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

UNITED STATES OF AMERICA, *ex rel*., JONATHAN D'CUNHA, M.D. *Plaintiff*, and v. DR. JAMES D. LUKETICH, UNIVERSITY OF PITTSBURGH MEDICAL CENTER, and UNIVERSITY OF PITTSBURGH, *Defendants*.	Civil Action No. 19-cv-495 District Judge Cathy Bissoon

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION AND THE HOSPITAL AND HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Defendants have persuasively explained why the Complaint fails to state a claim as a matter of law. *Amici* do not seek to repeat those compelling legal arguments. Instead, *amici* can best assist the Court in another way: by providing critical information, based primarily on documents incorporated in the Complaint, about the history, practice, and regulation of concurrent and overlapping surgeries during the time period relevant to this case.

The practice first came to widespread public attention with publication of a *Boston Globe* article in October 2015. It spurred a number of inquiries, and was certainly a catalyst for the American College of Surgeons (ACS) to update its guidance on the practice, the Senate Finance Committee to issue a report on the subject, and hospitals across the country to review and update their internal policies governing those surgeries. But one key stakeholder, the Centers for Medicare & Medicaid Services (CMS), did not change its preexisting billing guidelines because those guidelines already properly deferred to the medical expertise of individual surgeons and their teams. Then and now, CMS's billing guidelines correctly recognize that surgical teams perform a wide variety of medical procedures under widely differing circumstances, and so the guidelines appropriately defer to surgeons' knowledge and on-the-ground demands. To that end, CMS's *Medicare Claims Processing Manual* explicitly allows doctors to determine what portions of particular surgeries are "critical," and permits overlapping surgeries to occur so long as a qualified backup physician is available. This has allowed hospitals to develop policies for concurrent and overlapping surgeries that are consistent with ACS guidance, and best suited to their patients' individual circumstances and their surgical teams' own professional experience.

Despite the flexibility and deference contained in CMS's *Manual*, the United States Attorney's Office now seeks to impose its own view of proper medicine over that of a world-renowned hospital and its surgical staff. But that is not the job of the Department of Justice. Nor

is the function of the False Claims Act, which the Supreme Court has repeatedly explained "is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016) (quoting *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008)). At the very least, it is *CMS's* responsibility in the first instance as the expert agency that actually reimburses hospitals for medical services to develop meaningful guidance for concurrent and overlapping surgeries, if that guidance is needed. Only then, and only if CMS's guidance is not adhered to, are False Claims Act lawsuits appropriate. But CMS has not developed such guidance, and that fact alone fatally undermines this Complaint. Simply put, DOJ-driven False Claims Act lawsuits cannot be used to regulate concurrent and overlapping surgeries in CMS's stead.

More elementally, neither the Department of Justice nor the False Claims Act should be allowed to short-circuit the ongoing medical discussion about how to best ensure the efficacy and safety of overlapping surgeries. In light of the ACS' updated surgical guidance, hospitals revised their policies on the subject and, in so doing, demonstrated that they are capable of effectively managing overlapping surgeries consistent with their own unique medical needs. Indeed, studies discussed in Section II below—including the Senate Finance Committee's report, which is incorporated into the Complaint in paragraph 134—recognize that hospitals have taken varying approaches to overlapping surgeries since 2015. But contrary to implications in the government's Complaint, *CMS itself* has stated that patients are *not* endangered by the practice. *See* Staff of United States Senate Finance Committee, *Concurrent and Overlapping Surgeries: Additional Measures Warranted* 4 (Dec. 6, 2016), https://www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20Report%20Final.pdf

("SFC Staff Report") ("Both CMS and Joint Commission told Committee staff that in conducting oversight activities, they have not noticed the practices of concurrent or overlapping surgeries as contributing in any particular way to patient harm."). In fact, experts have found that overlapping surgeries are not just safe, but they allow more patients to receive lifesaving care when it is needed. As the chair of surgical quality at the Mayo Clinic's Rochester campus put it: "Our data shows that overlapping surgery as practiced here is safe.… We think [overlapping surgery] provides value to our patients because it allows more patients timely access to surgery and care by expert teams.'" Sharon Theimer, *Study of thousands of operations finds overlapping surgeries are safe for Mayo Clinic patients*, Mayo Clinic News Network (Dec. 1, 2016), https://newsnetwork.mayoclinic.org/discussion/study-of-thousands-of-operations-finds-overlapping-surgeries-are-safe-for-mayo-clinic-patients/.

