



ATTORNEY GENERAL ENDS AGENCY RULEMAKING THROUGH GUIDANCE DOCUMENTS

JANUARY 2018

On November 16, 2017, Attorney General Jeff Sessions issued a memorandum which calls for an end to government agencies regulating through guidance documents, as if guidance documents were equivalent to rule of law. In his memo Sessions reminded the Department of Justice that the fair and impartial administration of justice requires that the Department must abide by constitutional principles and follow the rules imposed by Congress and the President when promulgating regulations.

Sessions noted that the Administrative Procedure Act requires government agencies to use, in most cases, notice-and-comment rulemaking when purporting to create rights or obligations which are binding on members of the public or the agency. Sessions explained that agencies may use guidance and similar documents to educate regulated parties through plain-language restatements of existing legal requirements or to provide non-binding advice on technical issues through examples or practices to guide the application or interpretation of statutes and regulations. However, he warned that guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch, or to create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.

Sessions announced that, contrary to prior practices, government agencies may no longer issue guidance documents that purport to create rights or obligations binding on the individuals or entities outside the Executive Branch. Moreover, he directed government agencies to immediately adhere to the following principles when issuing guidance documents:

- Guidance documents should identify themselves as guidance, disclaim any force or effect of law, and avoid language suggesting that the public has obligations that go beyond those set forth in the applicable statutes or legislative rules.
- Guidance documents should clearly state that they are not final agency actions, have no legally binding effect on persons or entities outside the federal government, and may be rescinded or modified in the Department's complete discretion.
- Guidance documents should not be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation.
- Guidance documents should not use mandatory language such as "shall," "must," "required," or "requirement" to direct parties outside the federal government to take or refrain from taking action, except when restating—with citations to statutes, regulations, or binding judicial precedent—clear mandates contained in a statute or regulation. In all cases, guidance documents should clearly identify the underlying law that they are explaining.
- To the extent guidance documents set out voluntary standards (e.g., recommended practices), they should clearly state that compliance with those standards is voluntary and that noncompliance will not, in itself, result in any enforcement action.

Since issuing his memorandum, Sessions has already repealed 25 guidance documents that the Department's Regulatory Reform Task Force had deemed to be unnecessary, inconsistent with existing law, or otherwise improper. Although none of the repealed guidance documents directly affect the compounding industry, the Task Force continues to review existing guidance documents to repeal, replace, or modify.

LINKS:

Prohibition On Improper Guidance Documents (11/16/17)

<https://www.justice.gov/opa/press-release/file/1012271/download>

Attorney General Jeff Sessions Rescinds 25 Guidance Documents (12/21/17)

<https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-rescinds-25-guidance-documents>

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