

the Medicare and TRICARE programs, and caused the Government to pay HDL more than \$330 million.

II. Legal Standard

Rule 26(b)(1) outlines the scope of discovery in a civil case:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Rule 34 allows a party to serve on another party a request for production as to any matter "within the scope of Rule 26(b)" as outlined above. Fed. R. Civ. P. 34(a). Parties' objections to document production requests must be stated with particularity and specificity; objections may not be boilerplate. Fed. R. Civ. P. 33(b)(4). "A party must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the request." Fed. R. Civ. P. 34(b)(2)(E)(i). Rule 37(a)(3)(B) allows a party seeking discovery to move for an order compelling production or answers against another party when the latter has failed to produce documents requested under Rule 34. Fed. R. Civ. P. 37(a)(3)(B)(iii)-(iv). "[A]n evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(4).

III. Discussion

Mallory has indicated that most of the issues raised in her motion to compel have been resolved, but she is still pursuing discovery with regard to RFP Nos. 3, 12, 22, 25, 26, 27, 28, 29, and 30. (Dkt. No. 467.)

A. RFP No. 22

Mallory's RFP No. 22 seeks "all documents related to each and every 'medically unnecessary' test as alleged in the complaint." (Dkt. No. 406-1 at 10.) The Government has represented that it is "producing all non-privileged documents that are reasonably responsive to this request." (Dkt. No. 406-2 at 16.) In her Reply brief, Mallory does not provide the Court with any details about which documents she believes the Government is still withholding and why the Court should compel it to produce those documents. The Court therefore assumes that RFP No. 22 was included in Mallory's reply brief due to a scrivener's error. The motion to compel as to RFP No. 22 is denied without prejudice.

B. RFP Nos. 28 and 29

Mallory's RFP No. 28 seeks "documents issued by the OIG, CMS, DOJ or the Government prior to June 25, 2014 specifically concluding the payment of P&H fees to physicians was an actual violation of the federal Anti-kickback Statute" and/or the federal False Claims Act. Mallory's RFP No. 29 seeks "all documents issued by the OIG, CMS, DOJ or the Government prior to June 25, 2014 specifically referencing the payment of P&H fees to physicians as potentially violating the federal Anti-kickback Statute" or the federal False Claims Act. (Dkt. No. 406-1 at 11.) The Government initially interpreted the term "issued by" as used in these requests to mean documents that were formally issued or published, and the Government asserts that it has produced all publicly available documents in response to these requests. (Dkt. No. 470 at 2.) Mallory has since clarified that she seeks internal government communications that are responsive to the request.

The plain meaning of "issued" is to distribute, publish, or put out. While it is possible that an organization could issue a formal communication internally, in this case, Mallory's request is not reasonably interpreted to refer to an agency's internal issuance of formal

directives. Further, the term would never be used to refer to communications in general among employees within an organization; one does not “issue” an email to his colleague. For this reason, the Court finds that the Government has complied with Mallory’s RFP Nos. 28 and 29 by producing responsive documents that have been “issued.” Mallory’s request for internal government communications is a new discovery request that must be pursued in accordance with this Court’s May 1, 2017 Order pertaining to new motions to compel. (Dkt. No. 438.)

C. RFP No. 25

Mallory’s RFP No. 25 seeks documents in which “any attorney, law firm and/or Government agency has opined on the legality of the payment of P&H fees to physicians by any lab.” (Dkt. No. 406-1 at 11.) This request is identical to Defendant Dent’s RFP No. 30, which the Court ruled on in a previous order. (Dkt. No. 428 at 9-10.) In that Order, the Court explained that the documents targeted by this request (i.e., opinions on the legality of P&H fees) are privileged and that the Government had not waived the privilege. Mallory’s motion to compel as to RFP No. 25 is therefore denied for the same reasons.