In the end, as the history below makes clear, this Court must not allow one United States Attorney's office to dictate important medical decisions through the threat of civil and criminal False Claims Act liability for a surgical practice that CMS has not deemed harmful to patients. Accordingly, the Court should grant Defendants' Motion to Dismiss.

ARGUMENT

I. FEDERAL BILLING GUIDANCE CONTINUES TO AFFORD HOSPITALS SIGNIFICANT DEFERENCE FOR DECISIONS ON OVERLAPPING SURGERIES

At several points in its Complaint, the government references key moments in the recent history of concurrent and overlapping surgeries. For example, paragraph 128 mentions an October 2015 *Boston Globe* article that increased public awareness of those kinds of surgeries. Paragraphs 80 and 88 allude to revised guidance that was issued by the American College of Surgeons in the wake of the *Boston Globe* article. And paragraph 134 refers to a 2016 Senate Finance Committee

inquiry and report on concurrent and overlapping surgeries. This drive-by history, however, fails to offer the complete understanding that is needed for this case.

While this Court can and should review those incorporated documents itself and consider them in connection with Defendants' Motion to Dismiss[1], the discussion below provides a more accurate description of the context in which Defendants were acting during the time period covered by the Complaint. Most important, a comprehensive review of this time period makes clear that CMS's billing guidance did not change after 2015, and hospitals like Defendant-UPMC were accorded deference for important and complex medical decisions and practices before *and* after the publication of the *Boston Globe* article. This more fulsome picture of the history, context, and regulatory environment from 2015 to the present day demonstrates why the Complaint fails as a matter of law for the reasons set forth in Defendants' Motion to Dismiss.

A. An October 2015 *Boston Globe* Article Increased Public Awareness of Concurrent and Overlapping Surgeries

***Boston Globe* Article**. On October 25, 2015, the *Boston Globe* published a lengthy article about concurrent and overlapping surgeries at Massachusetts General Hospital (MGH). Written by the *Globe*'s Spotlight Team, the article discussed "personal and bitter" disputes within MGH about the "propriety and safety of a fairly common but little studied practice." Abelson J, Saltzman J, Kowalczyk L, Allen S., Clash in the name of care, *Boston Globe* (Oct. 25, 2015), https://apps.bostonglobe.com/spotlight/clash-in-the-name-of-care/story/. Specifically, the article focused on one "star surgeon," Dr. Dennis Burke, who went "to war with hospital administrators

[1] *See Buck v. Hampton Twp. Sch. Dist*., 452 F.3d 256, 260 (3d Cir. 2006) ("In evaluating a motion to dismiss, we may consider documents that are attached to or submitted with the complaint, and any 'matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case.'" (quoting 5B Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 1357 (3d ed. 2004).

and some of his peers over his assertion that running concurrent surgeries is ethically unthinkable and dangerous." *Id*. Dr. Burke, who the article described as an unapologetic "zealot" on the issue, was ultimately terminated for violating "hospital rules and possibly federal privacy laws" in connection with his efforts to end concurrent surgeries at MGH. *Id*. Before then, however, he led a "multi-year battle" within "one of the nation's top-rated hospitals" on the issue. *Id*. In describing that battle, the article discussed various allegations taken from patient malpractice lawsuits, as well as stories of surgeries that suffered complications, while at the same time noting that "[t]here is no known connection" between those medical `complications and the concurrent surgeries. *Id*.

For its part, MGH vigorously disputed Dr. Burke's assertions. For instance, the hospital "describe[d] [overlapping surgeries] as an extension of the teaching hospital's team approach, pairing senior doctors with residents—surgical trainees—and fellows, who have finished their general orthopedic surgery residency and are training in a subspecialty."[2] *Id*. MGH also maintained that overlapping surgeries did not pose any additional patient risks. It pointed to its own internal

[2] It is no coincidence that MGH emphasized its "team approach" to surgery. As the Court considers Defendants' Motion to Dismiss, it should not undervalue the centrality of the team approach in surgical medicine—and at teaching hospitals in particular. For example, the Mayo Clinic surgeon quoted in the introduction to this brief also pointed to the importance of surgical teams. *See* Sharon Theimer, *Study of thousands of operations finds overlapping surgeries are safe for Mayo Clinic patients*, Mayo Clinic News Network (Dec. 1, 2016), https://newsnetwork.mayoclinic.org/discussion/study-of-thousands-of-operations-finds-overlapping-surgeries-are-safe-for-mayo-clinic-patients/ ("'We think [overlapping surgery] provides value to our patients because it allows more patients timely access to surgery and care by *expert teams*.'" (emphasize added)). So, too, at the Johns Hopkins University School of Medicine. The chief resident of the Department of General Surgery there has stated: "'All the work we do as resident physicians is carried out within a team-based structure. Learners at all levels—medical students, residents, interns, and fellows—are critical to the overall functioning of the team…. It's when people understand their roles, feel like their contributions are valued, and have a sense of belonging that we can deliver patient care in the most optimal way.'" Association of American Medical Colleges, *Teamwork: The Heart of Health Care* (Sept. 27, 2016), https://www.aamc.org/news-insights/teamwork-heart-health-care. The importance of the team approach to surgery is reflected in the deferential CMS *Manual* and American College of Surgeons guidelines, both of which are discussed at great length below.

