IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* JONATHAN D'CUNHA, M.D.,	Case No. 19-495
Plaintiff,	
v.	The Honorable Cathy Bissoon
JAMES D. LUKETICH, M.D., UNIVERSITY OF PITTSBURGH MEDICAL CENTER, AND UNIVERSITY OF PITTSBURGH PHYSICIANS,	
Defendants.	

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS
UNITED STATES' COMPLAINT IN PARTIAL INTERVENTION

The United States' Complaint in Partial Intervention, ECF No. 66, purports to accuse UPMC, its subsidiary University of Pittsburgh Physicians ("UPP"), and one of its most prominent surgeons, Dr. James D. Luketich, of fraudulently billing for "concurrent" or "overlapping" surgeries[1] performed by teams of surgeons and other clinicians led by Dr. Luketich. It does that, tellingly, without ever identifying a single statute or regulation that specifies how such surgeries should be billed. That failure dooms the Government's claims—all of them.

While the Complaint makes passing references to 42 CFR § 415.172—the only federal regulation that orbits even remotely around the matters in dispute here—it is far more replete with allegations of supposed departures from CMS guidance, UPMC policies, and good medical practices, none of which will support an action under the False Claims Act ("FCA"). Meanwhile, as important to this Motion as what the Complaint does allege is what it does not—and cannot—allege. For example:

- The Government alleges that Dr. Luketich is not "immediately available" during portions of the surgeries his team conducts, but fails to allege—because it cannot—that during those absences there is not another, fully qualified surgeon on his team present;

- The Government alleges that Dr. Luketich is sometimes not present for the "time out" that precedes the "opening" in a surgical procedure, but fails to allege—because it cannot—that another fully qualified surgeon on his team is not present, or that any federal statute, regulation, rule, guidance or other promulgation prohibits such an arrangement;

- The Government alleges that Dr. Luketich's "hyper busy schedule" and insistence that he be present for or perform the portions of the procedures he deems to be

[1] The Government seems to think there is a meaningful legal difference between the terms "concurrent surgeries" and "overlapping surgeries." *See, e.g.,* Complaint, ECF No. 66, ¶ 88 (asserting, without citation to any authority, that "CMS will not pay for surgeries where the key or critical portions of each surgery take place at the same time, also known as concurrent surgery."); *see also* ¶ 86 (describing, again without citation to any authority, "overlapping surgeries" as those where "[t]he teaching physician [leaves] the first surgical procedure and/or commence[s] the second procedure when the key or critical portion(s) of the first procedure is complete."). To avoid confusion, this brief will refer collectively to "concurrent or overlapping surgeries."

key and critical causes delays that result in "unnecessary" anesthesia time, but fails to allege—because it cannot—that any federal statute, regulation, rule, or guidance renders anesthesia "unnecessary" when a surgery is delayed;

- The Government gratuitously points to a handful of unfortunate outcomes and post-operative setbacks suffered by several of Dr. Luketich's patients in the last seven years, but fails to acknowledge—because it chooses not to—the thousands of spectacular surgical outcomes on critically ill patients he and his team have achieved over the same time period.

In sum and as will be explained below, while the Complaint offers an unflattering portrayal of well-established and highly effective surgical practices that the Government apparently finds problematic—practices the Government has never attempted to regulate through legislation or notice-and-comment rulemaking—its allegations fall far short of stating a claim upon which relief may be granted under Rule 12(b)(6), let alone stating a claim for fraudulent billing under the FCA with the particularity required by Rule 9(b).

BACKGROUND

At the root of the Government's failure to state a claim under the FCA is its failure to identify a coherent, enforceable regulatory regime governing billing for concurrent or overlapping surgeries. Its Complaint instead serves up a muddled mash-up of regulation, sub-regulatory guidance, UPMC hospital policy, and supposed concern over patient safety, none of which—separately or in combination—can support claims for fraudulent billing against UPMC, UPP or Dr. Luketich.

According to the Government, UPMC, UPP and Dr. Luketich are violating federal law — and are liable under the FCA and various common law theories — because Dr. Luketich allegedly: (1) is not "immediately available" in one billed procedure when he is performing or participating in a second or third one; (2) is not present for the surgical "time out" preceding a billed procedure; and/or (3) subjects patients to unnecessary anesthesia time while he finishes a concurrent or

overlapping procedure. *See* Compl. ¶¶ 93 - 126. Those claims fall apart, however, once careful attention is paid to the regulatory regime under which this case has been pled and to the actual practices and procedures described in the Complaint.

I. The Regulatory Regime

Casting about for sources of the billing obligations it would have this Court impose on hospitals and physicians, the Government freely mixes into its Complaint regulation, guidance, and policy,[2] leaving it to Defendants (and this Court) to sort out this tangled web of legal requirements, pseudo-requirements, and irrelevancies.

A. The Teaching Physician Regulation

A close reading of the Government's Complaint reveals that the legal regime at issue in this case involves one—and only one—federal regulation, 42 CFR § 415.172, also known as the "Teaching Physician Regulation" or "TPR."[3] The portions of the TPR relevant to this matter or cited in the Complaint read as follows:[4]

> *(a)* ***General rule****. If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. . .*
>
> *(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.*

[2] Strangely, the Government also appears to be trying to milk legal obligations out of a newspaper article and a report from the Senate Finance Committee. *See* Compl. ¶¶ 128-29, 134.