D. RFP No. 3

Mallory’s RFP No. 3 seeks “all communications and documents relating to the plaintiff’s payment of the ‘false or fraudulent claims’ as alleged in the complaint, including, but not limited to, all internal government communication relating the payment of any such claim(s) and/or communication regarding whether any such claim(s) should be paid.” (Dkt. No. 406-1 at 8.) The Court notes that Mallory’s RFP No. 3 is broader than her RFP No. 25 which, as explained above, specifically targets privileged communications. Mallory has asked for all internal government communications about the payment of false or fraudulent claims, including whether such claims should be paid. The documents may, for example, be relevant to the Government’s mitigation as to Counts IV and V. The Government has represented that it has produced all documents that are

responsive to Mallory’s RFP No. 3 except for “internal Government documents reflecting legal discussions.” (Dkt. No. 452 at 12.) To the extent it has not already done so, the Government must review all documents that are responsive to Mallory’s RFP No. 3, produce all non-privileged documents, and provide a privilege log detailing each document it has withheld on the basis of the attorney-client privilege.

E. Deliberative Process Privilege (RFP Nos. 12, 26, 27, and 30)

The Government has stated that it is withholding documents responsive to RFP Nos. 12, 26, 27, and 30 based on the deliberative process privilege.¹ (Dkt. No. 452 at 14-17.)

1. RFP Nos. 26 and 27

Mallory’s RFP Nos. 26 and 27 seek, respectively, all documents “relied upon or considered by the OIG in determining to issue” the Special Fraud Alert of June 25, 2014, and “all documents, including all emails, correspondence, or other communications, exchanged between DOJ and OIG relating to the issuance of” the Special Fraud Alert. (Dkt. No. 406-1 at 11.) Defendant Mallory argues (1) that Talley has not properly invoked the deliberative process privilege; and (2) that Mallory’s need for the documents outweighs the Government’s need for confidentiality.² (Dkt. No. 460 at 5.)

a. Invocation of the Deliberative Process Privilege

The Government must comply with three procedural requirements to assert the deliberative process privilege: “1) the agency head must assert the privilege after personal

¹ The Government has asserted other privileges with respect to these individual RFPs which the Court addresses in each separate sub-section, below.

² Mallory also argued that the Government was withholding documents responsive to Mallory’s request that fall outside the scope of the deliberative process privilege. The Court finds that the Government has only asserted the deliberative process privilege with regard to Mallory’s RFP Nos. 28 and 29 which overlap with Dent’s requests that were addressed in Martha Talley’s affidavit. (Dkt. No. 426-2 at 3.)

consideration; 2) the agency head must state with particularity the information subject to the privilege; and 3) the agency must aver precise and certain reasons for preserving the confidentiality of the requested documents.” *Hugler v. Bat Masonry Co., Inc.*, No. 6:15-CV-28, 2017 WL 1207847, at *3 (W.D. Va. Mar. 31, 2017). Defendant Mallory argues that the privilege has not been properly invoked here³ because (1) the Secretary of the Department of Health and Human Services (“HHS”) did not delegate to Talley the authority to invoke the privilege on the agency’s behalf, and (2) Talley did not personally consider all of the allegedly privileged material but instead stated that she “personally reviewed or discussed the requested information with other agency personnel.” (Dkt. No. 460 at 8.)

Courts frequently allow delegation of authority to invoke the deliberative process privilege beneath the agency head. *See, e.g., Kaufman v. City of New York*, No. 98CIV.2648, 1999 WL 239698, at *5 (S.D.N.Y. 1999) (“[T]he governmental deliberative process privilege [may be asserted] through an affidavit by the agency head or a designated high-level agency decisionmaker who reviewed the withheld documents”); *Landry v. FDIC*, 204 F.3d 1125, 1136 (D.C. Cir. 2000) (“supervisory personnel . . . of sufficient rank” are permitted to invoke the privilege); *Marriott Int’l Resorts, L.P. v. United States*, 437 F.3d 1302, 1308 (Fed. Cir. 2006) (Assistant Chief Counsel responsible for the policies in question permitted to invoke the privilege); *In Deseret Mgmt. Corp. v. United States*, 76 Fed. Cl. 88, 98 (2007) (Assistant Chief Counsel in the Office of the Associate Chief Counsel of the IRS permitted to invoke the

