

Compliance Today – May 2021 HHS limits the use of guidance documents in civil enforcement actions

By Lester J. Perling, Esq., CHC, and Jamie Gelfman, Esq., CHC

Lester J. Perling (lester.perling@nelsonmullins.com) is a Partner in the Fort Lauderdale office, and Jamie Gelfman (jamie.gelfman@nelsonmullins.com) is a Partner in the Boca Raton office of the Nelson Mullins Riley & Scarborough LLP law firm.

- [linkedin.com/in/lester-perling-278a953b](https://www.linkedin.com/in/lester-perling-278a953b)
- [linkedin.com/in/jamie-gelfman-20b60b56](https://www.linkedin.com/in/jamie-gelfman-20b60b56)

The United States Department of Health & Human Services (HHS) has issued a regulation modifying certain practices with respect to civil enforcement actions, intended to promote “transparency and fairness”^[1] in such proceedings (the rule). HHS states that the rule is “designed to ensure accountability, fairness of how [HHS] uses guidance, proper use of guidance documents, and opportunities for third parties to be heard.”^[2] The rule became effective January 12, 2021, and applies to all HHS divisions, including Centers for Medicare & Medicaid Services (CMS).

General background: Issuance of Executive Order 13892

On October 9, 2019, President Donald J. Trump issued Executive Order 13892 (the order)^[3] The order, which notes that “regulated parties must know in advance the rules by which the Federal Government will judge their actions,” outlines various existing laws that are intended to provide transparency to the public regarding policies and rules that affect individual rights and obligations, such as the Administrative Procedure Act and the Freedom of Information Act. However, because “departments and agencies...in the executive branch have not always complied with these requirements,” the order officially prohibits departments and agencies in the executive branch from subjecting affected parties to civil administrative enforcement or adjudication “absent prior public notice of both the enforcing agency’s jurisdiction over particular conduct and the legal standards applicable to that conduct.” In furtherance of these requirements, the order prohibits agencies from using “guidance documents” to impose new standards of conduct on individuals “except as expressly authorized by law or as expressly incorporated into a contract.”^[4]

As a result of the order, HHS issued the rule to expressly incorporate the requirements set forth in the order to civil enforcement actions taken by HHS.

HHS applies the order to its civil enforcement actions

At the outset of the rule, HHS defines “civil enforcement actions” to mean “an action with legal consequence taken by the Department based on an alleged violation of the law.”^[5] These actions may include “administrative enforcement proceedings and enforcement adjudication (which is the administrative process undertaken by any component of the Department to resolve the legal rights and obligations of specific parties with regard to a particular enforcement issue pending before it).” The definition also notes that civil enforcement actions do not

include “actions taken in the normal course of the Department’s regulatory communications or decision-making.”

The rule states that whenever HHS pursues a civil enforcement action or “otherwise makes a determination based on an alleged violation of law that has legal consequence for a person or state,” it must allege or establish the violation of law by applying statutes or regulations and may not use guidance documents to impose binding requirements on individuals.^[6] Further, HHS may not base an individual’s noncompliance with a standard or practice that is announced solely in a guidance document but is not expressly mirrored in a statute or regulation as a violation of applicable statutes or regulations.

The rule clarifies that guidance documents may be used by HHS to explain how it interprets a statute or regulation with respect to certain conduct or a particular set of circumstances; however, it may only do so if HHS has notified the public of the guidance document in advance through HHS’s guidance repository.

This document is only available to members. Please [log in](#) or [become a member](#).

[Become a Member](#) [Login](#)