[3] CMS enacted this regulation over 25 years ago to ensure teaching physicians did not receive payment for services furnished by surgical residents – whose services CMS had already paid for – when the physician was either not involved, or only minimally involved, in the procedure. *See e.g.*, 60 Fed. Reg. 63142 (Dec. 8, 1995). In so doing, CMS was clear that it did not intend for the regulations to require "the presence of the teaching physician for the duration of every service or procedure billed in his or her name." *See id*. at 63144-45. As CMS put it, "the most important consideration [for payment] should be the presence of the teaching physician during the key portion of the service or procedure being furnished by the resident." *See id*. at 63139.

[4] A copy of the entire text of the TPR is attached as Exhibit A.

> *(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.*

Several important features of the TPR are immediately apparent:

- It does not specify or even suggest how concurrent or overlapping procedures are to be conducted or billed.
- It does not require the teaching physician to be present throughout a surgery, instead requiring his or her presence only for the "key" and "critical" portions of the procedure.
- It specifies that for surgery, "the teaching physician's presence is *not* required during opening and closing of the surgical field." (emphasis added)
- It does not otherwise specify what portions of a surgery are "key" or "critical," nor does it specify who makes that decision for a particular surgical procedure.
- It requires that during any portions of a surgery that are not "key" or "critical" the teaching physician must be "immediately available to furnish services[,]" but offers no further guidance on the meaning of "immediately available."

To be absolutely clear, the TPR does not expressly apply to concurrent or overlapping surgeries—or even refer to them. It does not prohibit or even address whether a billing surgeon can perform concurrent or overlapping surgeries. Nor does it limit the number of surgeries a billing surgeon may participate in at any one time or on a given day, nor require that the first surgery conclude before the surgeon begins a second surgery. Indeed, virtually every reference to a service or procedure in the regulation is just that, a reference to a single or solitary service or procedure; the TPR simply does not address multiple, let alone concurring or overlapping, services or procedures.

B. The CMS Manual

The first and only reference in *any* Medicare issuance to overlapping or concurrent surgeries appears in the CMS Manual, which did not undergo notice-and-comment rulemaking

and is therefore considered "sub-regulatory guidance."[5] The Manual expressly permits concurrent or overlapping surgeries by teaching physicians, providing that:

> *In order to bill Medicare for two overlapping surgeries, the teaching surgeon must be present during the critical or key portions of both operations. Therefore, the critical or key portions may not take place at the same time. When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure.*

See CMS Manual, Ch. 12, § 100.1.2(A)(2).

CMS Manual § 100.1.2(A)(2) also purports to impose two additional requirements on the teaching physician to bill for concurrent or overlapping surgeries:

> *The teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures.*
>
> *When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, he/she must arrange for another qualified surgeon to immediately assist the resident in the case should the need arise.*

Id.

Moreover, while this section purports to prohibit *billing* professional charges for three concurrent or overlapping surgeries, it explicitly acknowledges that teaching surgeons may *conduct* three such surgeries:

> *In the case of three concurrent surgical procedures, the role of the teaching surgeon (but not the anesthesiologist) in each of the cases is classified as a supervisory service to the hospital rather than a physician service to an individual patient and is not payable under the physician fee schedule.*

Id.

The CMS Manual thus offers decidedly mixed signals about concurrent or overlapping surgeries. On the one hand, the Manual indicates that the teaching surgeon may not have two

[5] *See infra* pp. 12-14.

ongoing operations unless he/she completes all the key portions of the first surgery before becoming involved in a second surgery, and generally indicates that a surgeon "participating in" another procedure would not be considered immediately available.[6] On the other hand, the Manual provides that a teaching surgeon may participate in other procedures when he/she designates a qualified backup surgeon to assist the resident during non-critical portions.

But nothing in the CMS Manual, nor in any federal legislation or regulation, circumscribes the broad discretion teaching physicians have—and must have—over the manner in which they conduct their surgeries. Indeed, the CMS Manual unequivocally endorses that discretion by entrusting the teaching physician with determining what portions of the procedure are "key" or "critical"—that is the parts for which the teaching physician must be present in order to bill. *See* CMS Manual, Ch. 12, at § 100 (Definitions: "Critical or Key Portion -That part (or parts) of a service that the teaching physician determines is (are) a critical or key portion(s).")[7] In this regard, CMS "recognize[s] both the expertise of the individual surgeon in making such a determination and that the critical portions can vary based upon the expertise of the residents, fellows, or technicians assisting in the operation or by the condition of the patients." *See Concurrent and Overlapping Surgeries: Additional Measures Warranted,* Senate Finance Committee Staff Report ("Senate Staff Report"), Dec. 6, 2016, p. 9 (cited approvingly in Compl. ¶ 134).

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[6] This "immediately available" standard is, as noted in the Senate Staff Report, "less definitive" than presence standards for other health care professionals in hospitals. The Senate Staff Report also found that the American College of Surgeons has "gone further than the CMS billing requirement by defining immediately available as "reachable through a paging system or other electronic means, and able to return immediately to the operating room," and suggesting that hospitals should adapt this definition according to their own needs. *See* Senate Staff Report at 13; ACS guidance cited by Compl. ¶ 88. Notably, this standard has not been amended since the Senate Staff Report's issuance.

[7] The Government concedes as much. *See* Compl. ¶ 78.

C. UPMC Policy

In furtherance of its mission to deliver the highest level of medical care to its patients, UPMC developed a policy, HS-OR0013, concerning "Overlapping Surgery and Procedures," that is consistent with the TPR, the CMS Manual, and guidance published by the American College of Surgeons ("ACS"). *See* Compl. ¶¶ 85, 88.[8] UPMC's policy also recognizes the practice of "team surgery," applying concepts from the CMS Manual and ACS Guidance, during which "at least one attending physician member of a team must be present during each key or critical portion of team surgery, [and] … [d]uring periods where there are no key or critical portions being performed, *any qualified attending surgeon member of the team may be present in the room or immediately available, or a named additional attending surgeon may be immediately available*." *See* UPMC Policy HS-OR0013, § IV(3) (emphasis added).

