

## Publications

### *Client Alert: USEPA Issues New Rule Establishing Procedures for Issuance of Guidance Documents*

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Anthony J. Giuliani

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**CLIENT ALERT** | 9.24.2020

The following is a summary of USEPA's newly promulgated rule establishing procedures for issuance of EPA guidance documents consistent with Executive Order (EO) 13891 "Promoting the Rule of Law Through Improved Agency Guidance Documents" (Oct. 15, 2019). In essence, the rule does three things.

- First, it establishes what a guidance document must contain in terms of identification and content.
- Second, it provides procedures for public notice of and comment on significant guidance documents.
- Third, it provides procedures for the public to petition for the modification, withdrawal or reinstatement of guidance documents.

A "guidance document" is defined as "an Agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation." (40 CFR § 2.503). There are several exclusions from the definition which includes, among others, rules, certain procedural rules, Agency adjudications, internal guidance not intended to have a substantial future effect on the behavior of regulated parties, Agency statements of specific applicability such as advisory or legal opinions directed to a specific party but not intended to apply generally.

A significant guidance document is defined as any guidance document that has been determined to be significant pursuant to EO 12866 and 13891 (40 CFR § 2.503). EO 12866 defines a "significant regulatory action", in part, as one that has an annual effect on the economy of \$100 million or more or has a material adverse affect on a sector of the economy, the environment, public health, etc. EO 13891 uses the EO 12866 definition to define a "significant guidance document."

An “active guidance document” is a “guidance document or significant guidance document in effect that EPA expects to cite, use or rely upon.” (40 CFR § 2.503). For public access, the rule requires that all active guidance documents shall appear on EPA’s Guidance Portal on its website. (40 CFR § 2.504).

The rule sets minimum requirements for guidance documents such that each include the term “guidance”, identify the issuing office, date of issuance, the activities to which it applies, and citations to the statute or rule to which it applies. (40 CFR § 2.505 (a) (1)-(6)). It also requires that the guidance document note if it is a revision to a previous guidance document and identify the guidance being modified or replaced, include a summary of the subject matter at the beginning of the document and include the disclaimer that the guidance document does not have the force and effect of law and is not binding except as authorized by law or contract. (40 CFR § 2.505(a)(7)-(9)). If it is authorized by law or contract to be binding, it must contain a statement to that effect. (40 CFR § 2.505(a)(9)). A guidance document issued by an EPA regional office must be approved by an Assistant Administrator of the relevant office at EPA headquarters. (40 CFR § 2,505(b)). The guidance document must also avoid using terms such as “shall, must, required or requirement” unless they describe a statutory or regulatory requirement. (40 CFR § 2.505 (c)).

With certain limited exceptions, the rule requires that issuance or withdrawal of significant guidance documents be issued in draft for public comment with at least a 30 day comment period with notice in the Federal Register. (40 CFR § 2.506 (a)-(c)). Public comments will be available in a docket or on the EPA website, and EPA’s response to comments will be included in the final significant guidance document or in a companion document. (40 CFR § 2.506 (c)). The EPA will publish notice in the Federal Register of its issuance, reinstatement, modification or withdrawal. (40 CFR § 2.506 (e)). Prior to issuance, the EPA Administrator, or other Presidentially-appointed EPA official will approve the significant guidance document. (40 CFR § 2.506(f)).

The public may submit a petition to EPA for the modification or withdrawal of an active guidance document and reinstatement of a rescinded guidance document. (40 CFR § 2.507 (a)). The petition must address the guidance document itself rather than addressing only the underlying statutory or regulatory text, and it must be submitted electronically through the Guidance Portal or by paper mailing to EPA’s designated address on the Guidance Portal. (40 CFR § 2.507 (a)(2)-(b)). The petition should include a heading designating the type of petition being filed (modification, withdrawal or reinstatement), contact information for the petitioner, identification of the guidance document at issue, nature of the relief sought, an explanation of the petitioner’s interest in the requested action, identification of specific text to be modified or withdrawn, and rationale for the petition. (40 CFR § 2.507 (c) and (d)). EPA will make information about the petition publicly available. (40 CFR § 2.507 (e)). If a petition fails to meet the requirements for submission, EPA has discretion to treat it as properly filed but is not required to do so. (40 CFR § 2.507 (f)). EPA has at least 90 days to respond, and may take up to 90 days longer if needed in which case it will notify the petitioner stating the reason for the delay and an estimated response date. (40 CFR § 2.507 (g)).

If you questions about the new rule please contact Anthony Giuliani or your Vorys attorney.