studies—as well as a University of Virginia research study, which was the "most extensive analysis of concurrent surgery" at the time—that identified "no significant difference in complication rates between overlapping and non-overlapping cases." *Id*. And the article gently observed that "[s]ome even wonder at [Dr. Burke's] motives, believing he is driven by outrage at the hospital for placing a Burke protege on academic probation and not hiring her." *Id*.

The Court will no doubt read the article itself, and so *amici* need not extensively summarize it here. But several features are worth highlighting. *First*, the article *in no way* suggested that this internal MGH dispute about the propriety of concurrent and overlapping surgeries raised *legal* concerns under federal billing rules. To the contrary, the article explicitly stated that MGH *fully complied with* federal billing guidance:

> [I]n order to bill Medicare, a surgeon managing simultaneous surgeries must be immediately available if a problem arises in either case or, if he cannot, to designate a backup attending to assist. *MGH's rules satisfied those federal regulations*, but offered little direction on which procedures are appropriate for double-booking, what are the key or critical parts, and how much overlap of cases is safe and ethical.

Id. (emphasis added).

Second, the article emphasized that there were differing views on the issue—not only at MGH, but at hospitals across the country. Inside and outside of MGH, physicians and hospital administrators had strong and principled views on both sides of the question whether and how hospitals should conduct concurrent or overlapping surgeries. It explained, for example, that similar discussions about concurrent and overlapping surgeries had occurred in recent years "at medical institutions in Chicago, Milwaukee, Nashville, and Syracuse." *Id*.

Third, the article explained how, as a result of these discussions, hospitals had started to revise their own policies regarding concurrent and overlapping surgeries. Even at MGH, the article noted, hospital administrators went beyond the billing requirements set forth in federal regulation.

See id. ("Yet the hospital did impose new limits on double-booking surgery after Burke spoke out, reining in what MGH's chief of surgery described in an e-mail—echoing a phrase of Burke's, he says—as the 'wild wild west' era of concurrent surgery."). The article explained how Dr. Peter Dunn, medical director of MGH's Operating Room, conducted a review of the hospital's guidelines for overlapping surgeries. According to the article, Dr. Dunn found that federal guidance merely "required that, in order to bill Medicare, a surgeon managing simultaneous surgeries must be immediately available if a problem arises in either case or, if he cannot, to designate a backup attending to assist." *Id*. At the same time, he "quickly learned how little scientific research there was about concurrent surgery to guide him." *Id*. Despite this indefinite regulatory and scientific environment, MGH did revise its policies. Those revised policies were so successful that, in 2015, it received a "letter from the executive director of the American College of Surgeons—who reviewed the guidelines at MGH's request—and deemed them an 'example of best practice and certainly exceed national standards.'" *Id*.

Fourth, the article led to widespread public attention to the questions surrounding concurrent and overlapping surgeries and was a catalyst for much of what followed.

American College of Surgeons Guidelines. In April 2016, following publication of the *Boston Globe* article, ACS released its updated general surgical guidance to specifically address the practice of concurrent and overlapping surgeries. *See* American College of Surgeons, *Statements on Principles* (April 12, 2016), https://www.facs.org/about-acs/statements/stonprin (hereinafter "ACS Guidelines"). As ACS later told the Senate Finance Committee, the new guidance had a limited purpose: "to clarify appropriate practice by separately defining terminology and adding more specific wording in some areas." SFC Staff Report 4. Critically, ACS did *not* intend to address, alter, or otherwise impact federal *billing* rules. *Id*. ("According to ACS officials, their

revised guidance, by design, does not depart greatly from CMS's billing guidance for teaching physicians."); *see* Abelson J, Saltzman J, Surgeons urged to better govern dual bookings, *Boston Globe* (Apr. 14, 2016), https://www.bostonglobe.com/metro/2016/04/13/surgery/Jn7Lb0Hq3VUGeZGBgjiw0M/story.html ("The world's largest surgeons' organization has issued its first-ever guidelines for surgeons managing simultaneous operations, saying the controversial practice is broadly permissible, within limits…. *That standard largely reiterates what is already prohibited under Medicare billing rules*—a fact swiftly noted by some who had hoped for more forceful action—but was seen by one member of the group that drafted the guidelines as a vital reminder to surgeons." (emphasis added)). Put another way, ACS's guidelines were revised only to address what ACS thought was appropriate from a patient safety perspective. By contrast, "CMS's billing requirements are not intended to comment on the practice of concurrent surgeries from a health and safety standpoint—that is, those requirements were developed to identify appropriate and inappropriate billing practices." *Id*. at 5.[3]

