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CLIENT ALERT

HHS Limits the Use of Guidance Documents in the Good Guidance Practices Rule and Advisory Opinion 20-05

By Jonah D. Retzinger and Robert E. Wanerman

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On December 7, 2020, the Department of Health and Human Services ("HHS") published the Good Guidance Practices final rule ("Rule"), which limits HHS's ability to issue and rely upon sub-regulatory guidance documents in enforcement actions, investigations, and audits, including actions relating to coverage and reimbursement for items and services under Medicare and other federal health care programs.[1] In addition, the HHS Office of the General Counsel ("HHS-OGC") released Advisory Opinion 20-05, which sets out HHS-OGC's interpretation of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019) ("*Allina*"), in which the U.S. Supreme Court held that HHS must use notice-and-comment rulemaking (as opposed to issuing guidance) when establishing or changing "substantive legal standards" that affect Medicare eligibility, benefits, or payments for services.[2] In Advisory Opinion 20-05, HHS-OGC defines its interpretation of the phrase "substantive legal standard," and addresses *Allina's* impact on HHS enforcement actions and the use of preamble text for rulemaking.

Ever since the Administrative Procedure Act ("APA") was enacted in 1946, federal agencies, regulated entities, and courts have struggled with defining the distinction between legislative regulations that must be issued through notice-and-comment rulemaking and have the force of law, and interpretive rules that do not require prior public notice and do not have the force of law but only "advise the public of the agency's construction of the statutes and rules which it administers."[3] Nevertheless, since many components of HHS have issued sub-regulatory guidance in manuals, program memoranda, and other publications, all individuals and entities that participate in programs administered by HHS, contract with HHS, or are regulated by HHS should be aware of the Rule and Advisory Opinion 20-05, as they can provide a basis on which to challenge actions taken by agencies within HHS and defend against enforcement actions premised solely on allegations of noncompliance with guidance documents.

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[1] 85 Fed. Reg. 78770-87 (Dec. 7, 2020) (regulations to be codified at 45 C.F.R. §§ 1.1 – 1.5).
[2] *See* HHS, Press Release, HHS Finalizes Good Guidance Practices Rule and Issues Advisory Opinion Regarding Compliance with Notice-and-Comment Obligations (Dec. 3, 2020), available at https://www.hhs.gov/about/news/2020/12/03/hhs-finalizes-good-guidance-practices-rule-issues-advisory-opinion-regarding-compliance-notice.html.
[3] *Perez v. Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1203-04 (2015), *quoting Shalala v. Guernsey Memorial Hospital,* 514 U.S. 87, 99 (1995).

I. The Good Guidance Practices Rule

The Rule follows the notice of proposed rulemaking issued by HHS on August 20, 2020,[4] as well as recent executive orders,[5] and other initiatives and policies published by HHS and the Department of Justice ("DOJ") to restrict the use of guidance documents in investigations and enforcement actions.[6] The Rule is binding on all components of HHS, but the Rule acknowledges that HHS intends to publish a separate rule governing the U.S. Food and Drug Administration's publication and use of guidance.

In sum, the Rule:

(1) **Prohibits the Issuance and Use of Improper Guidance**. The Rule prohibits HHS from (i) issuing any guidance document that establishes a legal obligation that is not reflected in an applicable statute or regulation, or (ii) using any guidance document for purposes of requiring a person or entity outside HHS to take any action, or refrain from taking any action, beyond what is required by an applicable statute or regulation.[7]

(2) **Requires That HHS Agencies Identify Guidance Documents**. The Rule requires that each HHS component identify guidance documents and explain their purpose and scope. In addition, unless there is a separate authorization that makes a guidance document binding, the Rule requires that guidance documents contain the following disclaimer: "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law."

(3) **Creates a Rulemaking Process for Significant Guidance Documents**. The Rule requires that "significant guidance documents" that are expected to have an annual impact of more than $100 million must (i) be approved by the Secretary of HHS, (ii) be subject to public notice and comment, and (iii) be reviewed before publication by the Office of Information and Regulatory Affairs within the Office of Management and Budget.[8]

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[4] 85 Fed. Reg. 51396-401 (Aug. 20, 2020).

[5] See Executive Order 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents (Oct. 9, 2019), 84 Fed. Reg. 55235-38 (Oct. 15, 2019).

[6] *See, e.g.,* DOJ Manual, § 1-20.0000, available at https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation ("Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents. . . ."; DOJ, Press Release, Associate Attorney General Brand Announces End To Use of Civil Enforcement Authority to Enforce Agency Guidance Documents (Jan. 25, 2018), available at https://www.justice.gov/opa/pr/associate-attorney-general-brand-announces-end-use-civil-enforcement-authority-enforce-agency.

[7] 45 C.F.R. § 1.3. The Rule exempts certain publications, including rules exempt from rulemaking under 5 U.S.C. § 553(a), internal agency guidance that is not intended to affect regulated parties, advisory opinions or no-action letters addressed to individual entities, or grant or contract solicitations and awards.

