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In a new memo, Attorney General Merrick Garland gave prosecutors at the Department of Justice (DOJ) the green light to incorporate subregulatory guidance, such as Medicare manuals, into their enforcement actions, reversing a position taken by the Trump administration.^[1] But Garland reiterated that guidance doesn't have the force of law, and "enforcement actions must be based on the failure to comply with a binding obligation, such as one imposed by the Constitution, a statute, a legislative rule, or a contract."

Garland rescinded the 2018 Brand memo^[2] on affirmative civil enforcement (ACE) actions, such as False Claims Act (FCA) lawsuits, and a related 2017 memo from former Attorney General Jeff Sessions, calling them "overly restrictive."^[3] The *Justice Manual* also will be updated accordingly.

The Brand memo, written by then-Associate Attorney General Rachel Brand, stated that "the Department should not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation." The scope of the Brand memo in health care was pretty broad. While all laws and regulations are always fair game for FCA cases because they have the force of law, the preambles to regulations, Medicare manuals and almost all guidance from the HHS Office of Inspector General (OIG) were out of bounds in the wake of the Brand memo.

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