WHITE PAPER
THE BRAND MEMORANDUM'S IMPACT ON THE FALSE CLAIMS ACT

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This Memorandum outlines the discussion I provided at the *Qui Tam* Litigation Group's CLE at the AAJ's Annual Conference, July, 2018.

I. Sessions Memorandum

On November 16, 2017, Attorney General Jeff Sessions published a memorandum (the "Sessions Memo"), in which he set forth a prohibition on the DOJ from promulgating guidance documents that create rights or obligations that bind regulated parties. In other words, if no statute or regulation requires or prohibits regulated parties to/from certain conduct, the Department of Justice cannot issue any guidance or instructions that would do so.

II. Brand Memorandum

On January 25, 2018, Associate Attorney General Brand issued a Memorandum (the "Brand Memo"), in which she expanded the reach of the Sessions Memo. She stated the DOJ may not use its enforcement authority to "effectively convert agency guidance documents into binding rules." In other words, resources such as Medicare Handbook provisions, on which many False Claims Act practitioners rely to establish false claims, may no longer form the sole basis for liability under the False Claims Act.

Brand notes that DOJ attorneys and False Claims Act ("FCA") practitioners may use agency guidance and instructions for a "proper purpose." For example, the Government may look to the Medicare Guidelines to show that a provider was aware of a particular mandate, thereby supporting the scienter requirement. The Brand Memo instructed that government officials shall

implement the policy immediately where "practicable" (i.e., in new cases, and pending cases where it makes practical sense).

III. Defendants' Positions

In response to the Brand Memo, Defendants have eagerly proffered views of how the Brand Memo changes the False Claims Act landscape in the potential defendants' favor. From the memoranda this writer has reviewed, defense counsel over state those positions. Nonetheless, it is important that the Relator's Bar remains mindful of the positions we may encounter as a result of the Brand Memo, and, consequently, I present them here.

We can expect that defense counsel will take a hardline position, forcefully stating that lack of medical necessity cannot form the basis of an FCA case. Because the Medicare statute and regulations do not define "medical necessity", practitioners have looked elsewhere, namely in the Medicare Handbooks and local and national coverage determinations (LCDs and NCDs) for such definitions. Through that analysis, Relators have asserted that because a procedure was not "reasonable and necessary" (based on Medicare guidelines, LCDs or NCDs), it was not medically necessary. The absence of medical necessity rendered the procedure non-compliant with the regulations. Such non-compliant procedure, therefore, supported a false claim under an implied certification theory (for the failure to comport with regulations). The Brand Memo certainly complicates and limits Relators from asserting an implied certification theory on such basis. Below, I will explore this issue, and make some suggestions on what I see as best practices to overcome this hurdle.

Defense counsel will also assert that Medicare does not require compliance with industry standards as pre-requisite for payment. Thus, where Relators may have previously looked to particular medical fields' standards of practice to show a provider's deviation from those, now,

Relators can no longer do so. So, if an oncologist is choosing to use a drug that the Association of Community Cancer Centers does not support, for instance, that alone cannot support a "lack of medical necessity" argument. Rather, the defense argument goes, Medicare should handle that matter administratively, perhaps denying claims. The "deviant" conduct, in other words, does not constitute a false claim.

Defendants will also argue that CMS can deal with Medicare coverage issues through administrative process and the FCA is not the appropriate tool to handle such matters.

Another area where we may the Brand Memo's impact is off-label marketing. Because the FDA regulations do not specifically prohibit such practice, defendants will argue that off-label marketing is not actionable under the FCA.

IV. AUSAs' Reaction to the Brand Memo

Because the Brand Memo only came out in January, it is still early to gauge the AUSAs' reaction. Some AUSAs remain unclear on what the Brand Memo means, so they are in a holding pattern on the relevant cases, not taking much action. Others, who first rejected a claim because it hinged on reasonable and necessary, have since reconsidered, realizing that a modifier 25[1] claim can be tied to a CMS form 1500, and thus, constitutes a knowing violation of the rules, forming a basis for false express certification claim.

Some False Claims cases were so far in the settlement process that (I surmise) it was "not practicable" to implement the policy. Two examples are cases that settled in the Spring of 2018: $4.1M settlement with Georgia Cancer Specialists, for fraudulent billing using modifier

[1] Modifier 25 is not a regulation, but rather a Medicare-imposed restriction on the filing of Medicare claims for services performed at the same visit as other services (for example, a minor surgical procedure at an evaluation visit), and thus, under the Brand Memo, not in itself an actionable basis under the FCA.

25; and FWC Urogynocology, also for fraudulent billing using modifier 25. https://www.justice.gov/usao-mdfl/pr/fwc-urogynecology-llc-agrees-pay-17-million-settle-false-claims-act-liability-misuse

Additionally, our firm was involved in a recent case where, pre-filing, the AUSA indicated he/she would not intervene in a case where modifier 25 formed the basis of the false claims. On the flip side, we have also had experience where the AUSA first rejected "reasonable and necessary" case based on a modifier 25, but then reconsidered and found that knowing violations of program rules can serve as basis for falsity in healthcare cases involving CMS form 1500.

V. Suggestions for Practice.

Again, because we find ourselves in the early stages of the interpretation of and repercussions from the Brand Memo, these practice suggestions are somewhat limited. That said, here are some analysis and practice tools we are considering. The main tool is to ground claims on regulations, using guidelines and instructions to show scienter. Research thoroughly what regulation a provider may have violated rendering the claims false. Then use LCDs, NCDs and guideline violations to bolster your claim.

Next, Relator's counsel must pay a attention to whether relevant sub-regulations went through notice and comment process. The overarching basis for the new policy enunciated in the Brand Memo is that guidelines and instructions did not have to go through such process. Thus, if the sub-regulations did, in fact, go through such process, that will aid in our discussions.

Remember that AUSAs and DOJ may still consider guidelines and instructions as factors; but those factors no longer carry a presumption or conclusion of fraud. The Brand Memo explicitly permits use of guidelines and instructions for a "proper purpose", so do not eliminate

those from your analysis and/or allegations. Further, knowing violations of Program rules should create basis for false certification case, so be sure to consider that as well.

Be mindful that ultimately, in healthcare fraud cases, the government wants to protect against patient harm. We must discourage providers from playing fast and loose with medical necessity. It is in the Medicare beneficiaries' best interest to eliminate patient harm as much as possible, and we should not lose sight of that in the morass of regulation and guideline discussions. Linking best practices in the medical fields to a regulation should assist in slowing the provision of unmedically necessary services.

Finally, to the extent we can, we should urge agencies to go through notice and comment process, which should firm up guidelines, instructions and sub-regulations as basis for False Claims Act cases. This will not only help in our *Qui Tam* practices, but it will have the benefit of protecting Medicare and Medicaid beneficiaries from those among medical professionals who wish to sacrifice patient care for greed.

If you have any questions regarding the foregoing, please visit my website: www.floridamedicarefraudlawyer.com and contact me.