



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

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TO: Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare

CC: Alec Alexander, Deputy Administrator and Director, Center for Program Integrity
Amy Bassano, Acting Director, Center for Medicare and Medicaid Innovation
Kathleen Cantwell, Director, Office of Strategic Operations and Regulatory Affairs
Kate Goodrich, Director, Center for Clinical Standards and Quality
Megan Worstell, Director, Office of Financial Management
Brady Brookes, Deputy Administrator and Deputy Chief of Staff, Centers for Medicare & Medicaid Services
Robert P. Charrow, General Counsel

FROM: Kelly M. Cleary, Deputy General Counsel & CMS Chief Legal Officer *KMC*
Brenna E. Jenny, Deputy General Counsel *BEJ*

SUBJECT: Impact of *Allina* on Medicare Payment Rules

This letter responds to your request for this Office's views on the impact of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), on Medicare payment rules and compliance actions based on those payment rules. The Supreme Court held in *Allina* 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 Supreme Court made clear that Congress has imposed more stringent procedural requirements for certain Medicare rules than the framework that otherwise would apply under the Administrative Procedure Act ("APA") Section 4, 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). The payment rules that you develop often form the basis for enforcement actions,¹ and

¹ Enforcement actions may include overpayment collections based on audits, but generally do not include routine claims and cost report procedures. We encourage consultation with the Office of the General Counsel regarding questions about whether an action constitutes an enforcement action.

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therefore it is important that the Center for Medicare appropriately conform its guidance documents to the rulemaking obligations set forth in *Allina*. Where the Department of Health and Human Services (“HHS” or “the Department”) 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 on violations of those payment policies is restricted. If the Center for Medicare intends for a particular guidance document to be used in enforcement actions, then the guidance must comply with *Allina*.

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 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. Where a statute or regulation is drafted narrowly enough to create the relevant payment norm, the agency can provide additional clarity through guidance without creating a new non-statutory or non-regulatory norm.

Conversely, to the extent that IOMs and similar guidance set forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under *Allina*, it was not validly issued. The critical question is whether the enforcement action could be brought 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. For example, a broadly-worded statute or regulation can be interpreted in a variety of ways, and where the Department issued discrete criteria purporting to explain statutory or regulatory requirements, that statement of policy can be viewed as creating a new norm, in contravention of our rulemaking obligations as interpreted in *Allina*. However, *Allina* does not preclude CMS from enforcing payment provisions in its contracts or agreements, provided that those provisions, if in the form of a guidance document, are expressly referenced as an obligation of the party to the contract.

Even a guidance document issued consistent with *Allina* may not be used as the sole basis for an enforcement action, although it may be relevant for other purposes, such as scienter or materiality. This reflects longstanding legal principles, as recently articulated in the Department of Justice’s Brand memorandum. For example, under *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. ___, 136 S. Ct. 1989 (2016), the touchstone of materiality is whether the government payor would have paid the claims at issue had it known of the defendant’s noncompliance with a law or regulation. Although *Escobar* left open the possibility that a violation may be material even if the government continued to pay with full knowledge of that violation, such cases are exceedingly rare. In the context of healthcare qui tam suits, components of HHS are the government payors, so the critical question is whether the alleged violation would have influenced our decision to pay. Guidance documents, in conjunction with

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the government's payment history, may shed light on this question.

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 payment determinations of the associated Medicare Administrative Contractor, and at higher levels of review, are not binding on HHS and therefore do not establish or change substantive legal standards. *See* 42 C.F.R. § 405.1062. But as a result of *Allina*, government enforcement actions based solely on LCDs are generally unsupportable.

It is unlikely that the Physician Self-Referral Law ("Stark Law") advisory opinion process will be affected by *Allina*. Stark Law advisory opinions generally do not establish or change substantive legal standards governing payment for services; rather, they "aid[] 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. Moreover, the processes for Stark Law advisory opinions are set out through separate statutory authority, and these more specific rules governing the issuance of advisory opinions supersede the more general statement in Social Security Act Section 1871(a)(2). *See* Social Security Act § 1877(g)(6). For the same reason, statutorily-authorized fraud and abuse waivers (*e.g.*, issued in the context of the Medicare Shared Savings Program or Center for Medicare and Medicaid Innovation models) need not be issued through notice-and-comment rulemaking. *See* Social Security Act § 1899(f); Social Security Act § 1115A(d)(1).

We are happy to discuss these issues with you at any time. We will continue to work with members of your teams to identify particular guidance documents that might be appropriate to issue through notice-and comment-rulemaking on a more expedited basis.

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