UPMC's policy, however, extends further than CMS's billing guidance by providing that the "time out" is a "key and critical portion of every surgical procedure." *See* Compl. ¶ 81. The "time out" is a patient safety measure in which a "surgical pause" occurs just before the initial incision to permit the surgical team to complete a verbal checklist regarding the identity of the patient and the procedure to be performed and to discuss the key and critical components of the procedure. *See* Compl. ¶¶ 79, 80. The TPR and CMS Manual make no mention of time outs or pre-surgical pauses, let alone obligate a teaching physician like Dr. Luketich to be present for them. To the contrary, the TPR expressly excuses a teaching physician from both the beginning

[8] Though the Complaint rests, in part, on alleged violations of this UPMC policy, the Government did not attach the relevant policy to the Complaint. Given the significance of UPMC Policy HS-OR0013 to the Government's claims, Defendants have attached it as Exhibit B so the Court may consider it in its entirety. *See American Corporate Soc. v. Valley Forge Ins. Co*., 424 Fed. Appx. 86, 88 (3d Cir. 2011) (the court may consider undisputedly authentic document attached as exhibit to motion to dismiss if plaintiff's claims are based on the document).

and ending of surgery. *See* 42 C.F.R. § 415.172(a)(1), Exhibit A, *supra* at 4.[9] The relevance of any UPMC policy to this matter, however, is hard to discern, since numerous courts have held that absent legislative, regulatory, or contractual obligations an alleged violation of such internal hospital policies cannot support claims under the FCA.[10]

II. The Government's Allegations

Dr. Luketich, whose surgical practice is at the core of the Government's Complaint, is the Chair of UPMC's Cardiothoracic Surgery Department and a teaching physician who uses residents in the care of his patients. *See* Compl. ¶ 17. He is a world-renowned thoracic surgeon, and a global leader in minimally invasive surgical procedures and other innovative and life-saving techniques. *Id.* ¶ 7. His surgical practice is one of UPMC's busiest. *Id*. ¶ 93. "Many of [Dr.] Luketich's surgical patients are elderly, frail, and/or very ill. They include the 'hopeless' patients … [who] choose UPMC and [Dr.] Luketich when other physicians and healthcare providers have turned them down." *Id*. ¶ 96.

To the extent Dr. Luketich performs concurrent or overlapping surgeries, he does so as the leader of teams of highly skilled clinicians that include not only residents but also fully qualified attending surgeons. *See* Compl. ¶ 113. When conducting these team-based surgeries, as the government repeatedly confirms, Dr. Luketich is always present for those portions of the

[9] Nothing in the TPR or CMS Manual provides patient safety guidance for academic medical centers or regulates how teaching physicians must run their operating rooms. Contrary to the Government's assertion, Compl. ¶ 77, the TPR was *not* designed to ensure patients receive appropriate care or that residents' work is adequately supervised. *See* 60 Fed. Reg. 63144 (Dec. 8, 1995) ("Many commenters believed that we developed the teaching physician proposal because we had concluded that beneficiaries in teaching hospitals receive substandard care when the teaching physician is not present during the service or procedure. Response: The policy was not intended to specifically address quality concerns. Rather, the policy addresses payment issues, in particular identifying when it is appropriate to make Medicare Part B payment to teaching physicians who oversee the services of interns and residents.")

[10] *See infra* p. 15.

procedures he deems to be key or critical. *See* Compl. ¶¶ 6, 9, 113. In fact, according to the Government, this is part of the problem.[11] *See id*. ¶¶ 113, 157. Incredibly, the Government seeks to recoup "tens of millions of dollars" in reimbursement for surgical procedures where Dr. Luketich was actually present for the key and critical portions.[12] *See* Compl. ¶ 160.

In this regard, the Government's central claim is that Dr. Luketich "regularly" participates in two or three concurrent or overlapping surgeries, which the Government alleges violates the TPR's requirement that he be "immediately available" during the entirety of each procedure he bills. *See* Compl. ¶ 156(b) & (c); *see also id*., ¶¶ 76, 83-84, 87, 89 (citing CMS Manual, Section 100.2). The Government does not—and cannot—allege, however, that when Dr. Luketich is absent from a second or third surgical procedure, another fully qualified surgeon is *not* available to immediately assist or otherwise conduct the other surgical procedure.[13] The Government simply alleges that Dr. Luketich *himself* cannot be "immediately available" because he is involved in another procedure.

Secondary to Dr. Luketich's alleged lack of immediate availability, the Government alleges

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[11] Ironically, Dr. Luketich's alleged insistence in this regard would appear to preclude labelling *any* of his surgeries as "concurrent" as the Government defines that term, because the key and critical portions of his overlapping surgeries could not possibly "take place at the same time." *See* Compl. ¶ 88.

[12] The Government appears to also contend that it is entitled to recoup damages for hospital charges related and ancillary to Dr. Luketich's professional services, *see* Compl. ¶ 160, but fails to plead *any* violation of an applicable *hospital* billing regulation.

