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Health Care Litigation ADVISORY ■

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HHS Places Additional Limits on the Use of Guidance Documents

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Over the years, it has been incredibly frustrating for health care companies to face punitive False Claims Act (FCA) liability or administrative enforcement for an alleged violation of something in a "guidance document" or manual that has never been subjected to notice-and-comment rulemaking. Even the Department of Health and Human Services (HHS) now recognizes the inherent unfairness and arbitrariness that can result from using these informal policies and documents along with the hammer of government enforcement.

On Tuesday, January 12, HHS announced a new rule that restricts the agency from pursuing enforcement actions that are based on alleged violations of the agency's sub-regulatory guidance materials. The new rule mirrors recent Department of Justice (DOJ) policy limiting the use of guidance documents in enforcement actions and a Supreme Court decision restricting HHS's ability to sidestep formal rulemaking.

The new rule has three important components. First, it prohibits HHS from using "guidance documents to impose binding requirements … except as expressly authorized by law or as expressly incorporated into a contract." Second, the rule prevents HHS from applying standards or requirements unless they have been publicly announced. Third, the rule requires HHS in most instances to notify regulated entities—and give them an opportunity to respond in writing—before instituting an enforcement action.

The new rule is "one component of the Department's broader regulatory reform initiative," and it follows a rule issued in December 2020 that requires HHS to post guidance documents on an online repository and formalizes the process by which the agency promulgates new guidance materials. The December 2020 rule further prohibits HHS from deviating from explicit statutory or regulatory requirements by: (1) establishing new legal obligations in a guidance document; and (2) using guidance documents to require a regulated entity to take action (or refrain from taking action). The earlier rule also explains how HHS must issue new guidance documents, requires HHS to publish guidance documents on an online portal, and allows any interested parties to petition the agency to withdraw or modify any guidance document.

These rules follow policy announcements from the DOJ, which recently changed its policy to similarly prohibit bringing civil or criminal enforcement actions based on "mere noncompliance with guidance documents." The Supreme Court in *Azar v. Allina Health Services* likewise concluded that HHS had to follow the rulemaking process when issuing new substantive legal standards.

The new rule provides important protections to providers and health care entities. But the rule is not a panacea. HHS can blunt the rule's impact by expressly incorporating more guidance documents (like Medicare manuals) in its contracts. Moreover, "guidance documents" do not include instructions or requirements imposed by Medicare administrative contractors. It is also uncertain how courts will apply the rule in cases brought by FCA relators. Prior attempts to use similar DOJ guidance and the Supreme Court's *Azar* decision in FCA litigation have had mixed results. In addition, it remains to be seen how the new rule and its December 2020 counterpart may fare in the incoming Biden Administration or the new Congress. Regardless, this is a positive step in the right direction for providing more certainty around enforcement decisions.

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