³ Mallory acknowledges that when the Court has ruled on Defendant Dent’s RFP No. 31 in a previous order, it found that the Government had met the procedural requirements to assert the privilege. (Dkt. No. 428 at 10-11.) The Court considers Mallory’s arguments here, acknowledging that she had not had the opportunity to respond to the Government’s assertion of the deliberative process privilege.

privilege); *Hugler*, 2017 WL 1207847, at *3. (Deputy Assistant Secretary for Program Operations permitted to invoke the privilege).

There are compelling policy reasons behind these decisions: allowing an agency to delegate the authority to invoke the deliberative process privilege promotes “efficiency in judicial administration and actual personal involvement in the complex process of invoking the privilege.” *Marriott*, 437 F.3d at 1307. In short, Courts do not strictly require the “pinnacle of agency authority” to assert the deliberative process privilege, likely because doing so would “surely start to erode the substance of ‘actual personal’ involvement.” *Landry*, 204 F.3d at 1135.

Talley occupies a sufficiently high-rank within the Department of Health and Human Services (“HHS”) to invoke the deliberative process privilege with regard to RFP Nos. 26 and 27.⁴ Talley is the Chief of the Industrial Guidance Branch (“IGB”) in the Office of Counsel within the HHS’s Office of the Inspector General (“OIG”) for HHS. The IGB prepares the advisory opinions and special fraud alerts for the anti-kickback statute and other laws. (Dkt. No. 426-2 at 2). Talley is therefore the chief of the division responsible for producing the documents Mallory and Dent are seeking with regard to the decision to issue the Special Fraud Alert. For this reason, it is difficult for this Court to conceive of an individual better placed to assert the deliberative process privilege than Talley.

⁴ Mallory also argues that authority to invoke the privilege was not properly delegated to Talley and that Talley did not personally consider the documents in question. The Court has found that Talley is of sufficiently high rank to assert the privilege in this case and is not aware of any binding precedent that requires it to reject the assertion of the privilege due to lack of sufficient paperwork documenting the formal delegation of this duty to Talley. Talley has stated that she “personally reviewed or discussed” the requested information which, in this case, is sufficient to show that she personally considered the material.

b. Balancing Discovery Needs with the Need for Confidentiality

In a previous order, this Court denied Dent's motion to compel because his production requests were drafted to specifically target predecisional deliberations about the decision to issue the Special Fraud Alert. (Dkt. No. 428 at 10-11.) The Court noted that if Dent believed "that he can overcome the privilege by showing that his need for the documents outweighs the potential harms of disclosure, he may file a new motion to compel." (Dkt. No. 428 at 11; *see Cobell v. Norton*, 213 F.R.D. 1, 5 (D.D.C. 2003) ("[O]nce the elements of the privilege have been met, the burden shifts to the party opposing the privilege to establish that its need for the information outweighs the interest of the government in preventing disclosure of the information.") Mallory has since advanced the argument that the Defendants' need for these documents outweighs concerns about potential harm to the Government from disclosure, and the Government has filed a brief in opposition. The Court excerpts portions of the parties' briefs here that reflect the crux of their arguments. Mallory argues the following:

