HHS OGC WEIGHS IN ON SUB-REGULATORY GUIDANCE IN ADVISORY OPINION: WHAT IT MIGHT MEAN FOR FALSE CLAIMS ACT CASES AFTER AZAR V. ALLINA HEALTH SERVICES

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The U.S. Supreme Court's 2019 decision in *Azar v. Allina Health Services*[1] effectively curtailed the enforceability of certain Medicare policies established without notice-and-comment rulemaking. As a result, health care fraud cases brought under the False Claims Act (FCA), which are predicated on sub-regulatory guidance, face heightened scrutiny after *Allina*.[2]

In a recent Advisory Opinion, the Health and Human Services Office of the General Counsel (HHS-OGC) provided its interpretation of *Allina* and how violations of sub-regulatory guidance affect the ability of governmental enforcement agencies and relators to bring and support FCA actions moving forward.[3] Specifically, on 3 December 2020, HHS-OGC issued Advisory Opinion 20-05 on Implementing *Allina*. While HHS-OGC considers the Advisory Opinion nonbinding and it lacks the force of law, the Advisory Opinion provides HHS-OGC's current views on the implementation of *Allina*, specifically surrounding the definition and interpretation of a "substantive legal standard." Key takeaways are as follows:

- After *Allina*, policies that establish or change substantive legal standards related to the scope and award of benefits under the Medicare Act are likely unenforceable as predicates to FCA actions unless promulgated under the formal rulemaking process. *Allina* has cast doubt on the viability of many health care fraud claims commonly brought under the FCA.
- The Advisory Opinion offers HHS-OGC's interpretation of *Allina*, stating that claims citing to guidance that is closely tied to statutory or regulatory requirements may continue, however, guidance that creates policies or rules not closely tied to statutory or regulatory requirements cannot be the basis for an enforcement action.
- Considering *Allina*, recent court opinions, and the Advisory Opinion, collectively, defendants facing FCA actions based solely on violations of sub-regulatory guidance may have a strong argument that falsity under the FCA cannot be established if the guidance is not tied directly to statutory or regulatory text and was issued without proper notice-and-comment rulemaking.
- The impact of *Allina* on the Government's and relators' ability to pursue FCA actions predicated on improperly issued sub-regulatory guidance is unknown but key to that determination will be how narrowly guidance must be tailored to existing statutes or regulatory requirements.

A review of *Allina* and the Advisory Opinion are described in further detail below.

THE *ALLINA* DECISION

In *Allina*, the Supreme Court considered whether HHS was required to undertake notice-and-comment rulemaking under the Medicare Act before implementing a change to a Medicare reimbursement formula.[4] According to the Supreme Court, while statements of policy may be treated as interpretive rules under the Administrative Procedure Act and, therefore, do not require notice-and-comment rulemaking, the Medicare Act's more stringent regulatory framework provides that "'statements of policy' *can* establish or change a 'substantive legal standard.'"[5] Consequently, under the terms of the Medicare Act, any issuance that "establishes or chang[es] a substantive legal standard" governing the scope of Medicare benefits, including the eligibility to provide services and payment for services, must undergo notice-and-comment rulemaking.[6]

Key to the Court's 7–1 decision is its holding that "when the government establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations under [the Medicare Act] § 1395hh(a)(2)…."[7] In practice, *Allina* means that any policy interpreting a broadly worded statute or regulation related to the scope and award of benefits under the Medicare Act is unenforceable absent this formal rulemaking process.[8]

HHS-OGC'S INTERPRETATION OF *ALLINA*

Allina did not define the term "substantive legal standard." However, the Advisory Opinion attempts to set forth HHS-OGC's current views for determining what may fall under the term's umbrella. First, HHS-OGC interprets a substantive legal standard as:

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 or regulation.[9]

Second, the Advisory Opinion explains that the critical question under *Allina* is "whether the violation of the Medicare rule can be shown without the guidance document."[10] A claim citing to guidance that is closely tied to statutory or regulatory requirements may be enforceable, as it does not establish or change a substantive legal standard as prohibited under *Allina*.[11] However, if the guidance creates policies or rules not closely tied to statutory or regulatory text, the guidance is not properly issued under *Allina* and cannot be the predicate for an enforcement action.

