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HHS Seeks to Increase Transparency and Promote the Rule of Law in the Development and Maintenance of Agency Guidance

On August 20, 2020, the U.S. Department of Health and Human Services (HHS) issued a [proposed rule](#) which would add to existing regulations surrounding the agency's release and maintenance of guidance documents. Current HHS regulations only address guidance from the Food and Drug Administration (FDA) and the proposal would add the new good governance practice requirements for all of the other divisions of HHS besides the FDA.

This proposed rule is based in part on and consistent with [President Trump's Executive Order 13891](#) which sought to "promote the rule of law through improved agency guidance documents." Among other things, these new good guidance practices are seeking to:

- Increase accountability by ensuring that the public receives appropriate notice of new guidance;
- Guard against unlawful regulation and improve the fairness of guidance issued by HHS by not imposing obligations on regulated parties that are not already reflected in law; and
- Safeguard the important principles underlying the United States administrative law system.

The proposed rule would apply to "guidance documents," including those which have been deemed to be "significant" by HHS, other than those guidance documents issued by the FDA. Guidance documents are any "statement[s] of general applicability which [are] intended to have a future effect on the behavior of regulated parties and set a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of statute or regulation." The substance, rather than the format, will dictate whether something is treated as guidance under these rules. Something need not be in a formal written document to be considered guidance under these rules and may include letters, memoranda, circulars, bulletins,

advisories, and preambles, including video, audio and web-based formats. The critical factor is whether it includes statements of general applicability intended to govern the future behavior of regulated parties. For example, statements of technical or scientific information would not be considered guidance unless they are accompanied by a policy on or related to that information which is intended to affect future behavior of regulated parties.

In contrast, agency statements of more specific applicability would not be considered guidance under these rules. Examples include advisory or legal opinions directed to particular parties regarding specific circumstances, notices regarding particular locations, facilities or products, and correspondence with individual persons or entities would not be considered guidance because of their specific vs. general applicability nature. Existing regulations, pre-enforcement rulings, letter rulings, and no-action letters applying the law to specific facts would also not be considered guidance. However, it is important to note that material embedded in these documents that otherwise satisfies the definition of a “guidance document” will still be treated as guidance for purposes of these proposed rules.

The proposed rules also add special requirements for “significant guidance documents” which are defined as guidance documents which are likely lead to an annual effect on the economy of \$100 million or more, adversely affect the economy or a sector of the economy in a material way, which create serious inconsistencies or other interference with actions taken or planned by another agency, which materially alter the budgetary impact of entitlements, grants, user fees, loan programs or the rights or obligations of recipients thereof, or which raise novel legal or policy issues arising out of legal mandates or priorities of HHS. The threshold for determining whether a guidance document is likely to have an annual effect on the economy of \$100 million or more will be HHS’ assessment of the benefits, costs, or transfer impacts imposed by the guidance document. Under these proposed rules, HHS presumes that a guidance document which it deems as “significant” is in fact a legislative rule that must go through notice-and-comment rulemaking under the Administrative Procedures Act.

HHS recognizes the impact that guidance documents can have on the regulated parties, including adding significant regulatory burdens and costs. Due to this fact, guidance documents will now go through a significant notice requirement (at least a 30-day notice and comment period) and will need to be fully supported by duly enacted statutes and regulations. This will ensure that HHS's actions are fully supported by appropriate legal authority. Further, guidance documents must contain a disclosure indicating that they are not legally binding upon regulated parties. The required disclosure is: "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law."

The new proposed rule also adds additional requirements for the contents of the guidance documents. Each guidance document issued must contain the following information:

- The activities to which the and the persons to whom the guidance applies;
- The date HHS issued the guidance document;
- A unique agency identifier;
- A statement indicating whether the guidance document replaces or revises previously issued guidance, and if so, identifying the replaced guidance;
- A citation to the statutory or regulatory provisions that the guidance document relies upon; and
- A short summary of the subject matter covered.

Additionally, HHS proposes to substantially improve how it maintains all its guidance in an online repository. The proposal would require that HHS create an online database on its website which organizes and contains all guidance documents in a fully text searchable format. This will allow regulated parties to have a useful tool to access of the agency's guidance documents and to ensure that these guidance documents have been appropriately reviewed and adopted in accordance with these new good guidance principles.

Finally, these rules will create a procedure for regulated parties to petition for administrative and judicial review of whether a guidance document inappropriately creates new obligations or is being used by HHS to create new obligations. Any interested party would be able to petition HHS to withdraw or modify the guidance document. The guidance document must include clear instructions on how to properly file a petition for review. HHS must respond to all petitions within 90 business days.

If you have questions about how the new good guidance rule may affect you as a regulated party or are interested in submitting comments to these proposed rules, please contact [Matthew R. Wagner](#), [Bill Williams](#), or any attorney with Frost Brown Todd's [Insurance Regulation & Risk Management Group](#).

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