

Litigation Alert

January 29, 2018

DOJ Limits Use of Guidance Documents in Affirmative Civil Enforcement Actions

On January 25, 2018, the Associate Attorney General directed the Department of Justice (DOJ) not to rely on agency guidance documents to establish a violation in affirmative civil enforcement (“ACE”) cases. She issued the directive through a memorandum to the heads of the DOJ civil litigating components and the United States Attorneys titled, “[Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases](#).” Agency guidance documents include letters to industry, policy manuals, handbooks and Frequently Asked Questions (FAQs).

Under the directive, DOJ “may not use its enforcement authority to effectively convert agency guidance documents into binding rules,” and “may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases.” However, agency guidance documents may be permissibly used to simply explain or paraphrase existing statutes or regulations, and DOJ may permissibly use evidence that a party read a guidance document in proving requisite knowledge of a statutory or regulatory mandate.

Clients should be aware of situations where DOJ or agencies cite guidance documents in the context of compliance actions, and they should consider whether the January 25 directive may be applicable. Historically, DOJ and agencies have at times cited guidance documents in compliance actions. Although this directive applies to DOJ, it may have broad impact across the federal government, as DOJ litigates enforcement actions for most federal agencies, including U.S. Department of Health and Human Services (HHS) agencies like the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS).

The January 25 directive builds on a directive issued in November 2017, that prohibits DOJ components from using guidance documents to create rights or obligations or to establish binding requirements (applicable outside the Executive Branch). The [November directive](#) explains that DOJ components may not issue guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. Both the November and January directives are part of the Administration’s ongoing efforts to reduce regulation.

The newly issued directive on guidance documents applies to both future ACE actions and ACE actions pending as of January 25, 2018.

Contact Information

If you have any questions concerning this alert, please contact:

Caroline L. Wolverton

cwolverton@akingump.com

202.887.4107

Washington, D.C.

Howard R. Sklamberg

hsklamberg@akingump.com

202.887.4055

Washington, D.C.