With that different purpose in mind, it is still important to understand exactly what the ACS guidelines say, in part because the Complaint occasionally nods towards them. Most fundamentally, the ACS guidelines state that concurrent surgeries are "inappropriate," but they do *not* say the same about overlapping surgeries. *See* ACS Guidelines II.D. Instead, the guidelines provide that "[i]n general, the patient's primary attending surgeon should be in the operating suite or should be immediately available for the entire surgical procedure," but there are "valid exceptions." *Id*. Specifically, the guidelines allow a primary attending surgeon to not be present

[3] Given the limited purpose of the ACS guidelines, it is unclear why the Complaint alleges (at ¶ 88) that ACS "expressly notes in its guidelines that CMS will not pay physicians for concurrent surgeries." As the Court can see for itself when it reviews those guidelines, the ACS guidelines say no such thing, let alone "expressly."

or immediately available when "another attending surgeon" is "assigned to be 'immediately available.'" *Id*. Thus, the guidelines permit primary surgeons to be absent in some circumstances, including when they are participating in portions of another surgery.

To that end, the ACS guidelines define concurrent surgeries as procedures as those for which the "critical or key components of the procedures … are occurring all or in part at the same time"; it defines overlapping surgeries as "surgical procedures where key or critical portions of the procedures are occurring at different times." *Id*. These definitions thus turn on the definition of "critical" or "key" portions of an operation. But like CMS's definition of that concept, *see infra* at 12-13, the ACS guidelines defer to expertise of the surgeon and her team on the ground:

> The "critical" or "key" portions of an operation are those stages when essential technical expertise and surgical judgment are necessary to achieve an optimal patient outcome. The critical or key portions of an operation are determined by the primary attending surgeon.

Id.[4] The *Boston Globe*'s Spotlight team accurately summarized the most pertinent features of these guidelines in a follow-up article shortly after they were published: "Like Medicare regulations, the ACS guidelines allow doctors to define the critical parts of the operation when they must be present. They also permit surgeons to overlap the critical part of one operation with the noncritical part of another as long as a second qualified surgeon can act as a backup if something goes wrong in the room that the attending has left." Abelson J, Saltzman J, Surgeons urged to better govern dual bookings, *Boston Globe* (Apr. 14, 2016), https://www.bostonglobe.com/metro/2016/04/13/surgery/Jn7Lb0Hq3VUGeZGBgjiw0M/story.html.

[4] It is again unclear why the Complaint states (at ¶ 80) that "[a]ccording to the American College of Surgeons, it is the primary surgeon's responsibility to lead the surgical team through the 'time out.'" The guidelines do not discuss the "time out," nor do they define it as a critical portion of a surgery.

Senate Finance Committee Staff Report. As the Complaint alleges (at ¶ 134), the Senate Finance Committee launched an inquiry into concurrent and overlapping surgeries in early 2016. After a year-long investigation, the Committee's staff produced a report that contained several significant observations. Again, the Court can and should read the report in its entirety, but several findings are worth underscoring.

The most striking aspect of the report was its repeated discussion about how little is known about concurrent and overlapping surgeries beyond the medical field and how deferentially it is regulated. The report notes at the very outset, for example, that prior to the publication of the *Boston Globe* article, the practice of concurrent and overlapping surgeries "was not widely understood beyond the medical field." SFC Staff Report 1. What's more, comments later in the report highlight that there had been little empirical study on the practice even within the medical field:

- "[Q]ueries to CMS, the HHS Office of Inspector General (OIG), the Agency for Healthcare Research and Quality (AHRQ), and The Joint Commission, as well as literature searches for data and research on [concurrent and overlapping surgeries], resulted in little if any data or research on its frequency, cost-effectiveness, or impact on surgical outcomes and patient health." *Id*. at 2.
- "Over 26 million surgeries were performed by hospitals in 2014. However, there is little empirical information about the extent of the practice of concurrent or overlapping surgeries." *Id*. at 16.
- "[T]he information we received to date or found from outside sources does not provide Committee staff with an adequate understanding about the scope of the issue." *Id*.