[13] The Government's omissions are not limited to this material point. For example, the Government makes much in the Complaint of the six dates on which Dr. Luketich allegedly billed for three concurrent surgeries. *See id*. ¶¶ 103-112. The Government fails to plead, however, any of the following: (1) the point at which Dr. Luketich was not "immediately available"; (2) that another qualified attending was not immediately available in Dr. Luketich's alleged absence; (3) whether any of the listed procedures were billed to a Government Health Benefit program; and (4) if so, whether Dr. Luketich billed as the "primary surgeon" or as a "co-surgeon" or "assistant surgeon." Such allegations, which are lacking, are essential to the Government's charge that the Defendants submitted materially false billing claims.

that he "regularly fails to participate in the 'time out' at the outset of surgical procedures," which UPMC considers, under policy HS-OR0013, to be a key and critical portion of every surgical procedure. *See* Compl. ¶¶ 81, 118, Exhibit B. Again, the Government fails to allege – because it cannot – that a designated attending surgeon was not present for the surgical "time out." Further, the Complaint does not allege – as it cannot – that any billing regulation (or even any agency guidance) designates the "time out" to be a "key" or "critical" portion of a surgical procedure.[14] Despite the absence of *any* regulation, or even CMS guidance, the Government alleges that each claim submitted by the Defendants for *any* surgical procedure performed by Dr. Luketich in which he was not present for the "time out" violated the FCA. *See* Compl. ¶ 156(a).[15]

Lastly, the Government alleges that Defendants violated the FCA by administering more anesthesia than allegedly would have been administered had Dr. Luketich been "immediately available." The Government has not alleged any statute or regulation, or even any CMS guidance, that supports its theory that anesthesia is rendered unnecessary when a surgery is delayed or is lengthy. Beyond this, the Complaint fails to particularly identify a specific portion of any single anesthesia claim submitted by UPMC to a Government payor, and certified by the anesthesiologist, that was "unnecessary."

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a claim as pled under Rule 8(a), and when the claim involves fraud, under the heightened pleading standard of Rule 9(b)

[14] Indeed, the TPR specifies that the surgical opening is not "key" or "critical" because the teaching physician need not be present for it, and the "time out" immediately precedes the opening.

[15] In Paragraph 156(a) the Government alleges that to the extent surgical procedures occurred in which Dr. Luketich "did not participate in… another [unspecified] key and critical component of the procedure," such claims are false. However, other than its allegations concerning the "time out," the Government has not alleged facts suggesting that Dr. Luketich was not present for any other allegedly "key" or "critical" portions.

as well. Though the court accepts as true a complaint's factual allegations and views them in the light most favorable to the plaintiff, *see Phillips v. Cty. of Allegheny*, 515 F. 3d 224, 228 (3d Cir. 2008), "a formulaic recitation of the elements of a cause of action will not do," nor will "mere labels and conclusions." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level," *id*., and be "sufficient to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The Third Circuit has established a three-step process for district courts to follow in analyzing a Rule 12(b)(6) motion: the court must (1) "tak[e] note of the elements a plaintiff must plead to state a claim"; (2) identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth"; and (3) "where there are well-pleaded allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Burtch v. Milberg Factors, Inc*., 662 F. 3d 212, 221 (3d Cir. 2011).

ARGUMENT

I. The Government Does Not Allege and Cannot Plausibly Allege that Defendants Submitted a "False" Claim.

The Government contends that Defendants' claims for payment were "legally false," when Dr. Luketich performed and billed for surgeries as the primary/teaching surgeon or co-surgeon while: (1) he "did not participate in the "time out" or another [unspecified] key and critical component of the procedure," Compl. ¶ 156(a); (2) "two other surgical procedures that he billed for as the primary/teaching surgeon or co-surgeon were ongoing," *Id*., ¶ 156(b); and (3) "at least one other surgical procedure that he billed for as the primary/teaching surgeon was ongoing and not yet through all key and critical components of that second (or third) procedure." *Id*., ¶ 156(c).

Even if this Court accepts those allegations as true, the conduct alleged cannot be an FCA violation. The first scenario rests entirely upon UPMC policy alone, which, as described in Section B below, cannot predicate a "false" claim. The second and third scenarios are drawn straight from the CMS Manual -- sub-regulatory guidance that was not subject to notice-and-comment rulemaking but purports to establish a standard governing payment for services. Under *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), and as detailed more fully below in Section A, these two billing prescriptions are thus invalid and unenforceable. Apparently recognizing the massive hole in its case, the Government attempts to draft around *Allina* by contending that Defendants violated the TPR's requirement that the teaching physician be "immediately available" throughout the surgical procedure. *See* Compl., ¶¶ 100-112. But artful pleading cannot save the Government's claims. As detailed more fully below in Section C, the TPR's "immediately available" requirement is ambiguous at best and the Government has not, and cannot, allege plausibly that Defendants' interpretation of this ambiguity was objectively unreasonable. To the contrary, Defendants' interpretation was wholly consistent with CMS' guidance.

A. Departures from the CMS Manual Do Not Make Claims "False."

As the Supreme Court recently made clear in *Azar v. Allina Health Services*, agency guidance which purports to establish or change a substantive legal standard governing payment for services is invalid and unenforceable unless it has been subject to notice-and-comment rulemaking under the Medicare Act. *See Allina*, 139 S. Ct. at 1817 (affirming D.C. Court of Appeals determination that government policy affecting Medicare hospital payments issued with no advance notice and opportunity to comment was invalid); 42 U.S.C. § 1395hh(a)(2) ("No rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . under [Medicare] shall take effect unless it is promulgated by . . . regulation.").

