



DOJ Limits the Use of Agencies' Guidance Documents in Civil Enforcement Actions

The Department of Justice ("DOJ") recently issued a memorandum limiting the ability of its litigators to use agency guidance documents in civil enforcement actions against private parties.

The memo expands on a directive the Attorney General issued last fall prohibiting DOJ from issuing guidance documents that impose binding standards on the public without going through notice-and-comment rulemaking. The new memo—sent on January 25, 2018, by the Associate Attorney General to all DOJ lawyers who engage in affirmative civil enforcement—applies that preference for notice-and-comment regulations to guidance documents issued by other federal agencies.

The memo directs DOJ litigators not to use their enforcement authority "to effectively convert agency guidance documents into binding rules" and not to use "noncompliance with guidance documents as a basis for proving violations of applicable law." DOJ lawyers may continue to use guidance documents for certain narrow purposes—such as to show that a party that read a guidance document explaining certain statutory or regulatory requirements had knowledge of those requirements. But because "agency guidance documents cannot create any additional legal obligation," DOJ attorneys may not treat a failure to comply with an agency's guidance document as presumptive or conclusive proof that a party violated the underlying statutory or regulatory requirement on which the guidance had expanded.

The new policy applies to suits on behalf of the United States to recover federal funds lost to fraud or other misconduct, including False Claims Act suits that DOJ initiates or in which it intervenes. In that respect, the policy may significantly affect cases involving the health care and life sciences industries, given the Food and Drug Administration's historical reliance on Draft and Final Guidance documents in lieu of regulations and the Centers for Medicare and Medicaid Services' reliance on sub-regulatory guidance, including various manuals. The DOJ policy also covers actions to impose penalties for health, safety, civil rights, or environmental violations.

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