The report also addressed how CMS and HHS-OIG regulated concurrent and overlapping surgeries. As an initial matter, the report repeatedly noted that "no CMS billing requirements exist when concurrent or overlapping surgeries occur outside a teaching setting." *Id*. at 2. But even for teaching hospitals, the report noted, the only requirements are found in CMS's *Medicare Claims Processing*. As relevant here, the Staff Report identified the *Manual*'s "most notable billing requirements":

- "The teaching physician must be physically present during all critical or key ('critical') portions of the procedure and be 'immediately available' during the entire procedure." *Id*. at 3.
- "CMS's *Medicare Claims Processing Manual* defines the critical portion to be the part(s) of a service that the surgeon determines to be critical and states that critical does not generally include the opening or closing of the surgical field." *Id*. at 3 n.13.
- "Immediately available is generally not defined, except to indicate that a surgeon performing another procedure would not be considered to be immediately available." *Id*.
- "If circumstances prevent the teaching physician from being immediately available during noncritical or non-key portions of the surgeries, then she/he must arrange for another qualified surgeon to be immediately available to assist with the procedure, if needed." *Id*. at 4.

Next, the report discussed how little the federal government historically enforced these billing rules. It explained that, remarkably, "CMS has not taken *any steps* to determine whether the existing billing requirements applicable to teaching physicians in hospitals are or are not being followed despite a history of problems in this area." *Id*. at 18 (emphasis added). In fact, CMS informed the Committee that it had "*never* undertaken a study to determine whether the surgical procedures Medicare paid for met CMS's billing requirements specific to overlapping surgeries performed in teaching hospitals." *Id*. at 6 (emphasis added). Likewise, "[o]fficials with HHS OIG also told Committee staff that they do not have any ongoing work specifically reviewing hospitals' adherence to the Medicare billing requirements for teaching physicians." *Id*. at 7.[5] Accordingly, the Committee staff recommended that HHS should "review the controls in place to ensure that hospitals and physicians are appropriately billing for physician services provided by teaching physicians." *Id*.[6]

[5] The report did note that HHS-OIG had audited teaching hospitals' billing practices generally, but it was clear that HHS-OIG had not specifically targeted concurrent or overlapping surgeries in at least the fifteen months following the *Boston Globe* article. *See id*.

[6] Given CMS's and HHS-OIG's past enforcement practices, there are serious materiality concerns in this case. *E.g.*, *United States ex rel. Spay v. CVS Caremark Corporation*, 875 F.3d 746, 763-764 (3d Cir. 2017). At best, the Complaint makes conclusory assertions (at ¶ 162) that "[h]ad the Government been aware of Defendants' fraudulent practices, the Government would not have paid the claims at issue." But those assertions are contradicted by prior HHS auditing and enforcement

B. The *Medicare Claims Processing Manual*'s Treatment of Concurrent and Overlapping Surgeries Has Not Changed

The publication of the ACS guidelines appropriately did not result in a change in CMS's *Medicare Claims Processing Manual*.[7] While those guidelines do not permit billing for surgeries

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practice as described in the public record, *i.e.*, the Senate Finance Committee Staff Report. *See In re Washington Mut. Inc.*, 741 Fed. App'x 88, 91 n.3 (3d Cir. 2018) ("We need not, however, credit factual allegations contradicted by matters of which we may take judicial notice."). Even absent that conflicting evidence, moreover, the Complaint's conclusory assertions regarding materiality would seem to fail under the basic *Iqbal*/*Twombly* pleading standard, let alone Federal Rule of Civil Procedure 9(b)'s more rigorous pleading standard for fraud and the FCA's heightened materiality standard under *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). *Compare United States ex rel. Scalamogna v. Steel Valley Ambulance*, Case No. 14-cv-00524, 2018 WL 3122391 at * 9 (W.D. Pa. June 26, 2018) (Bissoon, J.) ("materiality may be found where the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." (internal quotation marks omitted)), *with* Def.' Mot. to Dismiss 23 (the Complaint fails to sufficiently allege materiality because it does not allege that HHS previously refused to pay claims).