What constitutes a "substantive legal standard" is not defined in the Medicare Act, 42 U.S.C. § 1395hh(a)(2), and was not clarified by the *Allina* court. Following *Allina*, on December 3, 2020, HHS's Office of the General Counsel ("OGC") issued "Advisory Opinion 20-05 on Implementing *Allina"* ("Advisory Opinion") advising that the OGC of HHS interprets the phrase "substantive legal standard," "to mean any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to … payment by Medicare for services … and 3) sets forth a requirement not otherwise mandated by statute or regulation." *See* Advisory Opinion at 1-2 (citing *Select Specialty Hosp.-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53 (D.D.C. 2019)).[16]

In its Manual and Section 100.1.2(A)(2) in particular, CMS purports to set binding parameters governing the right to payment for services, specifically overlapping and concurrent surgeries, not otherwise mandated by statute or regulation. And it has done so unilaterally, in contravention of its rulemaking obligations. Therefore, under *Allina* and the Medicare Act, the billing guidance contained in the CMS Manual is a new substantive – and unenforceable – legal standard. As such, the Advisory Opinion concludes "to the extent that guidance documents set forth Medicare policies or rules that are not closely tied to statutory or regulatory standards, *the government generally cannot use violations of that guidance to inform the basis for any enforcement action, because under Allina, it was not validly issued*." (emphasis added). The "critical question," the Advisory Opinion continues, "is whether the violation of the Medicare rule could be shown absent the guidance document. If the answer is no, then the guidance document

[16]Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101111604-mh-advisory-opinion-20-05-on-implementing-allina_12.03.2020_signed.pdf.

establishes a norm and, under *Allina*, is invalid unless issued through notice-and-comment rulemaking." *See id*.

The Advisory Opinion's conclusion regarding the "critical question" is particularly relevant here, where the operative legal authority relied on by the Government – a proscription regarding three or more overlapping surgeries and statements about when a physician may begin to become involved in a second procedure, Compl., ¶¶ 84, 87, 89 – are "norms" found only in the agency guidance that did not undergo the requisite notice-and-comment rulemaking. These proscriptions are not found in the TPR or any other statute or regulation. In other words, the answer to the critical question raised by the Advisory Opinion is "no"—the violation of the Medicare regulation could not be shown absent the guidance document. Accordingly, the Manual's overlapping and concurrent surgery provisions cannot serve as the basis for FCA liability in this case. *See Polansky v. Executive Health Resources, Inc.*, 422 F. Supp.3d 916, 934-36 (E.D. Pa. 2019) (applying *Allina* to "compel[ ] the conclusion that there can be no FCA liability" based on alleged violation of a policy affecting hospitals' right to payment where the "policy was contained in agency manuals that had not been promulgated pursuant to notice and comment.").[17]

[17] On July 1, 2021, Attorney General Merrick Garland issued a Memorandum for Heads of All Department Components Regarding the Issuance and Use of Guidance Documents by the Department of Justice, https://www.justice.gov/opa/page/file/1408606/download. While this Memorandum rescinds earlier Department policy concerning the use of guidance documents in affirmative civil enforcement cases, it confirms the undisputed proposition that "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," and not by non-binding agency guidance. *See* Garland Memorandum at 2 (internal citations omitted). This is not inconsistent with *Allina*, addressing agency guidance that was not merely interpretive but established a new substantive legal standard. Absent notice-and-comment rulemaking, such guidance is not only non-binding, it is invalid and unenforceable.

B. Departures from UPMC Policy Do Not Make Claims "False."

The Government also cannot premise an FCA action on a violation of UPMC policy alone. The FCA does not "create liability merely for a healthcare provider's … improper internal policies," nor does it create liability for the violation of a proper internal policy. *United States ex. rel. Spay v. CVS Caremark Corp*., 913 F. Supp. 2d 125, 147 (E.D. Pa. 2012). Rather, "[i]t is the false *certification* of compliance" with an underlying material statute or regulation "which creates liability when certification is a prerequisite to obtaining a government benefit." *United States ex. rel. Hopper v. Anton*, 91 F. 3d 1261, 1267 (9th Cir. 1996) (emphasis in original); *see also United States ex rel. Schmidt v. Zimmer, Inc*., 386 F. 3d 235, 243 (3d Cir. 2004) (same).

Thus, absent an applicable rule created by statute or regulation, an alleged violation of UPMC policy – namely, the requirement that the attending physician be present for the "time out" – cannot be a "false" claim or material to the government's decision to pay. *See, e.g., United States ex rel. Pritzker v. Sodexho, Inc.,* 364 Fed. Appx. 787, 790 (3d Cir. 2010) (affirming dismissal of plaintiff's claim because the complaint did not identify any applicable regulation); *United States ex. rel. Thomas v. Lockheed Martin Aeroparts, Inc*., 2016 WL 47882, *7 (W.D. Pa. Jan. 4, 2016) (dismissing FCA complaint in which the alleged violation was not contained in a statute or regulation); *United States ex rel. Grant v. United Airlines, Inc*., 2016 WL 6823321, at *5 (D.S.C. Nov. 18, 2016) ("[V]iolations of internal policies alone are not sufficient to violate the [FCA] where the internal policies are not incorporated into contractual, statutory, or regulatory requirements").[18]

[18] The Government fails even to establish a violation of UPMC policy because it has not alleged that there was no attending surgeon present for the "time out." Assuming that an attending surgeon was always present for the "time out" in Dr. Luketich's team-based surgeries, which the Government well knows to be true, there was no violation of UPMC policy.

C. A Reasonable Interpretation of an Ambiguous Regulation Cannot Support a False Claim. The Complaint Does Not, and Cannot, Plausibly Allege that Defendants' Interpretation of the Ambiguous Teaching Physician Regulation is Objectively Unreasonable.

