicaid Services (“CMS”) issued guidance that, under *Allina*, should have been promulgated through notice-and-comment rulemaking, the Department’s ability to bring enforcement actions predicated solely on violations of those policies is restricted.

The Department sometimes cites to various non-regulatory CMS publications in its enforcement actions, such as the Internet-Only Manuals (“IOMs”) available on the CMS website. To the extent that IOMs and other CMS-issued guidance (including preamble text published with proposed or final rules) are closely tied to statutory or regulatory requirements, enforcement actions implicating these guidance materials can still be brought. The sub-regulatory guidance in these circumstances is not establishing or changing a substantive legal standard, but rather is “aid[ing] in demonstrating that the standards in the relevant statutory and regulatory requirements have been or have not been satisfied.” *See* Justice Manual § 1-20.202.

Conversely, to the extent that guidance documents set forth Medicare policies or rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance to inform the basis for any enforcement action, because under *Allina*, it was not validly issued. The critical question is whether the violation of the Medicare rule could be shown absent the guidance document. If the answer is no, then the guidance document establishes a norm and, under *Allina*, is invalid unless issued through notice-and-comment rulemaking. However, *Allina* does not preclude CMS from enforcing provisions in its contracts or agreements where those provisions, even if originally issued in the form of a guidance document, are expressly and specifically referenced as an obligation of the party to the contract or agreement.

If HHS subsequently codifies guidance in a retroactive regulation, *see* Social Security Act § 1871(e) (authorizing but limiting retroactive rulemaking), enforcement actions based on the violation of that rule may not always be appropriate. *Cf. Landgraf v. USI Film Prods.*, 511 U.S. 244, 266 (1994) (discussing the Constitution’s “antiretroactivity principle”). Nonetheless, such guidance could remain relevant in enforcement matters, for example, by demonstrating scienter or materiality.

We do not interpret *Allina* as compelling CMS’s contractors to promulgate Local Coverage Determinations (“LCDs”) using notice-and-comment rulemaking. LCDs reflect the determinations of the associated Medicare Administrative Contractor regarding whether a particular item or service is covered on a contractor-wide basis in accordance with the

“reasonable and necessary” standard in section 1862(a)(1)(A) of the Social Security Act. *See* Social Security Act § 1869(f)(2)(B) (defining “Local Coverage Determination”). As such, contractors may deny claims or make initial determinations as to possible overpayments based on LCDs. However, at higher levels of review, LCDs are not binding on HHS and therefore do not establish or change substantive legal standards. *See* 42 C.F.R. § 405.1062. But government enforcement actions based solely on LCDs are generally unenforceable.

III. Appropriate Use of Preamble Text for Rulemaking

Social Security Act Section 1871(a)(2) states that no Medicare issuance that establishes or changes a “substantive legal standard” governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, “shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).” Paragraph (1), in turn, explains that “[w]hen used in this title, the term ‘regulations’ means, unless the context otherwise requires, regulations prescribed by the Secretary.” Social Security Act § 1871(a)(1).

The Supreme Court in *Allina* did not address the procedures that HHS must undertake in order to comply with its “notice-and-comment obligations under § 1395hh(a)(2).” 139 S. Ct. at 1817. The D.C. Circuit recently reiterated that the dividing line “between the portions of a final rule with and without legal force is designation for ‘publication in the Code of Federal Regulations.’” *AT&T Corp. v. Fed. Comm’n Comm’n*, 970 F.3d 344, 350 (D.C. Cir. 2020) (quoting *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 539 (D.C. Cir. 1986) (Scalia, J.)). While preambles often contain interpretive statements that are not binding rules, agencies can satisfy notice-and-comment obligations under § 1395hh(a)(2) without codifying rules in the Code of Federal Regulations. Nonetheless, rulemaking through preambles only should be relatively rare, even for an agency as large as HHS: “statements in a preamble ‘may in some unique cases constitute binding, final agency action’ . . . [b]ut ‘this is not the norm.’” *AT&T Corp.*, 970 F.3d at 350 (quoting *NRDC v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) and citing 44 U.S.C. § 1510(a)); *see also* 1 C.F.R. § 8.1 (describing how the Code of Federal Regulations shall “contain each Federal regulation of general applicability and legal effect”). But when HHS engages in notice-and-comment rulemaking through preamble language only, the Department must be sufficiently clear to separate binding legal obligations from the rest of the preamble text that contains nonbinding interpretive statements. *See* HHS Good Guidance Practices Final Rule. Courts may “infer that the agency intended the preamble to be binding if what it requires is sufficiently clear.” *Kennecott Utah Copper Corp. v. U.S. Dep’t of Interior*, 88 F.3d 1191, 1223 (D.C. Cir. 1996). HHS will make clear its intent to engage in rulemaking through preambles by either: 1) specifically speaking to the Department’s intent in both the proposed and final rule preamble text, such as by using the phrase “HHS intends to bind itself” to the rule, or 2) stating that HHS would engage in notice-and-comment rulemaking in order to change the stated preamble policy.

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