The plaintiff's decision-making process is central to this case. The plaintiff must prove that Mallory's alleged conduct was done "knowingly." To support its contention, the plaintiff alleges that the HHS-OIG issued a number of advisory opinions on "problematic arrangements involving the provision of clinical laboratory services" prior to issuing the Special Fraud Alert. (ECF No. 75 ¶¶ 38-46, 77). Upon information and belief, the plaintiff's decision-making process with respect to Special Fraud will show that Mallory did not have actual knowledge, act in deliberate ignorance of the truth, or act in reckless disregard of the truth. Upon information and belief, it will show that these advisory opinions did not even give the plaintiff (including the various departments of the United States) reason to "know" that the payment of P&H fees was purportedly considered unlawful. Upon information and belief, there are communications between employees at the Department of Justice that reflect as of January 2014, the Department of Justice did not even "know" whether the payment of P&H fees by laboratories was unlawful. Upon information and belief, the information requested will show that the plaintiff knew its advisory opinions did not put laboratories "on notice" that their conduct violated the AKS as alleged in the Complaint. (ECF No. 75 ¶ 77). Upon information and belief, the requested information will negate the plaintiff's claim that Mallory had the requisite "knowledge."

(Dkt. No. 397 at 13-14.) The Government has argued the following in response:

[C]ontrary to Mallory’s contentions, none of the requested information – which involves the origin of the June 2014 Special Fraud Alert – will shed any light on whether Office of Inspector General Advisory Opinions issued *prior* to the June 2014 Special Fraud Alert put Mallory on notice that her conduct violated the Anti-Kickback Statute . . . By contrast, the United States has a strong interest in preventing disclosure of the requested information. As Ms. Talley explains, at length, in her Declaration, “release of the requested information would be . . . detrimental to OIG and thus contrary to the public interest.” Exhibit B (Declaration of Martha J. Talley) ¶¶ 8-15. Ms. Talley further explains, in part, “I have no doubt that if my staff or others within OIG expected that their comments, criticisms, suggestions, preliminary analyses, or proposed edits made during our process were to be publicly displayed in the context of a lawsuit, this would stifle much of the necessary candid dialogue among us.” *Id.* ¶ 14.

(Dkt. No. 426 at 12-13.) The parties essentially disagree on two points: (1) whether internal government discussions could possibly be relevant to Mallory’s scienter⁵ and, if so, (2) whether defendant’s need for the documents outweighs the Government’s interest in confidentiality.

The test for False Claims Act liability is (1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that involved a “claim,” because it caused the government to pay out money or to forfeit moneys due. 31 U.S.C. § 3729 *et seq.*; *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir. 1999). Claims that include items or services resulting from a violation of the AKS are false or fraudulent under the FCA. 42 U.S.C. § 1320a-7b(g). The requisite scienter under the FCA is “knowingly,” meaning with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(a), (b)(1); *see U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 703 (4th Cir. 2014). In the FCA context, “reckless disregard . . . is best understood as ‘an extension of gross negligence’ or an ‘extreme version of

⁵ Because they are similarly situated, documents that are relevant to Mallory’s scienter are also relevant to the BlueWave Defendants’ scienter.

ordinary negligence' that does not require willful or deliberate conduct." *U.S. ex rel. Mayers v. Lacy Sch. of Cosmetology, LLC*, No. 1:13-CV-00218-JMC, 2015 WL 8665345, at *2 (D.S.C. Dec. 14, 2015) (quoting *United States v. Krizek*, 111 F.3d 934, 941 (D.C. Cir. 1997)).

Federal courts look to a variety of factors to determine whether a defendant acted with reckless disregard, including "(1) the defendant's adherence to custom or industry practice; (2) the defendant's existing knowledge or expertise; (3) any legal advice the defendant received; (4) any professional or expert advice the defendant received; (5) the defendant's disclosure of its conduct to the government; (6) the existence of any guidance or authority from an administrative agency or court; (7) the reasonableness of the defendant's actions, positions, or interpretations; and (8) the defendant's motive." James Wiseman, *Reasonable, but Wrong: Reckless Disregard and Deliberate Ignorance in the False Claims Act After Hixson*, 117 Colum. L. Rev. 435, 450–51 (2017).