Bereft of an enforceable regulatory or statutory directive prohibiting overlapping or concurrent surgeries, the Government alleges Dr. Luketich's surgical practice violates the TPR requirement that he be "immediately available" during the non-key portions of a surgical procedure. But as detailed above, CMS has not defined the term "immediately available" in the TPR, the CMS Manual or any of its other sub-regulatory guidance and what CMS intended to require by the term is not clear. When a physician may be considered "immediately available" is plainly ambiguous and subject to multiple reasonable interpretations. As detailed below, even if CMS had issued an unambiguous interpretation of the term – it has not – UPMC developed and deployed an objectively reasonable interpretation of the only guidance that CMS has provided. The Government's claims cannot survive dismissal because it has not alleged and cannot allege that UPMC's interpretation was or is objectively unreasonable.

Recently, in *United States v. Harra*, 985 F. 3d 196, 215 (3d Cir. 2021), a criminal prosecution for a false statement, the Third Circuit joined the majority of Circuits, adopting the principle that when there is ambiguity in the statute or regulation governing the defendant's conduct, the government must prove the defendant's statement is objectively false. *See id.* at 214 (collecting cases). The Court held that to carry its burden to prove "falsity," the Government must establish "either (a) that its interpretation is the only objectively reasonable interpretation and that, under this interpretation, the defendant's statement was false, or (b) that the defendant's statement was false under each alternative objectively reasonable interpretation." The Court continued, "[p]ut another way, if the Government cannot prove . . . that a defendant's statement was false

under each objectively reasonable interpretation of an ambiguous reporting requirement, it cannot prove the element of falsity." *Harra*, 985 F. 3d at 215.

While *Harra* was a criminal case involving proof beyond a reasonable doubt, and while the Third Circuit has yet to apply the *Harra* standard for measuring falsity in a civil False Claims Act complaint, the logic applies with equal force because "falsity" is an element of both civil and criminal FCA claims. This same standard has, moreover, been applied in civil FCA cases in other Circuits. *See e.g., United States ex rel. Wilson v. Kellogg Brown & Root, Inc*., 525 F. 3d 370, 376-78 (4th Cir. 2008)("imprecise statements or differences in interpretation growing out of a disputed legal question are [ ] not false under the FCA"); *United States ex rel. Hixson v. Health Mgmt. Sys., Inc*., 613 F. 3d 1186, 1191 (8th Cir. 2010)("As we have said, to prevail here the relators must show that there is no reasonable interpretation of the law that would make the allegedly false statement true."); *United States ex rel. Lamers v. City of Green Bay*, 168 F. 3d 1013, 1018 (7th Cir. 1999) (same). [19]

UPMC's Manual-driven interpretation of "immediately available" is eminently and objectively reasonable. First, it conforms with the only guidance that CMS has provided on that otherwise undefined term—and the Government has not and cannot plead otherwise. The CMS Manual directs that when a teaching physician like Dr. Luketich is not present during non-critical portions of one procedure while participating in another surgical procedure, he may permissibly bill for both if he "arrange[s] for another qualified surgeon to immediately assist the resident in

[19] The Government may point to the Third Circuit's recent decision in *United States v. Care Alternatives*, 952 F. 3d 89 (3d Cir. 2020), to suggest that the Court of Appeals has rejected the need to demonstrate an objective falsehood. But in that case, the Court held only that the District Court had placed too much emphasis on whether the statement at issue was objectively false, as a factual matter, and failed to consider whether the statement may have been legally false. The decision did not address the question whether a statement can be shown to be legally false when the regulation on which the claim is based is subject to multiple reasonable interpretations.

the other case should the need arise." *See* CMS Manual, Ch. 12, §100.1.2(A)(2); Compl. ¶ 87. Second, UPMC's interpretation is also consistent with CMS's regulatory intent, to ensure the billing physician is present for the key or critical portion, but not requiring the billing physician's presence for the entire procedure. *See* 60 Fed. Reg. 63144-45 (Dec. 8, 1995) (CMS implemented the requirement to be present for the "key" or "critical portion," "to provide flexibility and to avoid requiring the presence of the teaching physician for the duration of every service or procedure billed in his or her name.").

Consistent with this guidance, UPMC and Dr. Luketich have structured his team-based practice to ensure there is always another qualified surgeon designated and immediately available to assist the resident when Dr. Luketich is participating in another surgical procedure. *See* Exhibit B, Policy HS-OR0013, Overlapping Surgery and Procedures §§ III, IV (cited in Compl. ¶¶ 81, 85). The Government has not pled to the contrary and it cannot. As noted above, the Government *never* alleges that a qualified attending physician was not immediately available in Dr. Luketich's absence during any surgical procedure for which the Government was billed.[20] *See, supra*, at 9.

II. The Government Fails to and Cannot Plausibly Allege that Defendants Acted with the Requisite Scienter.

UPMC's reasonable interpretation of an ambiguous regulation, as outlined above, also is inconsistent with the scienter that the United States must plead to state an FCA claim. *See United States v. Allergan, Inc*., 746 Fed. Appx. 101 (3d Cir. 2018). Unlike the falsity prong, the FCA's scienter requirement is statutorily defined: a party must act "knowingly," *see* 31 U.S.C. §

[20] In fact, it is the Government's interpretation, not UPMC's, that is objectively unreasonable. By alleging that the teaching physician cannot perform or participate in another procedure while he/she has a surgical procedure ongoing in which all key or critical portions are not yet complete the local U.S. Attorney's Office endeavors to make overlapping or concurrent surgeries illegal, a step neither Congress nor CMS has taken. The Government's novel interpretation, unsupported by statute or regulation, also ignores the CMS Manual guidance that designating a second, qualified, attending surgeon can solve any potential "immediate availability" problem.

