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Incorporating government guidance in compliance programs still recommended, despite DOJ declarations

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Within just weeks of each other in February and March of 2017, the U.S. Department of Justice (DOJ) and the U.S. Department of Health and Human Services' Office of Inspector General (OIG) issued separate guidance documents that healthcare organizations may use to design, implement, evaluate, and improve their compliance programs. Months later, on November 16, 2017, Attorney General Jeff Sessions released a memorandum prohibiting the DOJ from issuing binding guidance documents.[1] In renewing this commitment, the Associate Attorney General Rachel Brand released another memorandum in January 25, 2018 that prohibits the DOJ from using noncompliance with guidance documents to prove violations of the law in affirmative civil enforcement actions.[2]

This article provides a brief overview of the key compliance documents and memoranda issued by DOJ and OIG, so that healthcare organizations may incorporate the government's declarations when assessing and implementing their compliance programs.

The DOJ's memoranda prohibiting binding guidance documents

Through the release of the two memoranda, the DOJ minimized the strength that agency-issued guidance documents carry, now and in the future. In the November 2017 memorandum, Attorney General Sessions declared that, effective immediately, the DOJ will not engage in past practices of issuing guidance documents that create binding obligations or rights for parties outside of the Executive Branch (e.g., healthcare organizations). While recognizing that guidance documents are appropriate to educate regulated parties, the memorandum seeks to prevent the DOJ from circumventing rulemaking processes (e.g., notice and comment periods) that administrative agencies typically must follow when creating rules and obligations.

The November 2017 memorandum directs the DOJ to follow several principles when issuing guidance documents, which emphasize that: (1) guidance documents do not have the force or effect of law; (2) guidance documents cannot create obligations for the public beyond those established in statutes and regulations; and (3) non-compliance with voluntary standards, such as recommended practices, will not "in itself" result in any enforcement action. The Attorney General also directed the Associate Attorney General to identify existing guidance documents to repeal, replace, or modify in light of the outlined principles.

The memorandum does not apply to the DOJ's adjudicatory actions that bind only the parties involved or documents informing the public of the DOJ's enforcement priorities or considerations when exercising its prosecutorial discretion. It also does not apply to the DOJ's internal directives and materials for its personnel on how to carry out duties or to positions taken by the DOJ in litigation. The DOJ Fraud Section's "Evaluation of Corporate Compliance Programs" (discussed later in this article) is one example of a DOJ-issued document that

may qualify as exempt from the November 2017 memorandum and is still relevant to healthcare organizations, absent a declaration to the contrary.

Further minimizing the control of agency guidance documents, the January 2018 memorandum prohibits the DOJ from using its enforcement powers to convert guidance documents into binding rules, or using noncompliance with guidance documents to prove violations of the law in affirmative civil enforcement actions. The January 2018 memorandum clarifies, however, that certain reliance on agency guidance documents may still be proper to prove requisite intent or explain the underlying law. Because healthcare organizations are routinely subjects of affirmative civil enforcement actions (e.g., suits to recover monies allegedly lost to fraud, such as False Claims Act lawsuits, or to impose penalties for violations of federal healthcare laws), this memorandum clarifies that not every piece of guidance must be followed for fear that non-compliance will prove an underlying violation of the law.

With that said, healthcare organizations should not view the DOJ's recent declarations regarding guidance documents as an unencumbered blessing to scale back their compliance efforts, particularly when tailored to agency-issued guidance. Prudent healthcare organizations will still turn to agency-issued guidance documents regarding compliance programs and interpretations of healthcare law and regulations when implementing compliance programs and evaluating compliance efforts.