[8] 45 C.F.R. § 1.3(b). These requirements may be waived in the case of an emergency or other compelling reason for a waiver.

(4) **Establishes a Guidance Repository**. The Rule provides for the creation of a guidance repository, available at https://www.hhs.gov/guidance/, which includes all guidance that has been issued by any component of HHS. Notably, any document not included in the guidance depository by January 6, 2020, is deemed rescinded.[9]

(5) **Establishes a Petition Process to Challenge Guidance**. The Rule creates a petition process that allows any interested party to petition HHS to withdraw or modify any particular guidance document because it imposes binding obligations on parties beyond what is required by the terms of applicable statutes and/or regulations, or because a component of HHS is using a guidance document to create additional legal obligations beyond what is required by the terms of applicable statutes and/or regulations.[10] In the Rule's preamble, HHS explained that this petition process does not create a requirement that a party exhaust the petition process as a prerequisite to a challenge in court under existing case law, but rather it provides an additional path for review for parties who would prefer to resolve a dispute without the need for litigation.[11]

For those individuals or entities that are presently subject to False Claims Act ("FCA") *qui tam* suits, audits, denials of claims, or other audit or enforcement actions based exclusively on allegations of noncompliance with guidance documents, the Rule provides a new basis to rebut these allegations. Indeed, separate and apart from the Rule's prohibitions against the improper issuance and use of guidance documents, in the Rule's preamble, HHS specifically directs regulated parties to file petitions with HHS seeking clarification as to the appropriate scope of guidance documents when actors outside of HHS, such as *qui tam* relators, use guidance documents inappropriately in a manner that attempts to impose new binding obligations on regulated parties.[12]

The Rule is set to take effect on January 6, 2021. However, HHS is encouraging interested parties to submit petitions to bring any instances of inappropriate guidance documents to its attention before the effective date.

II. Advisory Opinion 20-05 on Implementing *Allina*

Section 1871 of the Social Security Act limits the use of sub-regulatory guidance documents by the Centers for Medicare & Medicaid Services ("CMS"). Section 1871 requires that CMS engage in public notice-and-comment rulemaking whenever there is an action 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 …."[13] In *Allina*, the U.S. Supreme Court distinguished this standard from the rulemaking standard in the APA and held that HHS is expressly required to follow notice-and-comment-rulemaking procedures prior to

[9] 45 C.F.R. § 1.4.
[10] 45 C.F.R. § 1.5.
[11] 85 Fed. Reg. at 78784.
[12] *Id.*
[13] 42 U.S.C. § 1395hh(a)(2).

establishing "substantive legal standards." Following the *Allina* decision, on October 31, 2019, the former and current Deputy General Counsel & CMS Chief Legal Officer issued a joint letter ("Cleary-Jenny Memo") to internal CMS leadership that addressed the impact of *Allina* and the use of guidance documents in enforcement actions.[14]

On December 3, 2020, HHS's General Counsel issued Advisory Opinion 20-05 to clarify how CMS will comply with *Allina.*[15] In Advisory Opinion 20-05, HHS-OGC sets forth its informal interpretation of the phrase "substantive legal standard,"[16] and further opines that "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." Advisory Opinion 20-05 also states that while HHS-OGC does not interpret *Allina* as compelling CMS's contractors to promulgate Local Coverage Determinations ("LCDs") using notice-and-comment rulemaking, "government enforcement actions based solely on LCDs are generally unsupportable." Although Advisory Opinion 20-05 is not binding, it is an important resource for any individual or entity that works with CMS or is regulated by CMS.

III. Important Considerations

Read together, and in combination with the other HHS and DOJ initiatives to curb the improper use of guidance documents, the Rule and Advisory Opinion 20-05 demonstrate a commitment by the federal government to provide clarity to health care providers, federal health care program participants, and other regulated parties regarding the issuance and use of guidance documents. The Rule and Advisory Opinion 20-05 serve to protect regulated parties against enforcement actions that rely upon guidance documents, and the new petition process provides a formal mechanism for interested parties to engage HHS to challenge guidance documents or obtain clarification as to the appropriate scope of guidance documents.

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This Client Alert was authored by **Jonah D. Retzinger** *and* **Robert E. Wanerman***. If you are presently subject to an enforcement action or FCA* qui tam *matter premised upon noncompliance with guidance documents, if you would like to discuss the new petition process for challenging guidance documents or the use of guidance documents, or if you would like additional information about any other issues or information discussed in this*

[14] *See* Jeff Overley, Law360, HHS Attys Say High Court Ruling Curbs Billing Enforcement (Nov. 21, 2019), available at https://www.law360.com/articles/1222453/hhs-attys-say-high-court-ruling-curbs-billing-enforcement (including the Cleary-Jenny Memo as an attachment).

[15] HHS-OGC, Advisory Opinion 20-05 on Implementing Allina (Dec. 3, 2020), available at https://www.hhs.gov/sites/default/files/allina-ao.pdf.

[16] Advisory Opinion 20-05 explains that CMS will interpret the phrase "substantive legal standard" in Section 1871(a)(2) as meaning "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."

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