[7] The only express reference to concurrent or overlapping surgeries in a relevant CMS document is in the *Medicare Claims Processing Manual*, which is presumably why the Complaint focuses so heavily on it (and why this *amicus* brief addresses it at length). That being said, the Complaint occasionally cites to 42 C.F.R. § 415.172, a more general regulation related to reimbursements for teaching physicians that does *not* specifically address overlapping surgery. But that regulation similarly defers to surgeons by requiring that "the teaching physician must be present during all critical portions of the procedure" without defining what constitutes a "critical" portion. 42 C.F.R. § 415.17(a)(1). Indeed, CMS made clear that this regulation does *not* require "the presence of the teaching physician for the duration of every service or procedure billed in his or her name." *See* Department of Health and Human Services, Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1996, 60 Fed. Reg. 63124, 63144 (Dec. 8, 1995). Quite the opposite, CMS proposed the "concept of the key portion of a service or procedure *to provide flexibility*." *Id.* (emphasis added); *see* Defs.' Mot. to Dismiss 4 (discussing gaps in 42 C.F.R. § 415.172). Likewise, 42 C.F.R. § 415.172 does *not* define the term "immediately available," thereby affording the same deference to surgical teams. More to the point, CMS interpreted "immediately available" in the *Medicare Claims Processing Manual* to allow for the availability of backup surgeons—and thus did not "warn away" hospitals from that interpretation. *United States v. Allergan, Inc.*, 746 Fed. Appx. 101, 106 (3d Cir. 2018) (whether a defendant was "warned away" from its interpretation of an ambiguous regulation is relevant to whether an FCA violation is properly alleged). By actually adopting that interpretation, CMS's gloss on the term proves the reasonableness of UPMC's reading. And just as CMS did not update its *Medicare Claims Processing Manual* after ACS issued its guidance, CMS also did not change this regulation to specifically address concurrent or overlapping surgeries.

in which "critical" portions occurred at the same time, they unambiguously permit billing when those "critical" periods are not at the same time. More importantly, the *Medicare Claims Processing Manual* expressly leaves it to the individual surgeon at teaching hospitals to determine what was a "critical" period. *See* CMS *Medicare Claims Processing Manual,* Rev. 4173 (11-30-2018), Chapter 12, § 100 ("**Critical or Key Portion** - That part (or parts) of a service that the teaching physician determines is (are) a critical or key portion(s)."). Equally important for purposes of this case, the *Medicare Claims Processing Manual* allows teaching physicians to be not immediately available during non-critical portions of overlapping surgeries so long as another qualified physician is immediately available. *See id*. at Chapter 12, § 100.1.2.A.2 ("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 other case should the need arise.").

It is important to emphasize these features of the *Medicare Claims Processing Manual* because the Complaint is not always clear about exactly what those billing guidelines require. For example, the Complaint correctly alleges (at ¶ 78) that individual surgeons may determine what is and is not a critical portion of the surgery, but it then implies that the "time out" is a "critical" portion as a matter of law. It is not. The *Medicare Claims Processing Manual* does not address the "time out" at all. Presumably for that reason, the Complaint only cites (at ¶¶ 81-82) UPMC policy when it alleges that the "time out" is "critical." But there cannot be an FCA violation for alleged violations of hospital policy. *E.g*., *United States ex rel. Grant v. United Airlines, Inc*., No. 2:15-cv-00794, 2016 WL 6823321, at *5 (D.S.C. Nov. 18, 2016) ("[V]iolations of internal policies alone are not sufficient to violate the False Claims Act where the internal policies are not incorporated into contractual, statutory, or regulatory requirements."); *see* Defs.' Mot. to Dismiss

15. This Court should be extremely wary of the Complaint's attempt to transform UPMC policy into actual law that can give rise to an FCA violation, and it should reject at the threshold any efforts to do so.

Similarly, the Complaint is less-than-consistent with respect to the *Medicare Claims Processing Manual*'s requirements for a teaching physician's availability. For example, paragraph 84 alleges that "if a teaching physician cannot be physically present during the non-critical portions of the surgery, the physician must be 'immediately available' to return to the procedure; that is, 'he/she cannot be performing another procedure.'" But that is an incomplete statement of what the *Manual* actually allows, *i.e.*, a surgeon to be absent so long as a backup physician is immediately available. The Complaint mentions the other vital portion about backup surgeons several paragraphs later (at ¶ 87), but repeats *only* the "immediately available" portion of the *Manual* again and again as if that were the sole option the *Manual* provides. *E.g.*, Compl. ¶¶ 111, 112, 133; *see id*. at Heading to Section V.A.i ("Luketich Regularly Plans to Perform, Performs, and Bills for, Three Complex Surgical Procedures that Overlap in Time, in Violation of the Requirement that He Be 'Immediately Available' Throughout Such Procedures"). And to make matters far worse, when the Complaint offers its allegations about Dr. Lukevitch's surgeries, it *never once* alleges that he did not assign another qualified physician to be immediately available. *Compare* Compl. Section V, *with Goldberg v. Rush University Medical Center*, 929 F.Supp.2d 807, 820 (N.D. Ill. 2013) (denying motion to dismiss in part because "[t]he fraud Relators allege consists of submitting Medicare claims for overlapping surgeries in which the teaching physician was *not* immediately available and did *not* arrange for another surgeon to be immediately available to assist").