3729(a)(1)(A), which occurs if he or she "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

The scienter requirement is "rigorous" and constitutes a key element of an FCA claim, which can be evaluated even at the motion to dismiss stage. *See Universal Health Services, Inc. v. U.S. ex rel. Escobar,* 136 S.Ct. 1989, 2002 (2016); *U.S. ex rel. Sheldon v. Forest Laboratories, LLC*, 499 F. Supp. 3d 184, 207 (D. Md. 2020). "Consistent with the need for a knowing violation, the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." *Allergan,* 746 Fed. Appx. at 106 (quoting *United States ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 287-88 (D.C. Cir. 2015) (recognizing defense based on reasonable, but erroneous, interpretation of ambiguous statute).

In *Allergan*, the Third Circuit affirmed the dismissal of an FCA complaint alleging underpayment of Medicaid rebates to the States under the Medicaid Drug Rebate Program. At issue on appeal was whether the defendants, nine drug manufacturers, had knowingly violated the FCA by excluding certain credits they received from their customers when calculating a drug's Average Manufacturer's Price ("AMP"). The Third Circuit concluded, as had the District Court, that the statute defining the AMP was ambiguous, and even assuming the drug manufacturers' interpretation of the statute was erroneous as alleged, it was not objectively unreasonable. *See Allergan*, 746 Fed. Appx. at 110. Thus, the Court affirmed the District Court's dismissal of the relator's complaint because "this reasonable interpretation of an ambiguous statute was inconsistent with the reckless disregard [the plaintiff] was required to allege." *See id*.

In doing so, the Third Circuit adopted an objective scienter standard for an FCA claim, susceptible to resolution on a motion to dismiss, as first articulated by the Supreme Court in *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 68-70 (2007), a case brought pursuant to the Fair Credit Reporting Act.[21] Under this approach, a reasonable, but erroneous, interpretation of a statute undermines the "reckless disregard" (the floor of the FCA's scienter standard) necessary to state an FCA claim when (1) the relevant statute is ambiguous; (2) the defendant's interpretation of that ambiguity was not objectively unreasonable; and (3) the defendant was not "warned away" from that interpretation by available administrative and judicial guidance. *See Allergan*, 746 Fed. Appx. at 106. *See also United States v. Supervalu, Inc*., 9 F. 4th 455, 465 (7th Cir. 2021) (granting summary judgment for defendant in FCA action because plaintiff could not establish requisite scienter under test for determining whether defendant's interpretation of ambiguous regulation was objectively reasonable); *Sheldon,* 499 F. Supp. 3d at 212 (D. Md. 2020) (dismissing FCA complaint because, in addition to an inability to establish falsity, relator could not plausibly allege requisite scienter when CMS Manual did not warn defendant away from its interpretation of the applicable regulation); *United States ex rel. Complin v. North Carolina Baptist Hospital*, 818 Fed. Appx. 179, 184 (4th Cir. 2020) (affirming dismissal of FCA complaint because "establishing … reckless disregard of the truth or falsity of the information, is difficult when falsity turns on a disputed interpretive question").

Here, as in *Allergan*, *Supervalu*, *Complin*, and *Sheldon,* the relevant regulation, the TPR, is ambiguous. The Government has alleged that the TPR dictates that the teaching physician is

[21] The Third Circuit is not alone. Every other circuit court to discuss the relevance of *Safeco's* scienter standard to the FCA has arrived at the same conclusion. *See, e.g., United States v. Supervalu, Inc*., 9 F. 4th 455, 465 (7th Cir. 2021); *United States ex rel. McGrath v. Microsemi Corp*., 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F. 3d 874, 879-80 (8th Cir. 2016).

not "immediately available," if he is performing another procedure. But the Government does not allege and cannot allege that Defendants' interpretation of the "immediately available" requirement—namely that the requirement is satisfied when Dr. Luketich has a licensed and credentialed attending available at all times during his absence—is objectively unreasonable. Moreover, far from being "warned away" from this interpretation, UPMC and Dr. Luketich's interpretation is wholly consistent with the guidance contained in the CMS Manual: (1) permitting billing for two overlapping surgeries; (2) expressly condoning teaching physicians performing three overlapping surgeries; and (3) requiring the designation of another attending's immediate availability when the teaching physician is involved in another procedure. *See*, *supra*, at 5. Thus, the Government cannot plausibly allege even the minimum standard of scienter – reckless disregard – necessary to sustain an FCA action.

III. The Government Fails to Allege with the Requisite Particularity under Rule 9(b) Why Defendants Claims were "False," or Materially So.

Beyond the basic pleading standard of "plausibility," the Government must also plead its FCA claims with particularity in accordance with Rule 9(b). That is, the Government must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F. 3d 153, 157-58 (3d Cir. 2014). A plaintiff alleging fraud, including the government, must therefore support its allegations "with all of the essential factual background that would accompany the first paragraph of any newspaper story – that is, the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props., Inc. Securities Litig*., 311 F. 3d 198, 217 (3d Cir. 2002). This must include information such "as to who provided the payments, to whom the payments were made, [and] under what criteria the payments were awarded." *United States ex rel. Scalamogna v. Steel Valley Ambulance*, Case No. 14-cv-00524, 2018 WL 3122391 at * 3

(W.D. Pa. June 26, 2018) (Bissoon, J.) (quoting *United States ex rel. Whatley v. Eastwick Coll.*, 657 Fed. Appx. 89, 94 (3d Cir. 2016)).

