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Are government and health care contracts the exception that swallows the Brand Memo's rule on FCA enforcement?

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One of the Trump administration's enduring goals has been to alleviate the burdens of complying with federal administrative rules. The U.S. Department of Justice has led those efforts, and the Brand Memo, issued by then-Associate Attorney General Rachel Brand in January 2018, has been a representative centerpiece.

The Brand Memo prohibits all "civil litigating components" of the DOJ from relying on "noncompliance with [agency] guidance documents" in affirmative civil litigation, including litigation filed under the False Claims Act.[1]

Following prior directives from Attorney General Jeff Sessions, the memo reiterates that guidance "cannot create binding requirements that do not already exist by statute or regulation."[2] Guidance can, however, "explain or paraphrase legal mandates from existing statutes or regulations."[3]

In the months since the memo's issuance, DOJ leadership has repeatedly reaffirmed its commitment to the positions the memo sets forth.[4] And, after months of pressure from Congress,[5] financial regulators have followed the DOJ's lead by issuing their own policies on the permissible (and impermissible) use of guidance.[6] Those are all welcome signs for regulated parties.

For government contractors, however, an important question remains: Under the Brand Memo, what happens when the government contract requires the contractor to abide by all agency guidance? (In this article we refer to government health care agreements and the private parties to those agreements as "government contracts" and "government contractors," respectively.)

That question is important, particularly when it comes to the FCA. The Brand Memo defines "guidance document" as "any agency statement of general applicability and future effect … that is designed to advise parties outside the federal Executive Branch about legal right and obligations."[7]

Government contracts are not agency statements of general applicability. They are agreements that set forth the obligations of the contracting parties. And here is the rub: Government contracts commonly include catch-all certifications that require contractors to abide by agency guidance.

In the Medicare context, for example, providers must "agree to abide by the Medicare laws, regulations, and program instructions" and "all applicable conditions of participation in Medicare."[8] Medicare Advantage Organizations must agree to comply with "applicable federal statutes, regulations, and policies (*e.g.*, policies as described in the Call Letter, Medicare Managed Care Manual, etc.)."[9]

Similarly, contracts with the Department of Veterans Affairs often require contractors to comply with "Federal laws, regulations, standards, and VA directives and handbooks."[10]

Under the Brand Memo, what happens when the government contract requires the contractor to abide by all agency guidance?

"Program instructions," "applicable conditions of participation," "policies," "standards," "agency directives," and "handbooks" (not to mention "etc.") fit squarely within the Brand Memo's definition of "guidance." So, under the memo, FCA enforcement cannot be based on alleged noncompliance with such guidance.

But what happens when a government contract incorporates that guidance and a private party agrees to comply with it by entering into the government contract? In that instance, one could argue that FCA enforcement is not based on noncompliance with guidance per se; instead, enforcement arguably is based on noncompliance with a bargained-for contractual obligation.

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So, under the Brand Memo, is FCA enforcement on the table or off the table for noncompliance with incorporated guidance?

Government contractors, relators' counsel, DOJ prosecutors and defense counsel have frequently asked that question since the Brand Memo was issued. The answer has significant implications because many government contracts include catch-all certifications.

Unfortunately, neither the memo nor DOJ statements about it directly answer the question. In addition, current and former DOJ prosecutors have expressed different opinions on the issue.

In the absence of a definitive answer, we turn to the memo's history and purpose as well as the DOJ's enforcement practices following its issuance. These factors suggest that the memo likely prohibits guidance-based FCA enforcement when a government contract generally incorporates guidance by way of a catch-all certification. When a government contract expressly incorporates specific guidance, however, the memo likely permits FCA enforcement based on noncompliance with that guidance.

HISTORY: THE PROBLEM WITH GUIDANCE

The imposition of legal obligations through guidance violates the notice-and-comment requirements of the Administrative Procedure Act.