That is a fatal deficiency under the most basic pleading standards, as well as Federal Rule of Civil Procedure 9(b)'s heightened standard. As a matter of law, Defendants could not have

violated the law unless Dr. Luketich was not immediately available *and* no other qualified physician was assigned. Consequently, the Complaint does not actually allege a violation of the *Medicare Claims Processing Manual* or the FCA. *See* Defs.' Mot. to Dismiss 22-23. Given the stakes of FCA cases like these—particularly because the Act has both criminal and noncriminal application, as well as serious reputational consequences for doctors and hospitals—courts must scrupulously ensure that plaintiffs accurately state regulatory requirements and allege that *all* such requirements were violated before allowing FCA claims to move past a motion to dismiss. *See, e.g.*, *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301, 1313 n.24 (11th Cir. 2002) ("When a plaintiff does not specifically plead the minimum elements of their allegation, it enables them to learn the complaint's bare essentials through discovery and may needlessly harm a defendants' [sic] goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are baseless allegations used to extract settlements.") (case cited in *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 439–40 (3d Cir. 2004)); *United States ex rel. Gohil v. Sanofi-Aventis U.S., Inc.*, 96 F.Supp.3d 504, 519-20 (E.D. Pa. 2015) ("Rule 9(b) demands to know specifically why the prescriptions would not be eligible for reimbursement. To satisfy this standard, Mr. Gohil must plead for what unaccepted medical indications Aventis promoted Taxotere.… There are any number of ways in which Aventis could have marketed Taxotere which could have disqualified the drug for reimbursement. Thus, to properly limit the scope of this complaint and provide Aventis sufficient notice of the claim, Mr. Gohil must allege unaccepted medical indications.… [R]equiring Mr. Gohil to plead the unaccepted medical indications comports with Rule 9(b)'s objective[ ] of ... prevent[ing] plaintiffs from filing baseless claims then attempting to discover unknown wrongs." (internal quotation marks omitted)).

Finally, the foregoing discussion assumes that a violation of the *Medicare Claims Processing Manual* is sufficient to give rise of an FCA violation. Defendants have convincingly argued, however, that *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), forecloses such liability. *See* Defs.' Mot. to Dismiss 12-14. For that reason, any post-2015 history of the regulation of concurrent and overlapping surgeries would be incomplete without discussing HHS's failure to engage in a notice-and-comment rulemaking process.

That history is straightforward: CMS did not substantively update its *Medicare Claims Processing Manual*, or engage in a rulemaking to codify its billing guidance after *Allina*. Critically, the agency was well-aware of the consequences of not engaging in rulemaking for billing guidance like those in the *Manual*. On October 31, 2019, CMS's Chief Legal Officer issued a legal memo entitled "Impact of *Allina* on Medicare Payment Rules." Memorandum from Kelly M. Cleary, Deputy General Counsel & CMS Chief Legal Officer to Demetrious Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare Re: Impact of *Allina* on Medicare Payment Rules (Oct. 31, 2019), https://www.alston.com/files/docs/20191031-CMS-Memo-re-Medicare-Payment-Rules.pdf.[8] The memo explained that that where HHS or CMS has issued guidance that, under *Allina*, should have been promulgated through notice-and-comment rulemaking, the government's "ability to bring enforcement actions predicated on violations of those payment policies is restricted." *Id*. Indeed, the memo concludes: "If the Center for Medicare intends for a particular guidance document to be used in enforcement actions, then the guidance must conform

[8] Courts in this circuit have considered agency memoranda like the Cleary Memo when evaluating motions to dismiss. *E.g*., *Karkalas v. Marks*, *Civil Action No*. 19-948, 2019 WL 3492232, at *18 n.212 (E.D. Pa. July 31, 2019) ("We may consider public documents like Congressional testimony and Drug Enforcement Agency memoranda as these are matters of public record."); *J.R. v. Camden City Bd. of Educ*., Civil Action No. 11–5060, 2013 WL 6074063, at *2 n.6 (D.N.J. Nov. 15, 2013) (considering on motion to dismiss "letters or memorandums … issue[d] from U.S. or New Jersey government").

