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New OMB review process could impede FDA issuance of guidance documents

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Starting on May 11, 2019, there will be an additional layer of government review that may slow down the issuance of certain U.S. Food and Drug Administration (FDA) guidance documents. On April 11, 2019, the Office of Management and Budget (OMB) issued a Memorandum for the Heads of Executive Departments and Agencies (Memo) that establishes new procedures for federal agencies that issue guidance documents, including FDA.

Enhancing OIRA's centralized review of policymaking

Although the subject of the Memo is identified as "Guidance on Compliance with the Congressional Review Act," arguably the most significant implications of the Memo relate not to review of guidance documents by Congress but by OMB's Office of Information and Regulatory Affairs (OIRA). This new directive expands OIRA's role in reviewing and assessing guidance documents, which will enhance OIRA's centralized control of policymaking. It may also have the effect of discouraging agencies from providing transparency through guidance about their enforcement policies and interpretations of statutes and regulations they administer.

In the past, FDA rarely submitted guidance documents for review by OIRA because Executive Order 12866, regarding centralized review of regulatory actions, has been interpreted by FDA and most agencies to cover regulations, not guidance documents. The Memo acknowledges that "OIRA does not consistently receive" guidance documents from agencies through the centralized review process under this executive order. However, the Memo states that the Congressional Review Act (CRA) provides for OIRA review of all "rules" to determine whether they are "major" in terms of their importance and economic impact.

Among other things, a determination that a rule is major triggers a Government Accountability Office (GAO) report and a delayed effective date, during which Congress may consider whether it will rescind the rule through a resolution of disapproval passed by both houses of Congress and signed by the president. During the Trump administration, the CRA was used to invalidate 14 Obama-era regulations, although the 1996 law had only been used one time before that.

Expanding OIRA and CRA review to cover guidance documents

Significantly, the Memo advances a literal interpretation of the scope of the CRA, broadly interpreting "rule," consistent with the Administrative Procedure Act, to include, with few exceptions, guidance documents, policy statements, and interpretive rules. Agencies will need to submit guidance for a CRA determination by OIRA at least 30 days before public issuance, and if

OIRA designates the guidance as major, agencies are to delay the effective date by 60 days. In addition, agencies will need to start submitting guidance documents to Congress along with a report identifying whether OIRA determined that the guidance is major.

The Memo summarizes the CRA definition of a "major" rule, which is based on a finding by OIRA that the rule "has resulted in or is likely to result" in the following:

- An annual effect on the economy of US$100 million or more.
- A major increase in costs or prices for consumers; individual industries; federal, state, or local government agencies; or geographic regions.
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets.

The Memo asserts that the CRA definition of "major" sweeps very broadly in that "a rule may qualify as major…if it imposes disproportionate costs on a particular group in comparison to the burdens experienced by other groups or the benefits experienced by the burdened group."

Requiring economic analyses of guidance documents

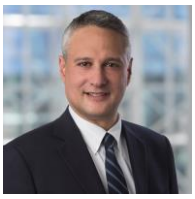
Agencies will need to submit to OIRA an economic analysis of the guidance documents submitted for CRA review. The Memo states: "Insufficient or inadequate analysis may delay OIRA's determination and an agency's ability to public a rule and to make the rule effective." This signals that agencies will need to devote additional resources to conduct these newly required economic analyses.

The economic analyses of guidance documents will be uniquely challenging for agencies because guidance documents are, by definition, nonbinding, and the economic effects, if any, may be more indirect and thus harder to quantify. The Memo recognizes the quantification challenge in assessing whether a rule is major and suggests that a "qualitative analysis" will be acceptable when a quantitative analysis is not "reasonably possible."

In the past, OMB has recognized in the Final Bulletin for Agency Good Guidance Practices that the costs associated with guidance documents are "dependent on third party decisions and conduct." 72 FR 3432, 3435 (Jan. 25, 2007). Similarly, OMB stated that "guidance documents *often will not be amenable to formal economic analysis* of the kind that is prepared for an economically significant regulatory action." *Id.* (emphasis added).

Yet, the Memo indicates that OIRA will "designate certain categories of rules as presumptively not major in order to prioritize the evaluation of rules more likely to be major." In light of the fact that FDA issues thousands of guidance documents each year, the burden to review all federal agency guidance documents and economic analyses would be substantial for OIRA. How this provision – establishing presumptively nonmajor categories of guidance – is implemented will be critical to assess the impact of the Memo on agency guidance documents. We will continue to monitor this issue and report on how this OMB Memorandum may affect FDA guidance development.

Contacts



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