# Health Industry Alert

Akin Gump
STRAUSS HAUER & FELD LLP

## HHS Proposes to Rein in its Use of Regulatory "Dark Matter"

September 14, 2020

### Key Points

- HHS is overhauling its process for developing interpretive guidance documents under a new Proposed Rule.
- HHS proposes to no longer use "guidance documents" to establish broadly applicable legal obligations on the public that are not reflected in existing statutes or formal regulations.
- This Proposed Rule establishes a process for regulated entities to challenge the scope or application of existing guidance documents, creates a new system for stakeholder input on any new "significant guidance documents," and creates a pathway to judicial review.
- HHS has also released an RFI seeking feedback from the public on which of its existing, informal and non-binding guidance documents should be required to go through formal notice and comment rulemaking. That RFI closes October 12, 2020.

With relatively little fanfare, the United States Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking entitled "Department of Health and Human Services Good Guidance Practices" on August 20, 2020.[1] As explained further below, this rulemaking is a response to Executive Order 13891 and proposes to establish clarity regarding how the Department and its agencies (except for the Food and Drug Administration (FDA))[2] will issue sub-regulatory guidance documents and how the public can engage with the Department in this process. The stated purpose of the Proposed Rule is "to increase accountability, improve the fairness of guidance issued by the Department, guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system."

Guidance documents, sometimes referred to as sub-regulatory guidance, are what regulatory agencies often use to announce policy, establish agency procedures or provide an interpretive gloss on what may be ambiguous statutory or regulatory provisions. Guidance documents take a variety of forms, including Frequently Asked


**Contact Information**

**If you have any questions concerning this alert, please contact:**

**John R. Jacob**
Partner
jjacob@akingump.com
Washington, D.C.
+1 202.887 4582

**Kelly M. Cleary**
Partner
kcleary@akingump.com
Washington, D.C.
+1 202.887.4020

**Daniel David Graver**
Counsel
dgraver@akingump.com
Washington, D.C.
+1 202.887.4562

Questions (FAQs), informational bulletins, compliance guides and memoranda. Guidance can also be provided through video, audio or Web-based formats.

Sub-regulatory guidance has been dubbed regulatory "dark matter." It exists in seemingly boundless quantities alongside statutory law and formally promulgated rules under the dictates of the Administrative Procedure Act (APA). How the form and function of sub-regulatory guidance affects the world around it remains a matter of extensive debate and often spurs uncertainty—and litigation. This type of guidance is technically not binding on the public and, therefore, agencies issue it with relatively little bureaucratic red tape and zero opportunity for public comment. To be sure, however, it is often used as a tool to shape the prospective behavior of regulated entities.

In recent years, there have been a number of important reforms aimed at curbing the inappropriate use of sub-regulatory guidance. At the Department of Justice (DOJ), for instance, a pair of memos from then-Attorney General Jeff Sessions and United States Associate Attorney General Rachel Brand curbed that Department's use of sub-regulatory guidance and limited the ways in which other agencies' guidance could be used in civil enforcement actions (like the False Claims Act) and in criminal prosecutions. Taking DOJ's cue, the President issued a pair of Executive Orders (EOs) applying these principles across the executive branch, directing every department and agency to adopt their own reforms to curb inappropriate issuance and use of guidance for enforcement purposes (EOs 13891 and 13892, respectively). This Proposed Rule implements EO 13891 at HHS.

A proposal by HHS to follow the rulemaking requirements of APA may seem unremarkable. But several of the proposed changes to agency guidance practice and procedure could carry brass tacks practical significance for the health care industry, as discussed below.

## De-Risking Regulatory Compliance Decisions

For heavily regulated industries like health care, a functional compliance compass is key to survival. It is important to know what the law is—if you break it, you could be subject to significant financial penalties—or worse. But knowing what the law is not can be important too—this knowledge gives organizations freedom to make decisions that may be informed by, but not required by, a regulator's preferences or recommendations.

For example, the Centers for Medicare & Medicaid Services (CMS) issued COVID-19 guidance to State Survey Agency Directors on March 13, 2020, which stated that nursing homes should actively screen employees for fever and respiratory symptoms. If you are running a nursing home that is short-staffed, do you need to shift staff away from other duties to screen for "respiratory symptoms"? Is this a suggestion or a legally binding requirement? And what do you do if CMS decides to try and enforce this as a Medicare Condition of Participation?

If finalized, this Proposed Rule, in theory, will sharpen regulatory shades of gray to something closer to defining what are, in fact, black-and-white legal obligations. HHS is, from the ground up, attempting to reinvent its interpretive guidance process and de-risking regulatory compliance decisions across the health care landscape. A potential side benefit, of course, would be the establishment of processes that would also reduce the amount of litigation over the import and impact of sub-regulatory guidance.

Under the Proposed Rule, any generally applicable "guidance document" intended to have future effects on the behavior of regulated parties by setting a department policy or interpreting a statute or regulation will be subject to additional oversight. More specifically, the HHS, Office of General Counsel, after discussions with senior officials within the Department, would make a legal determination regarding the following: (1) whether a document is excluded from the term "guidance document;" (2) whether a purported "guidance document" is, in fact, a legislative rule that must go through formal notice and comment rulemaking; or (3) whether the contents of a certain document related to Medicare should nonetheless go through formal rulemaking because of the heightened formal rulemaking requirement dictated by the Supreme Court in Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019).

