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CLIENT ALERT

HHS Limits Use of Guidance Documents in Civil Enforcement Actions and Issues First Good Guidance Practices Petition Response

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On January 14, 2021, the Department of Health and Human Services ("HHS") published the Transparency and Fairness in Civil Administrative Enforcement Actions final rule ("Rule").[1] The Rule amends and supplements the HHS Good Guidance Practices Rule ("GGPR") published on December 7, 2020,[2] and provides additional protections against the use of improper guidance and the application of unpublished standards or practices in enforcement actions brought by HHS.

On January 8, 2021, HHS released Good Guidance Petition ("GGP") Response 21-01, which is HHS's first formal response to a petition submitted under the GGPR's new petition process to challenge improper guidance.[3] In GGP Response 21-01, HHS agreed to withdraw certain guidance documents that the petitioner, DaVita, Inc., challenged as unlawful because the guidance documents set forth new requirements solely through sub-regulatory guidance.

Stakeholders and parties regulated by HHS should be aware of these significant developments, as they affect many agency decisions and actions, including claims reviews, audits, and government investigations.

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[1] 86 Fed. Reg. 3010-15 (Jan. 14, 2021) (regulations to be codified at 45 C.F.R. Part 1), https://www.federalregister.gov/documents/2021/01/14/2021-00592/department-of-health-and-human-services-transparency-and-fairness-in-civil-administrative; *see also* HHS, Press Release, *HHS Improves Agency Procedures Relating to Transparency and Fairness in Civil Enforcement Actions* (Jan. 12, 2021), available at https://www.hhs.gov/about/news/2021/01/12/hhs-improves-agency-procedures-relating-transparency-fairness-civil-enforcement-actions.html.

[2] *See* Jonah Retzinger and Robert Wanerman, HHS Limits the Use of Guidance Documents in the Good Guidance Practices Rule and Advisory Opinion 20-05 (Dec. 10, 2020), available at https://www.ebglaw.com/news/hhs-limits-the-use-of-guidance-documents-in-the-good-guidance-practices-rule-and-advisory-opinion-20-05/ (discussing the GGPR regulations).

[3] Good Guidance Petition Response 21-01 (Jan. 8, 2021), available at https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf.

I. The Transparency and Fairness in Civil Administrative Enforcement Actions Rule

While the Rule confirms that the GGPR regulations apply only to the U.S. Food and Drug Administration ("FDA") until HHS updates the FDA's existing good guidance regulations, the new regulations in the Rule are binding on all components of HHS, including FDA.

The Rule was published under an exception to the Administrative Procedure Act that exempts "rules of agency organization, procedure, or practice" from the usual public notice and comment procedures.[4]

In brief, the Rule:

(1) **Limits HHS's Reliance on Guidance Documents in Civil Enforcement Actions**. The Rule requires "civil enforcement actions" to be based on violations of statutes and regulations (HHS defines a "civil enforcement action" as "an action with legal consequence taken by [HHS] based on an alleged violation of the law"). It further prohibits HHS from using guidance documents to impose binding requirements or prohibitions, except as authorized by law or expressly incorporated into a contract, and from treating noncompliance with a standard or practice announced solely in a guidance document as itself a violation of statutes or regulations, except as expressly authorized by law.[5]

(2) **Requires Fairness and Notice in Civil Enforcement Actions and Administrative Inspections**. The Rule requires that HHS apply standards and practices in civil enforcement actions that "have been publicly stated in a manner that would not cause 'unfair surprise'" (defined as "a lack of reasonable certainty or fair warning, from the perspective of a reasonably prudent member of regulated industry, of what a legal standard administered by an agency requires"). The Rule further provides that HHS must avoid unfair surprise when imposing penalties or adjudging past conduct, and mandates that HHS conduct civil administrative inspections according to published rules of agency procedure.[6]

(3) **Requires Fairness and Notice in Jurisdictional Determinations**. The Rule requires that when HHS relies on certain decisions to assert new or expanded claims of jurisdiction (e.g., a claim to regulate a new subject matter or a new basis for liability, or a relinquishment of a claim of jurisdiction), HHS must first give fair notice by publishing the initial decision either in the *Federal Register* or in the new HHS guidance repository available at https://www.hhs.gov/guidance/.[7]

[4] 5 U.S.C. § 553(b)(3)(A).
[5] 45 C.F.R. § 1.6.
[6] 45 C.F.R. § 1.7.
[7] 45 C.F.R. § 1.8.

(4) **Requires HHS to Provide Opportunities to Contest Agency Determinations**. The Rule mandates that HHS, prior to taking a civil enforcement action, issue a notice to the affected party of initial legal and factual determinations and provide for an opportunity for the affected party to respond, with limited exceptions.[8]

For those individuals or entities subject to 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.

While the Rule is limited in its application to only civil enforcement actions taken by any component of HHS, it is consistent with the shift in policy by the Department of Justice ("DOJ") in its regulations and internal rules to prohibit the issuance and use of improper guidance documents.[9] As a whole, this may provide a basis to defend against actions pursed by non-government entities (e.g., *qui tam* relators) that are based solely on alleged noncompliance with improper guidance.

II. Good Guidance Petition Response 21-01

In GGP Response 21-01, HHS responded to a petition brought by DaVita Inc. that challenged certain Centers for Medicare & Medicaid Services ("CMS") transmittals and publications requiring dialysis facilities to report dialysis treatment time on claims. DaVita argued that these were guidance documents that improperly created new legal obligations beyond what is required under the applicable statutes and regulations. HHS announced that it would be amending the guidance documents to remove the reporting requirement because it was set forth "solely through sub-regulatory guidance . . . that impose[d] binding new obligations that are not reflected in duly enacted statutes or regulations . . . ."

While GGP Response 21-01 is HHS's first formal response under the GGPR's petition process, it represents HHS's second announcement in as many months that it would rescind a guidance document that imposed binding obligations that exceed statutory and regulatory requirements.[10]

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[8] 45 C.F.R. § 1.9.

[9] *See* Department of Justice, Prohibition on the Issuance of Improper Guidance Documents Within the Justice Department, 85 Fed. Reg. 50951-3 (Aug. 19, 2020); 28 C.F.R. § 50.26(a)(3); *see also* 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. . . .").

[10] *See* HHS, Guidance Document Rescinded For Non-Compliance With *Allina* and the Administrative Procedure Act (Dec. 3, 2020), available at https://www.hhs.gov/sites/default/files/hhs-guidance-announcement-and-rfi.pdf (announcing that CMS had rescinded a draft guidance document incorporated into the CMS State Operations Manual relating to ligature risks in psychiatric hospitals because it imposed binding obligations on providers that exceeded statutory and regulatory requirements).

III. Important Considerations

HHS's priorities may change under the incoming Biden administration, but the regulations in the Rule and the GGPR, along with other recent HHS and DOJ initiatives to curb the improper use of guidance documents, demonstrate a commitment by HHS to clarify the distinction between binding statutes and regulations and the publication and use of non-binding guidance documents. This may make it easier for health care providers, suppliers, and other stakeholders to determine what they need to do to comply with the multiple requirements for participation in programs administered by HHS, or when they seek reimbursement from those programs for their services. Furthermore, GGP Response 21-01 reinforces the concept that the GGPR petition process can be a valuable tool for regulated parties to seek relief from HHS when they find themselves suddenly subject to new requirements in guidance documents that are not founded in valid statutes or regulations.

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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 premised upon noncompliance with guidance documents, if you would like to discuss the Transparency and Fairness in Civil Administrative Enforcement Actions Rule, or if you would like additional information about any other issues or information discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*