Here too the Complaint fails. Far from laying out the regulatory criteria that would have made any particular claim by Defendants fraudulent, the Government pleads a miasma of supposed problems with Dr. Luketich's team-based approach, including:

- supposed unavailabilities of unspecified duration (Compl. ¶¶ 136-138, 159);
- perceived deficiencies in consenting procedures (*Id*. ¶¶ 147-149);
- anesthesia prolonged beyond indeterminate boundaries (*Id*. ¶¶114-115);
- participation in two—or perhaps three—supposedly concurrent or overlapping surgeries (*Id*. ¶¶ 101-112, 156(b), 156(c));
- absence from the "time out" or other key portions as designated by some unidentified arbiter (*Id*. ¶156(a)); and
- after-the-fact identification of "undue" complications (Compl. ¶159).[22]

Neither Defendants nor this Court can know which of these alleged problems, individually or in combination, would make a particular claim "false" or what "statute or regulation" makes it so. Nor without further specification can the Government carry its burden to plead the materiality of any of these accusations. *See Escobar,* 136 S.Ct. at 2003 (the materiality standard is "rigorous" and "demanding" because the FCA is not "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.").

[22] In a single paragraph, Compl. ¶ 159, the Government alleges "on information and belief" that it has suffered additional losses related to increased risk scores for Dr. Luketich's patients who were members of UPMC's Medicare Advantage Plan. This allegation is too vague and speculative to enable UPMC to respond, much less satisfy Rules 8(a) or 9(b).

Though the Government conclusively alleges the TPR and CMS Manual guidance "are central to the Government's bargain with teaching hospitals, and are not minor or insubstantial," Compl. ¶ 77, this allegation is belied by what the Government has not alleged: that it has *ever* denied a claim submitted by Defendants, or any other teaching hospital or teaching physician, on the grounds that the teaching physician was not "immediately available" under the TPR. *See Escobar*, 136 S. Ct. at 2003. Furthermore, CMS has repeatedly made clear in both the TPR and when publishing the final rule that the "most important consideration" for payment is the teaching physician's presence during the key portion(s) of the service. S*ee* 42 CFR § 415.172(a), Exhibit A; 60 Fed. Reg. 63139 (Dec. 8, 1995). Because the Complaint establishes that Dr. Luketich is present for the critical portions of his surgeries (as he determines them to be), *any* alleged non-compliance with the TPR can only be minor or insubstantial, not material.[23]

Were this Court not to dismiss the Complaint for failure to state a claim under Rule 12(b)(6), it should deploy the stricter pleading standards of Rule 9(b) and require the Government to specify:

1. Each criterion that it asserts makes any claim submitted by Defendants false under the FCA;

2. The legal authority for that criterion; and

3. Why departure from that criterion would be material under the FCA.

[23] The Government acknowledges as much in the Complaint. This is the tell: "But these are not merely technical violations of billing requirements or internal policies." Compl. ¶ 5. As purported evidence of "materiality," that paragraph then details alleged violations of the standards of care, abuse of trust, and malpractice which are wholly unrelated to a violation of a billing rule.

IV. The Government Fails to State Claims for Unjust Enrichment and Payment by Mistake.

The Complaint purports to state common law claims for unjust enrichment and payment by mistake of fact—but fails. These two alternative theories of recovery "are essentially duplicative and seek the same relief." *See Smith v. Carolina Medical Center*, 274 F. Supp. 3d 300, 326 (E.D. Pa. 2017). Under Pennsylvania law, a claim for unjust enrichment falls into one of two categories: "(1) a quasi-contract theory of liability, in which case the unjust enrichment claims is brought as an alternative to a breach of contract claim; or (2) a theory based on unlawful or improper conduct established by an underlying claim, such as fraud, in which case the unjust enrichment claim is a companion to the underlying claim." *SodexoMAGIC, LLC v. Drexel University*, 333 F.Supp.3d 426, 472 (E.D. Pa. Aug. 2, 2018). Under either theory, the elements necessary to prove unjust enrichment are: "(1) benefits conferred on defendant by plaintiff; (2) appreciation of such benefits by defendant; and (3) acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value." *Durst v. Milroy Gen. Contracting, Inc*., 52 A. 3d 357, 360 (Pa. Super. Ct. 2012).

Where, as here, "the unjust enrichment claim rests on the same improper conduct as the underlying [FCA] claim, the unjust enrichment claim will rise or fall with the underlying claim." *SodexoMAGIC*, 333 F.Supp.3d at 473; *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc*., 171 F.3d 912, 937 (3d Cir. 1999) (dismissing the plaintiff's unjust enrichment claim because it was based on the same improper conduct as the plaintiff's traditional tort claims, which were dismissed for lack of proximate cause). Here, because the Government fails to state plausible and specific claims for relief under the FCA, a separate claim for unjust enrichment or payment by mistake cannot stand.

To the extent the Government contends it may plead unjust enrichment in the alternative, this argument fails. In Pennsylvania, the unjust enrichment doctrine is "inapplicable when the relationship between the parties is founded on a written agreement or express contract." *Hollenshead v. New Penn Financial*, *LLC*, 447 F.Supp.3d 283, 293 (E.D. Pa. Mar. 18, 2020) (internal quotations omitted). The Complaint alleges Defendants maintain express agreements with Government Health Benefit Programs to provide services. *See e.g.*, ¶¶ 25, 31, 44. This effectively precludes the Government from pleading a claim for unjust enrichment under a quasi-contract theory, even in the alternative, because there is no dispute concerning the validity or enforceability of these express agreements. *See Hollenshead,* 447 F.Supp.3d at 293 (dismissing unjust enrichment claim when a written contract existed, which neither part claimed was invalid or unenforceable).

CONCLUSION

For the foregoing reasons, the United States' Complaint in Partial Intervention must be dismissed, with prejudice.

Dated: November 1, 2021

Respectfully submitted,

[redacted]