

## HEALTH CARE LITIGATION ALERT

5/2/18

### Department of Justice Issues Memorandum Regarding Civil Enforcement Actions

By [Sarah Costa](#), Associate

Recently, the Department of Justice (“DOJ”) issued a memorandum significantly limiting the use of guidance documents in civil litigation matters. Federal agencies often issue guidance documents to aid in the interpretation of existing statutes and regulations and to advise individuals of their legal rights and obligations. While the original purpose of these documents was to guide entities through a vague and complicated regulatory landscape, the DOJ and regulatory agencies have used these guidance documents as evidence that an entity violated a statute or regulation (i.e., failure to act in accordance with guidance documents was akin to violating the law which the guidance sought to explain). Now, the DOJ has expressly forbidden the use of guidance documents as akin to “binding law” in civil litigation cases.

As a result, prior to prosecuting a civil enforcement action, the DOJ will require administrative agencies to assess whether or not the case could be brought without reliance on guidance documents. This limitation, however, does not apply to the regulated entity defending against an enforcement action. Accordingly, defendants may introduce their compliance with a guidance document in an effort to prove they complied with a statute or regulation. In addition, while the inability to use a guidance document as conclusive proof of a regulatory violation will affect the way the DOJ assesses and litigates cases, it does not mean that the DOJ must cease using guidance documents completely. Guidance documents may continue to be used for proper purposes, such as to explain or paraphrase legal mandates or to show that a party had the requisite knowledge of a legal mandate.

This memorandum only applies to civil enforcement actions brought by the DOJ. It is unclear how this memorandum will effect enforcement actions brought by individual regulatory agencies through their own administrative law courts and independent administrative agencies that have the ability to litigate matters in federal court independent of the DOJ. These agencies may continue to hold that a violation of a guidance document proves that the underlying statute or regulation was violated. If these decisions are challenged on appeal, however, the guidance document will be treated as non-binding by the DOJ litigator. This may perhaps pressure administrative agencies and independent agencies to begin to treat guidance documents in the same manner as the DOJ.

This change may greatly affect the healthcare industry. Agency guidance is often relied upon in litigation matters, particularly Medicare coverage decisions and Office of Inspector General (“OIG”) advisory opinions, fraud alerts and bulletins. Being unable to rely on such guidance alone as evidence of a legal violation likely will affect the type and kind of cases brought by the DOJ.

For further information or to discuss the potential effects of this memorandum, we encourage you to contact one of the Roetzel attorneys listed below for a more detailed and necessary analysis of your specific circumstances.

#### Author

Sarah Costa  
[scosta@ralaw.com](mailto:scosta@ralaw.com)

Christina M. Kuta  
[ckuta@ralaw.com](mailto:ckuta@ralaw.com)

Michael Brohman  
[mbrohman@ralaw.com](mailto:mbrohman@ralaw.com)

#### Additional Contacts

Ericka L. Adler, Manager  
[eadler@ralaw.com](mailto:eadler@ralaw.com)

This Alert is informational only and should not be construed as legal advice. ©2018 Roetzel & Andress LPA. All rights reserved.  
For more information, please contact Roetzel’s Marketing Department at 330.762.7725.