PUBLICATION

Proposed HHS Rule Would Further Solidify Limitations on Enforcement of Agency Guidance Documents

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Consistent with President Trump's actions seeking to rein in the use of sub-regulatory guidance in government enforcement actions, the U.S. Department of Health and Human Services (HHS) issued a notice of proposed rulemaking on August 20, 2020 setting forth proposals to memorialize limitations on the issuance and enforceability of guidance documents. If formally adopted, these regulations will significantly limit HHS's ability to implement or enforce new policies through sub-regulatory guidance that did not go through notice-and-comment rulemaking. In issuing the proposed rule, HHS noted that this is one component of the Department's broader regulatory reform initiative to guard against unlawful regulation through guidance, and safeguard the important principles of administrative law and procedure.

The proposed rule would apply to "guidance documents" as defined in regulations, and impose heightened requirements for "significant" guidance documents as discussed below. Notably, the proposal applies to all divisions within HHS, with the exception of the Food and Drug Administration (FDA), which operates under its own guidance practice regulations.

Comments on the proposed rule are due by **September 16, 2020.**

Definition of "Guidance Document" and "Significant Guidance Document"

HHS proposes to define "guidance document" based on the function of the document. Guidance documents would include any statements of general applicability intended to have effect on the prospective behavior of HHS-regulated parties, and that set forth "***policy*** on a statutory, regulatory, or technical or scientific issue," or otherwise interpret a statute or regulation. Guidance may be of any format, including without limitation, letters, memoranda, bulletins, and advisory documents, or video, audio or web-based information. While the proposed definition is broad, HHS proposes to set forth specific exceptions. Importantly, guidance documents would not include internal HHS documents intended to guide the behavior of HHS itself, or HHS employees. Exceptions would also include, for example, internal legal advice or opinions, legal briefs and court filings, as well as pre-enforcement rulings directed at particular parties based on a specific set of facts, such as advisory opinions, notices of non-compliance, and letter rulings.

Guidance documents that are "significant" and subject to additional procedures would include those likely to lead to an annual effect on the economy of $100 million or more. In addition, "significant guidance documents" would include:

- documents that adversely affect in a material way the economy, productivity, competition, jobs or other enumerated issues,
- documents that create inconsistencies with actions taken by other agencies,
- documents that materially alter budgetary impact of entitlements, loan programs or grants, and
- documents that raise novel legal or policy issues arising out of legal mandates or the President's priorities.

As proposed, this language leaves significant room for interpretation as to what qualifies as a "significant guidance document."

Requirements Issuance and Use of Guidance Documents

Purportedly reiterating "existing legal principles" of HHS, the proposed rule would prohibit the issuance of any guidance document to establish legal obligations on regulated parties that are not reflected in enacted statutes or regulations promulgated thereunder. The rule will also require all guidance documents to include specific language stating that the document does not "have the force and effect of law" and is not "meant to bind the public in any way unless specifically incorporated into a contract." The language would further note that the document is intended only to provide clarity regarding existing requirements of the law. In addition, the guidance document would be required to include identifying information including, but not limited to, the citation to the statutory or regulatory provision that the document is interpreting or to which it is applying.

Requirements for Significant Guidance Documents

Any documents that are deemed to be significant guidance documents by HHS will be subject to additional requirements, including review and approval by the Secretary without delegation; submission for review by the Office of Management and Budget (OMB); and a 30-day public notice and comment period. HHS will also be required to publish responses to any major concerns raised during the comment period. The proposed rule would allow for exemptions to this process only if the Secretary and OMB agree that exigency, safety, health or other compelling cause warrants an exemption. There is also a potential process for OMB to make categorical determinations that certain classes of documents do not qualify as significant.

Guidance Repository

As modified by a subsequently issued correction notice, the proposed rule also will require that HHS maintain a repository of all guidance documents on its website at www.hhs.gov/guidance. All existing guidance documents currently in effect would need to be posted to the repository by November 16, 2020, or would otherwise be considered rescinded. Guidance documents issued after the effective date of the rule would need to be posted to the repository within three business days of issuance.

Administrative and Judicial Review

The proposed rule sets forth a process by which interested parties could petition HHS to withdraw or modify a guidance document for any of the following reasons: (1) the document imposes binding obligations on parties beyond those required by law or regulations; (2) the document is being used by a component of HHS to create additional legal obligations; or (3) HHS improperly failed to follow the issuance requirements set forth in the rules. Petitions would follow a timeline for HHS response within 90 business days unless the timeline is tolled to gather additional information from the requestor. Any determination by HHS would be considered a final agency action subject to judicial review.

Takeaways

This proposed rule reinforces prior issuances both from the President (Executive Order 13891) and the Department of Justice (January 2018) seeking to limit the enforcement and applicability of agency guidance not subject to notice and comment rulemaking. If finalized, this will solidify in regulation the limitations of agency guidance documents and provide a potential mechanism for challenging such documents through an administrative process that is subject to judicial review.