In parallel with this Proposed Rule, HHS also released a Request for Information (RFI) seeking feedback from the public on which of its existing, informal and non-binding guidance documents should be reissued as formal regulations through formal notice and comment rulemaking procedures because they are not, in fact, guidance documents as defined in the Proposed Rule. That RFI closes October 12, 2020.

Under the Proposed Rule, once a determination is made that a document is, in fact, a "guidance document," then HHS would be required to set forth precise language (provided in the Proposed Rule) in each document that makes the following clear: (1) the contents do not have the force of law; (2) the guidance does not bind the public in any way; and (3) the guidance is only meant to provide clarity regarding existing requirements under the law. Moreover, each guidance document issued after the Final Rule would also need to include the following information: "(1) The activities to which and the persons to whom the guidance applies; (2) the date HHS issued the guidance document; (3) a unique agency identifier; (4) a statement indicating whether the guidance document replaces or revises a previously issued guidance document and, if so, identifying the guidance document that it replaces or revises; (5) a citation to the statutory provision(s) and/or regulation(s) (in Code of Federal Regulations format) that the guidance document is interpreting or applying; and (6) a short summary of the subject matter covered in the guidance document."

## Further Safeguards and Public Input Regarding Significant Guidance

This Proposed Rule also raises up a heightened category of guidance that is considered significant: "Significant guidance documents" are defined as follows:

*[A] guidance document that is likely to lead to an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866, Regulatory Planning and Review.*

HHS will make the determination regarding whether guidance is significant and it is HHS' presumption that a significant guidance document is actually a legislative rule that must go through formal notice and comment rulemaking. Therefore, HHS believes

that only a relatively small subset of guidance documents would satisfy the "significant" definition.

Once HHS determines that a document is a significant guidance document, it would submit that document to the Office of Information and Regulatory Affairs (OIRA) for review. Economically significant documents (impact on the economy of $100 million or more) would also have to undergo a separate Regulatory Impact Analysis. Finally, under the requirements of the Proposed Rule, the Secretary, on a non-delegable basis, would have to approve any significant guidance document before its release.

Before HHS releases any significant guidance document, however, the Proposed Rule also sets forth the requirement of a public notice and comment period of at least 30 days. HHS would publish a public notice in both the Federal Register and the guidance repository (described below). This public notice would define the comment period and process. After the close of the comment period, HHS would be required to review all comments and provide a public response to all of the major concerns raised. Only then would HHS be able to publish formally the significant guidance document.

## Making Guidance Navigable through a Central Repository

Another notable proposal in the rulemaking is that HHS also plans to end the interpretive guidance scavenger hunt that regulated entities often have to undertake. The Proposed Rule, if finalized, would require HHS to compile all enforceable guidances at "www.hhs.gov/guidance" by November 16, 2020.[3]

The guidance repository would be fully searchable. Interestingly, any guidance not listed by the deadline is deemed rescinded. If the Department is interested in having any rescinded guidance included in the repository, it would need to follow the procedures outlined in the rulemaking for new guidance in order to have it included.

## Stakeholders Have an Opportunity to Petition for Administrative and Judicial Review

Significantly, the Proposed Rule also sets forth a process for regulated entities to challenge whether a guidance document actually creates new obligations or is being used by HHS (or one of its components) to create new obligations. A stakeholder could also petition HHS to review HHS' improper exemption of a document from the procedures set forth in the rulemaking.

An interested petitioner would first be able to ask in writing that HHS remedy the perceived deficiency by withdrawing or modifying the guidance document. The guidance repository would contain all the necessary instructions for submitting such a petition and who would be responsible for reviewing the petition in the Department. In general, HHS would have 90 days to respond to the petition, which would then become the final agency decision reviewable in court.

## Final Thoughts

On its face, this Proposed Rule would provide clarity of process, transparency, opportunities for public engagement and judicial review. If finalized, this certainly seems to be a positive development for entities regulated by HHS, which would clearly reduce the amount of dark matter sub-regulatory guidance floating around the Department. But the devil is in the details and the implementation, and it is easy to see

how these new processes would be championed by the lawyers in the Office of General Counsel, but looked at quite differently by the staff actually driving and developing the policies of the Department.

Comments on the Proposed Rule are due no later than 11:59 PM on September 16, 2020. Given the short comment period, the fact that the rollout of this Proposed Rule was given relatively little fanfare, and the rapidly approaching dates proposed for responses to the RFI (October 12) and postings to Guidance Repository (November 16), it seems clear that the Department has made finalizing this rulemaking a near-term priority. As a result, it is reasonable to expect a Final Rule with relatively few significant changes to be published before the end of the year.

1. A correction to this Proposed Rule was published on August 26, 2020.

2. The FDA already instituted its own good guidance principles and is expected to further amend those existing principles in response to EO 13891.

3. The date was changed from November 2, 2020, to November 16, 2020, in the correction to the Proposed Rule published on August 26, 2020.

akingump.com