In *Perez v. Mortgage Bankers Association*, Justice Antonin Scalia explained, "An agency may use interpretive rules to advise the public by explaining its interpretation of the law. But an agency may not use interpretive rules to bind the public by making law."[11]

Justice Scalia warned that, by deferring to agency guidance that purports to interpret statutes and regulations, the court has "allowed agencies to make binding rules unhampered by notice-and-comment procedures."[12]

Since 2015, federal agencies and Congress have been more vocal in acknowledging the problem. For example, on Nov. 16, 2017, Sessions issued a department-wide memorandum stating, "It has come to my attention that the department has in the past published guidance documents — or similar instruments of future effect by other names, such as letters to regulated entities — that effectively bind private parties without undergoing the rulemaking process."[13]

On April 17, U.S. Rep. Blaine Luetkemeyer, R-Mo., the chairman of the House Financial Services Committee, questioned Vice Chairman Randal Quarles of the Federal Reserve Board of Governors about "concerns that guidance was being treated by examiners as creating binding obligations on the institutions they supervise."[14]

Quarles admitted that, "in some instances, the practices of the banking regulators have blurred the role between guidance and rules."[15] He also expressed a desire to make sure that guidance "doesn't supplant the rulemaking process."[16]

The problem with guidance does not stop with its circumvention of the APA's notice-and-comment requirement. At some federal agencies, guidances had grown "so voluminous they cannot be read," hence threatening "constitutional norms" of fair notice and due process.[17]

> The Brand Memo likely prohibits guidance-based FCA enforcement — even when a government contract generally incorporates guidance with a catch-all certification.

During his tenure as a federal appellate judge, Neil M. Gorsuch summed up the problem in his decision in *Caring Hearts Personal Home Service Inc. v. Burwell*.[18] In that case, the Centers for Medicare and Medicaid Services incorrectly applied its own voluminous guidance — "literally thousands of new or revised guidance documents (not pages) [issued] every single year [that] providers must follow exactingly if they wish to provide health care services to the elderly and disabled under Medicare's umbrella."[19]

Writing for a panel of the 10th U.S. Circuit Court of Appeals, then-Judge Gorsuch warned that such unrestrained issuance of guidance had created "a strange world where the government itself — the very 'expert' agency responsible for promulgating the 'law' no less — seems unable to keep pace with its own frenetic rulemaking. A world Madison worried about long ago, a world in which the laws are 'so voluminous they cannot be read' and constitutional norms of due process, fair notice and even the separations of powers seem very much at stake."[20]

For government contractors, that strange world is even more treacherous given the threat of the FCA. Noncompliance with the complex, voluminous and sometimes internally inconsistent regime of administrative guidance could mean treble damages and penalties of over $20,000 for each false claim — i.e., knowingly submitting claims for goods or services that do not comply with guidance.

Before the Brand Memo the DOJ pursued this approach. For example, in *U.S. ex rel. Poehling v. UnitedHealth Group*, the DOJ alleged that Medicare Advantage "organizations must comply with requirements set forth in statutes, such

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as the FCA, and guidance documents, such as the Medicare Managed Care Manual, the Medicare Prescription Drug Benefit Manual, and Medicare Advantage operating instructions."[21]

On June 14, then-acting Associate Attorney General Jesse Panuccio acknowledged those concerns in his address to the American Bar Association's 12th National Institute on Civil False Claims Act and Qui Tam Enforcement.[22] He emphasized that failure to restrain the use of guidance in affirmative litigation is inconsistent with "the rule of law, fair notice and due process."[23]

PURPOSE: ADDRESSING THE PROBLEM

Under Sessions, the DOJ has attempted to address those problems. In his Nov. 16, 2017, memorandum to all DOJ components, Sessions stated, "Effective immediately, department components may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch."[24]

And "[t]o avoid circumventing the rulemaking process," the attorney general also directed the Regulatory Reform Task Force, led by then-Associate Attorney General Brand, to review existing DOJ documents and recommend candidates for repeal or modification in accordance with the policy.[25] Since then the attorney general has rescinded a number of guidance documents.[26]

On Jan. 25, the Brand Memo took the Sessions Memo a step further. Then-Associate Attorney General Brand instructed the heads of civil litigating components and U.S. attorneys that "Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in affirmative civil enforcement cases."[27]

The Brand Memo specifies that the prohibition "applies when the department is enforcing the False Claims Act, alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements."[28]

Under the Brand Memo, the DOJ may not "use noncompliance with guidance documents as a basis for proving a violation" of the FCA.[29]

PRACTICE: FCA ENFORCEMENT

After the Brand Memo, the DOJ's FCA enforcement tactics changed in one of its most high-profile cases. In Poehling, the DOJ's pre-Brand Memo complaint broadly alleged that Medicare Advantage Organizations "must comply with requirements set forth in statutes, such as the FCA, and guidance documents, such as the Medicare Managed Care Manual, the Medicare Prescription Drug Benefit Manual, and Medicare Advantage operating instructions."[30]

But after the Brand Memo, the word "guidance" did not appear in the DOJ's summary judgment motion.[31] Nor did the DOJ continue to allege that Medicare Advantage Organizations "must comply with requirements set forth in … guidance documents."