Mallory's argument that the Government has placed its internal deliberations "at issue" or that they are somehow "central to this case" is hyperbolic. Nonetheless, HHS's internal communications about the decision to issue the Special Fraud Alert may be relevant to the reasonableness of the Defendants' actions, positions, or interpretations with regard to their determination that the claims at issue were not tainted by an illegal kickback scheme. *See United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 564 (E.D. Va. 2003) ("[B]oth the clarity of the regulation and the reasonableness of a contractor's interpretation are relevant in deciding whether a failure to disclose charging practices is indicative of a reckless disregard of their falsity."); *see also U.S. ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 316 (S.D.N.Y. 2011), *aff'd sub nom. Colucci v. Beth Israel Med. Ctr.*, 531 F. App'x 118 (2d Cir. 2013) ("[W]hether a claimant acted knowingly in submitting a false claim turns on "the

reasonableness of [the claimant's] interpretation.”) The Court finds that the requested documents may be relevant to defendants’ scienter even if defendants were not aware of the content of the Government’s internal communications. *See SEC v. Kovzan*, No. 11-2017-JWL, 2012 WL 4819011, at *4 (D. Kan. Oct. 10, 2012) (disagreeing with Magistrate’s determination that “scienter relates to what defendant knew or should have known, and that therefore information may be relevant to scienter only if known to the public or to defendant” and allowing discovery of “internal [SEC] documents concerning a final decision as to what guidance, if any, the SEC staff may provide to reporting companies regarding the meaning of the requisite disclosure regulations and the definition of internal control over financial reporting.”).

Having determined that the Government’s internal deliberations leading up to their decision to issue the Special Fraud Alert may be relevant to Defendants’ scienter, the Court must decide whether Defendants’ interest in discovering the documents outweighs the government’s interest in confidentiality. Courts consider the following factors to determine whether the defendant’s interest in a particular document outweigh the government’s need for confidentiality: (1) the relevance of the document to the litigation; (2) the availability of other evidence; (3) the government’s role in the litigation; (4) the seriousness of the litigation; and (5) the extent to which disclosure would chill future deliberations. *FDIC v. Giancola*, 2015 WL 5559599, *5-6 (N.D. Ill. Sept. 18, 2015) (citations omitted). The Court has no trouble finding that the Government’s role in this litigation is significant and that the litigation is serious. While other evidence is surely available that would shed light on whether Defendants’ interpretation was reasonable, internal government discussions about the need to issue further guidance may contain particularly strong evidence on this point. The Court is also cognizant of the obvious risk that “officials will not communicate candidly among themselves if each remark is a potential

item of discovery and front page news.” *Dep’t of Interior v. Klamath Water Users Protective Ass’n*, 532 U.S. 1, 8–9 (2001). Because this balancing test requires a fact-specific inquiry of the documents in question, the Government is hereby ordered to submit documents that are responsive to Mallory’s RFP Nos. 26 and 27 to this Court for in camera review.

2. RFP No. 12

Mallory’s RFP No. 12 seeks “all documents and communications in any way involving Mallory, including but not limited to emails sent to Mallory, received from Mallory, on which Mallory was [copied] and/or [that] mention Mallory.” (Dkt. No. 406-1 at 9.) The Government has produced the following documents that are responsive to Mallory’s request: “every HDL, Singulex and BlueWave document with [Mallory’s] name on it, including every email on which she was a recipient or the sender, the Medicare and TRICARE provider applications and BlueWave Sales Agreement contract documents Mallory signed, the HDL Waiver documents previously withheld, every HDL P&H Agreement she signed, and other responsive documents.” (Dkt. No. 452 at 14.) The Government represents that the only documents it has not produced that are responsive to the request are “internal Government documents that refer to [Mallory], specifically, all documents in which Government attorneys and investigators working on the investigation or this litigation referred to her.” (Dkt. No. 452 at 14.) The Government argues that these documents are (1) Not relevant to any party’s claims or defenses [including Mallory’s scienter]; (2) Not proportional to the needs of the case; (3) Protected by the attorney-client privilege and the work product doctrine; (4) “[N]ecessarily involve communications within the Government about the investigation and prosecution of this case”; and (5) “[C]oncern inter-agency and intra-agency deliberations” that are protected by the deliberative process privilege. (*Id.* at 14–15). The Court has considered all of the Government’s arguments (1–5, above) in turn.

