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Citing Inefficiency, HHS Proposes to Void Good Guidance Practices Rule

By Nina Youngstrom

In a theme emerging around agency guidance, HHS on Oct. 19 proposed to repeal recent rules on Good Guidance Practices (GGP) and fairness in enforcement^[1] a few months after the Department of Justice rescinded the 2018 Brand memo,^[2] which prohibited the use of subregulatory guidance to prove violations in affirmative civil enforcement cases unless it was rooted in laws or regulations.

In a nutshell, the GGP and enforcement regulations, which were published in the waning days of the Trump administration, require HHS to put “significant” guidance through notice and comment rulemaking and limit the use of subregulatory guidance in administrative enforcement actions.^[3] The GGP rule also allows interested parties, such as providers, to petition HHS to withdraw guidance that has purportedly strayed too far from a law or regulation, which is what led CMS to remove Medicare manual guidance on split/shared billing—and draft a replacement in the 2022 proposed Medicare Physician Fee Schedule rule.^[4]

But HHS said it has run into problems with the rules. “The Department has taken a renewed and critical look at the HHS GGP and civil enforcement rules and has concluded that both rules frustrate the Department’s ability to efficiently direct and operate in the interest of public health and are inconsistent with the policies and goals of the current Administration,” according to the proposed rule. HHS wants to junk GGP specifically because “it delays or prevents the issuance of guidance documents”; requires agencies to abide by “uniform, inflexible requirements” that don’t sufficiently “account for the agencies’ different operations and are likely to cause confusion among regulated entities and members of the public”; and diverts agency resources that are better used elsewhere, among other reasons.

With the Biden administration reversing Trump administration regulations, attorney Daniel Hettich is tempted to say “there’s a new sheriff in town,” but he thinks that may be overstating it. “Though there’s a clear shift in emphasis, both administrations agree that guidance documents alone can’t give rise to an enforcement action but that there has to be a link to an underlying statute or regulation that imposes the obligation,” said Hettich, with King & Spalding in Washington, D.C. “Indeed, most of the reasons HHS gives for repealing the rules are practical” (e.g., causing a delay in providing valuable information). Hettich is not shocked the current administration would propose to undo rules enacted in the final weeks of the previous administration. “Still, emphasis matters, and this administration is clearly signaling a renewed willingness to rely on subregulatory guidance documents in pursuing its agenda,” he noted.

But another attorney has a different take on the proposed GGP reversal.

‘It’s a Philosophical Divergence’

“It reflects fundamentally different approaches to governing,” said attorney Scott Memmott, with Morgan Lewis in Washington, D.C. “On the one hand, in the old administration, they claimed to be focused on fairness and accountability and not allowing executive agencies to regulate through subregulatory guidance that they thought

was unlawful. On the other hand, you have an administration more comfortable with a more robust regulatory approach, and they think these final rules from the very late days of the prior administration unnecessarily hamstrung them. It's a philosophical divergence on the role of government."

Over at DOJ, Attorney General Merrick Garland in a July memo rescinded the Brand memo on affirmative civil enforcement actions, such as False Claims Act lawsuits, calling it "overly restrictive."¹ The Brand memo stated that "the Department should not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation." But Garland reiterated that guidance doesn't have the force of law, and "enforcement actions must be based on the failure to comply with a binding obligation, such as one imposed by the Constitution, a statute, a legislative rule, or a contract."

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¹ Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures, 86 Fed. Reg. 58,042 (October 20, 2021), <https://bit.ly/3G8aSoO>.

² Rachel Brand, "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases," memorandum, January 25, 2018, <https://bit.ly/3l6BGuH>.

³ Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770 (December 7, 2020), <https://bit.ly/2RDlebl>.

⁴ Nina Youngstrom, "Proposed MPFS: Some Telehealth Stays Through 2023; Split/Shared Billing Has New Math," *Report on Medicare Compliance* 30, no. 26 (July 19, 2021), <https://bit.ly/3azT2wu>.

⁵ Merrick Garland, "Issuance and Use of Guidance Documents by the Department of Justice," memorandum, July 1, 2021, <https://bit.ly/3ttxUR2>.

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