Instead, the DOJ narrowed its allegation to noncompliance with "the obligation" in specific guidance — namely, the "Medicare Managed Care Manual" — that "was expressly incorporated into all of the [government] contracts."[32]

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The history and purpose of the Brand Memo and the DOJ's enforcement practices thereunder suggest that the DOJ will not pursue guidance-based FCA claims if the government contract *generally* incorporates that guidance via a catch-all certification. However, the agency may pursue guidance-based FCA claims if the government contract *expressly* incorporates specific guidance.

> The imposition of legal obligations through guidance violates the notice-and-comment requirements of the Administrative Procedure Act.

As courts have warned, unlawful and expansive administrative guidance endangers constitutional principles of fair notice, due process and separation of powers. Regulated parties must have fair notice of their legal obligations, and all legal obligations must be properly created either by statute or regulation. The purpose of the Brand Memo was to safeguard those principles against agency overreach by, inter alia, prohibiting FCA enforcement based on noncompliance with unlawful guidance.

That effort would be pointless if the Brand Memo carves out an exception whenever a government contract includes a catch-all certification. FCA actions almost always involve government contracts, and most government contracts include catch-all certifications incorporating agency guidance. It would make no sense to prohibit guidance-based FCA enforcement on the one hand but to allow such enforcement whenever there is a catch-all certification. For government contractors, that would be a case of the exception swallowing the rule.

The DOJ's position in *Poehling* reinforces that conclusion. The enforcement action also shows that the DOJ may pursue FCA actions based on noncompliance with expressly

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incorporated guidance. Before the Brand Memo, in Poehling the DOJ broadly relied on noncompliance with "guidance documents."[33] But after the memo, the word "guidance" did not appear in court filings at all. The DOJ mentioned only one specific guidance document — the "Medicare Manage Care Manual."[34]

In addition, the DOJ repeatedly emphasized that the government contract "expressly incorporated" the manual.[35] Indeed, the catch-all certification in that government contract required compliance with "statutes, regulations, and policies (e.g. policies as described in the Call Letter, *Medicare Managed Care Manual*, etc.)."[36]

> The DOJ may pursue guidance-based FCA claims if the government contract expressly incorporates specific guidance.

That narrower, post-Brand Memo approach is less likely to implicate concerns regarding fair notice and due process. A catch-all certification generally incorporates all guidance without specifically identifying which guidance is pertinent to the contract at issue.

For a Medicare contract, that could be tens of thousands of guidance documents, and from year to year that number has grown by the thousands. In contrast, express incorporation that identifies specific guidance does not implicate the same fair-notice and due-process concerns that Judge Gorsuch identified in *Caring Hearts*.

CONCLUSION

The Brand Memo has the potential to offer much-needed relief for government contractors navigating the "strange world where the government itself … seems unable to keep pace with its own frenetic rulemaking"; "laws are so voluminous they cannot be read"; and "constitutional norms of due process, fair notice and even the separations of powers seem very much at stake."[37]

However, uncertainty surrounding government contracts, incorporated guidance and FCA enforcement can undermine the Brand Memo's laudable goals. It would benefit all to have definitive "guidance" from the DOJ on that important issue.

In the meantime, the history and purpose of the memo and the enforcement practices under it provide encouraging signs that the DOJ will not rely on catch-all certifications to circumvent the memo.

NOTES

[1] U.S. Dep't. of Justice Office of the Assoc. Att'y Gen., Memorandum for Civil Litigating Components: Limiting Use of Guidance Documents in Affirmative Civil Enforcement Cases, Jan. 25, 2018, available at https://bit.ly/2u9k1cu (the "Brand Memo").

[2] *Id.* at 2.

[3] *Id.*

[4] *See* William S.W. Chang et al., Financial Regulators Have Gotten the Memo-The "Brand Memo," SA FINANCIAL REGULATION JOURNAL, Sept. 21, 2018, *available at* https://bit.ly/2AxVimw.

[5] Letter from Rep. Blaine Luetkemeyer, U.S. House of Representatives, to Randal K. Quarles, Vice Chairman for Supervision, Federal Reserve Board of Governors (June 13, 2018), *available at* https://bit.ly/2Az3p2h.

[6] Chang et al., *supra* note 4.

