

New OMB Policy Will Likely Reduce Informal Agency Guidance

April 22, 2019

On April 11, 2019, acting director of the Office of Management and Budget (OMB) Russell Vought announced a policy for review of federal agency rules and guidance that represents a significant change of process for issuance of informal guidance materials and can be expected to decrease informal agency guidance. The directive, in the form of a memorandum to all heads of executive departments and agencies, requires agencies to submit to OMB's Office of Information and Regulatory Affairs (OIRA) a summary of any proposed guidance document or rule and, in most cases, a detailed analysis of the expected impact of the proposed guidance or rule. Following OIRA's review, Congress will have the option of review pursuant to the Congressional Review Act. While Congress typically does not exercise the option, it may invalidate any rule through a joint resolution of disapproval, which is subject to presidential veto.

Currently, many federal agencies often disseminate their interpretations of statutory and regulatory requirements via informal guidance that is not presented to OIRA or Congress. For example, the Food and Drug Administration (FDA) routinely issues many types of guidance, including: to explain how to meet the requirements of a technical regulation governing safety or efficacy; to indicate what a sponsor might include in a medical product application; or to explain how the agency will exercise enforcement discretion when implementing a new statutory provision or regulation. The U.S. Environmental Protection Agency (EPA) likewise uses guidance documents to address a wide range of topics, including to announce policy changes, for instance its recent reversal of the "Once In, Always In" policy that precluded a facility once classified as a "major source" under the Clean Air Act from subsequently altering that classification. Some independent agencies also utilize informal guidance. The Federal Trade Commission's (FTC) Bureau of Consumer Protection, as an example, issues guidance to businesses on advertising and marketing topics such as health claims and environmental benefit claims like "green" and "eco-friendly."

The Vought memorandum explicitly recognizes an expansive definition of "rule" that facially encompasses all agency guidance materials, including of independent agencies, and requires them to be presented to OIRA at least 30 days prior to publication (unless designated by OIRA as not "major") and then to Congress as prescribed by the Congressional Review Act. This will be a substantial departure from

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current practice where most agency guidance is not presented to OIRA (and thus also not to Congress).

In addition, the memorandum establishes a default presumption that any rule, including guidance materials, is subject to a rigorous process for determination of whether it constitutes a “major rule.” The presumption applies without regard to the statutory definition of “major rule” (viz., a rule that will cause an annual effect on the economy of \$100,000,000 or more, a major cost or price increase, or significant adverse effects on employment or other economic indicators). The memorandum states that OIRA “anticipates” identifying certain categories of rules as “presumptively not major” but leaves that identification to OIRA’s discretion and provides no specifics on how it will be made, other than that OIRA will “work with senior agency officials.”

Clients should anticipate a reduction in informal agency guidance once the Vought memorandum takes effect on May 11, 2019. They also may see a spike in guidance issuing before the effective date. Clients may wish to consider suggesting to OIRA, perhaps through their regulating agencies, that particular types of guidance should be deemed “presumptively not major.”

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