- (1) The Government has not made a compelling argument as to why documents in which internal government attorneys and investigators have referred to Mallory would not be relevant to any claims or defenses in this case. The Court presumes that most such documents are, in fact, relevant to the claims against Mallory and to her potential defenses.
- (2) The Government argues that this request is not proportional to the needs of this case without providing any context for that assertion. The Government has brought serious charges against Mallory and several other defendants, making it difficult for the Court to conceive of documents that are responsive to her request (*i.e.*, those that specifically refer to her and/or her role) but are disproportionate to the needs of the case (*i.e.*, her need to defend herself).
- (3) There is nothing inherent about an internal government document produced by an investigator or attorney that makes that document immune from discovery. (*See* Dkt. No. 428 at 7-8 for this Court's Order with regard to discovery of fact work product).
- (4) For the same reason given for (3), above, this argument does not support withholding documents that are responsive to this request.
- (5) The Government's assertion that "documents that mention Mallory and concern inter-agency and intra-agency deliberations and advice are privileged under the deliberative process privilege in any event" is a tautology that cannot be the basis for withholding documents. (*Id.* at 14-15). The Government has not explicitly invoked the deliberative process privilege with regard to documents that are responsive to Mallory's request (Dkt. No. 426-2), and Mallory's request does not target documents that are necessarily part of the deliberative process.

For the above reasons, the Government is hereby ordered to respond in full to Mallory's RFP No. 12. If the Government intends to withhold any documents that are responsive to this request based on the attorney-client privilege or work product doctrine, it must detail its reasons in a privilege log.

3. RFP. No. 30

Mallory's RFP No. 30 seeks "all documents relating to lab industry standards relating to the payment of P&H fees." (Dkt. No. 406-1 at 11.) This request is identical to Dent's RFP No. 35 which the Court addressed briefly in its Order on Dent's motion to compel. (Dkt. No. 428 at 5.) The Government has represented that some of the documents that were responsive to Dent's RFP No. 35 (and would therefore be responsive to Mallory's RFP No. 30) were third-party documents. (Dkt. No. 380 at 25; Dkt. No. 452 at 6.) The Court understands that the parties have resolved their discovery dispute with regard to the third-party documents. (Dkt. No. 479.)

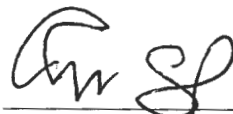
In its response in opposition to Mallory's motion to compel, the Government claimed, with little support, that RFP No. 30 (like her RFP Nos. 25, 26, and 27) is not relevant to Mallory's scienter and is subject to at least one privilege. (Dkt. No. 452 at 15-16.) Documents that would be responsive to Mallory's RFP No. 30 are not necessarily covered by the attorney-client privilege or work product doctrine, and the Government has not explicitly invoked the deliberative process privilege with regard to these documents. For this reason, the Government is hereby ordered to produce all documents that are responsive to Mallory's RFP. No. 30. If the Government withholds any responsive documents on the basis of the attorney-client or work product privilege, it must document those reasons in a privilege log.

F. Conclusion

For the above reasons, Mallory's motion to compel (Dkt. No. 406) is DENIED without prejudice as to RFP Nos. 22, 25, 28, and 29. The motion to compel is GRANTED with regard to

RFP Nos. 3, 12, 27, 26, and 30. The Government is ordered to produce responsive documents in accordance with this order. Documents responsive to RFP. Nos. 26 and 27 should be submitted to this Court for in camera review by June 30, 2017.

AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

June 17, 2017
Charleston, South Carolina