[7] Brand Memo at 1 n.1 (emphasis added).

[8] Medicare Enrollment Application for Eligible Ordering, Certifying and Prescribing Physicians, and Other Eligible Professionals, Department of Health and Human Services CMS Form 8550 Certification Statement at 8, *available at* https://go.cms.gov/2yAsaKb.

[9] *See, e.g.,* Motion for Partial Summary Judgment filed by plaintiff United States of America, Ex. 1 (Medicare Advance Contract H0543 Between UnitedHealthcare of California and CMS), *United States ex rel. Poehling v. UnitedHealth Grp. Inc.,* No. 16-cv-8697, Dkt. No. 234-3. (C.D. Cal. May 22, 2018).

[10] *See, e.g.,* VA Information and Information System Security/Privacy Requirements, VA Solicitation No. 36C24118Q0258 for Preventative Maintenance Volcano IVUS Systems, *available at* https://bit.ly/2Og5y6y.

[11] 135 S. Ct. 1199, 1211 (2015) (Scalia, J. concurring).

[12] *Id.* at 1212.

[13] U.S. Dep't. of Justice Office of the Att'y Gen., Memorandum for all Components: Prohibition on Improper Guidance Documents, Nov. 16, 2017, *available at* https://bit.ly/2E2otkb (the "Guidance Policy").

[14] Letter from Rep. Blaine Luetkemeyer, U.S. House of Representatives, to Randal K. Quarles, Vice Chairman for Supervision, Federal Reserve Board of Governors (June 13, 2018), *available at* https://bit.ly/2Az3p2h.

[15] *Id.*

[16] *Id.*

[17] *See Caring Hearts Personal Home Serv. Inc. v. Burwell,* 824 F.3d 968, 969 (10th Cir. 2016) (citing The Federalist No. 62, at 381 (James Madison) (Clinton Rossiter ed., 1961)).

[18] *See id.*

[19] *Id.* at 970.

[20] *Id.* at 976-77.

[21] Intervenor Compl. Against Defs. UnitedHealth Group Inc. et al., *United States ex rel. Poehling v. UnitedHealth Group Inc. et al.,* No. 16-cv-8697, Dkt. No. 114 (C.D. Cal. May 17, 2017).

[22] Acting Assoc. Att'y Gen. Jesse Panuccio, Remarks at the American Bar Association's 12th National Institute on the Civil False Claims Act and Qui Tam Enforcement (as prepared for delivery) (June 14, 2018), *available at* https://bit.ly/2yDmGy.

[23] *Id.*

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[24] Guidance Policy at 1-2.

[25] *Id.* at 2.

[26] *See, e.g.,* Press Release, U.S. Dep't. of Justice, Attorney General Jeff Sessions Rescinds 24 Guidance Documents (July 3, 2018), *available at* https://bit.ly/2KJUIr.

[27] Brand Memo at 2.

[28] *Id.*

[29] *Id.*

[30] Intervenor Compl. Against Defs. UnitedHealth Group Inc. et al., *United States ex rel. Poehling v. UnitedHealth Group Inc. et al.,* No. 16-cv-8697, Dkt. No. 114 at ¶ 54.

[31] *See* Motion for Partial Summary Judgment filed by Plaintiff United States of America, *United States ex rel. Poehling v. UnitedHealth Group Inc. et al.,* No. 2:16-cv-08697, Dkt. No. 234-1.

[32] *Id.* at 9; *see also id.* at 17 (relying on "United's MA Contracts (including the Managed Care Manual and MA regulations expressly incorporated into the contracts").

[33] *See* Intervenor Compl. Against Defs. UnitedHealth Group Inc. et al., *United States ex rel. Poehling v. UnitedHealth Group Inc. et al.,* No. 16-cv-08697, Dkt. No. 114 at ¶ 54.

[34] Motion for Partial Summary Judgment filed by Plaintiff United States of America, *United States ex rel. Poehling v. UnitedHealth Group Inc. et al.,* No. 16-cv-08697, Dkt. No. 234-1 at 6, 9-11, 17.

[35] *Id.* at 9, 17.

[36] Motion for Partial Summary Judgment filed by plaintiff United States of America, Ex. 1 (Medicare Advance Contract H0543 Between UnitedHealthcare of California and CMS), *United States ex rel. Poehling v. UnitedHealth Group Inc. et al.,* No. 16-cv-08697, Dkt. No. 234-3 at 2.

[37] *See* 824 F.3d 968 at 969, 976.

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