ALLINA AND THE FCA IN THE COURTS TO DATE

Allina has cast doubt on the viability of many health care fraud claims commonly brought under the FCA. Specifically, in FCA actions, the Government and relators often base allegedly false claims on sub-regulatory guidance that was not subject to notice-and-comment rulemaking. As of December 2020, at least one federal district court applying *Allina* to an FCA case maintained that dismissal was appropriate because the claims at issue were improperly premised on sub-regulatory guidance.[12] In *Polansky v. Executive Health Resources, Inc.*, the district court considered the viability of an FCA action based on a Centers for Medicare & Medicaid Services (CMS) policy, set forth in the 1981 CMS Manual, which classified outpatients as those that spent less than 24

hours in the hospital.[13] Applying the holding in *Allina*, the district court considered whether the 24-hour CMS reimbursement policy was a substantive legal standard within the scope of Section 1395hh(a)(2). *Polansky* adopted the D.C. Circuit's opinion that a substantive legal standard is one that "includes a standard that creates, defines, and regulates the rights, duties, and powers of parties."[14] The district court elaborated on this interpretation, stating that "if a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a 'substantive legal standard.'"[15] Accordingly, as the 24-hour policy affected a hospital's right to payment—setting the standards by which a hospital was entitled to reimbursement rates—the policy was a substantive legal standard that required notice and comment prior to implementation.[16]

WHAT TO EXPECT NEXT

While the Supreme Court has not weighed-in on the meaning of "substantive legal standards," the Advisory Opinion, with the additional context provided by *Polansky*, demonstrates the challenge the Government and relators may face in FCA matters moving forward. The Advisory Opinion acknowledges the practical thrust of *Allina*'s holding: Much of the Medicare guidance previously relied upon by the Government as the basis for claims is unenforceable, absent notice-and-comment rulemaking. Considering *Allina*, *Polansky*, and the Advisory Opinion collectively, defendants facing FCA actions premised solely on violations of sub-regulatory guidance not tied directly to statutory or regulatory text may have a strong argument that falsity under the FCA cannot be established because the guidance itself was issued without proper notice-and-comment rulemaking.

Polansky provides one example of improperly promulgated sub-regulatory guidance establishing or changing "substantive legal standards." However, how widely *Allina* will affect, and possibly foreclose, the Government's and relators' ability to pursue FCA actions predicated on improperly issued sub-regulatory guidance is presently unknown. Key to that determination will be how narrowly guidance must be tailored to existing statutes or regulatory requirements. This question is left open by *Allina* and similarly is unaddressed by the Advisory Opinion's interpretation of "substantive legal standard."[17]

For example, the Advisory Opinion states that HHS-OGC does not believe Medicare administrative contractors are required to promulgate local coverage determinations (LCDs) using notice-and-comment rulemaking. HHS-OGC reasoned that because LCDs are not binding on all levels of HHS during the administrative appeals process, LCDs do not establish or change substantive legal standards. It is unclear whether this specific rationale extends to the use in FCA actions of transmittals and other guidance documents purportedly interpreting LCDs or whether HHS-OGC's reasoning will withstand the development of post-*Allina* case law.

K&L Gates' investigations, enforcement, and white collar practice group and its health care fraud and abuse practice group will continue to monitor the response to the *Allina* decision and provide periodic updates on developments as the courts and other Government agencies seek to respond to these questions.

FOOTNOTES

[1] Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019).
[2] *See*, *e.g.*, Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 931–32 (E.D. Pa. 2019).
[3] HEALTH & HUM. SERVS. OFF. OF THE GEN. COUNSEL, ADVISORY OPINION 20-05 ON IMPLEMENTING ALLINA 1 (Dec. 3, 2020), https://www.hhs.gov/sites/default/files/allina-ao.pdf [hereinafter Advisory Opinion].

[4] *Allina*, 139 S. Ct. at 1808; see 42 U.S.C. § 1395hh(a)(2).
[5] *Allina*, 139 S. Ct. at 1811 (emphasis in original).
[6] *Id.* at 1810.
[7] *Id.* at 1817.
[8] *See id.*; Advisory Opinion at 1.
[9] Advisory Opinion at 1–2 (citing Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F. Supp. 3d 53 (D.D.C. 2019)).
[10] Advisory Opinion at 2.
[11] *Id.*
[12] *Polansky*, 422 F. Supp. 3d at 931–32.
[13] *Id.* at 919.
[14] *Id.* at 934 (quoting Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017)).
[15] *Id.*
[16] *Id.* at 934–35.
[17] *See* Advisory Opinion at 2.

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