with *Allina*." *Id*. Accordingly, under the plain terms the Cleary Memo, the Department of Justice cannot now bring an enforcement action under the FCA because CMS failed to follow *Allina* when it did not engage in notice-and-comment rulemaking for the concurrent and overlapping surgery billing guidelines. At the very least, hospitals cannot be found to have the requisite FCA *scienter* for assuming that CMS would not enforce payment rules that did not satisfy *Allina*'s straightforward procedural requirements.[9]

All in all, the hallmark CMS's regulatory history on this issue is stasis. CMS did not undertake any substantive or procedural changes for the teaching hospital billing requirements in the *Medicare Claims Processing Manual* or respond to a seminal Supreme Court decision that called into question future enforcement actions based on the *Manual*'s guidelines. Consequently, the same deferential billing guidelines that were in effect before 2015 remain in effect today.

II. AFFORDED SUBSTANTIAL DEFERENCE UNDER CMS'S BILLING GUIDANCE, HOSPITALS HAVE DEVELOPED TAILORED POLICIES AND PRACTICES FOR OVERLAPPING SURGERIES

By continuing to afford individual surgeons and hospitals reasonable deference in its *Medicare Claims Processing Manual*, CMS has implicitly recognized that hospitals—not the

[9] The Department of Justice adopted a similar policy with respect to agency guidance documents. In a January 25, 2018 memorandum, Associate Attorney General Rachel Brand ordered that, "effective immediately for [affirmative civil enforcement] cases, the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules." Memorandum from The Associate Attorney General to Heads of Civil Litigating Components & United States Attorneys Re: Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), https://www.justice.gov/file/1028756/download. The memo further provided that DOJ officials "may not use noncompliance with guidance documents as a basis for proving violations of applicable law" in affirmative civil enforcement cases. Notably, this policy was issued before *Allina* and before CMS's own legal guidance, both of which further backstopped DOJ's policy. In July 2021, Attorney General Merrick Garland rescinded the Brand Memorandum. *See* Memorandum from The Attorney General to Heads of All Department Components Re: Issuance and Use of Guidance Documents by the Department of Justice (July 1, 2021), https://www.justice.gov/opa/page/file/1408606/download. But the validity of the Brand Memorandum during the events at issue in the Complaint is all that is relevant for *scienter* purposes.

federal government—are best-suited to regulating those practices. *See, e.g.*, SFC Staff Report 9 ("Although defined slightly differently, both CMS and ACS guidance permit each surgeon to determine which portions are critical. This position is intended to recognize 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 patient.").

Two studies best illustrate the variation in hospital policy and practice in the face of this deferential regulatory framework: (1) the 2016 Senate Finance Committee Staff Report discussed above and (2) a survey of hospitals that was published in April 2021in *The Journal of Law, Medicine, and Ethics, see* Margaret B. Mitchell, et al., A Survey of Overlapping Surgery Policies at U.S. Hospitals, 49 *J.L., Med., and Ethics* 64 (Apr. 2021) ("JLME Article"). The Senate Finance Committee Report surveyed 17 unidentified teaching hospitals; the JLME article contained information on 28 hospitals. Both revealed that hospitals policies on overlapping surgery can reasonably differ.

To take one example, the surveyed hospitals had a range of definitions of "critical" in both 2016 and 2021. Indeed, the Senate Finance Committee Staff Report observed three-quarters of hospitals had one of two approaches. Half left the determination of critical portions to the attending surgeon, "consistent with CMS's billing requirements and ACS guidance." SFC Report 9. The other half "have developed, or expect to develop, lists of procedures, generally by surgical department, of the critical component." *Id*. Critically for purposes of this case, only "*some* hospital policies" in 2016 deemed the "time out" to be critical. *Id*. (emphasis added). The 2021 JLME article further reported:

> Sixty-three percent (12/19) defined "critical portions" within the [hospital's] policy, and of these 12, half (n=6) were either identical to or very similar to the ACS

> definition (7). Two hospitals defined "critical portions" more broadly as "skin incision to skin closure." Three hospitals (16%) defined this term on a departmental level and had predetermined lists of "critical portions" for certain procedures (a fourth hospital was in the process of creating such lists).

JLME Article at 70.[10]

Another example typifies the variation in hospital policy. The Senate Finance Committee Staff Report correctly noted that "CMS billing requirements and ACS guidance essentially state that if the primary surgeon is not immediately available to assist when needed, the surgeon must designate a backup surgeon." SFC Staff Report at 13. But, as with defining "critical" portion of a surgery, hospitals imposed different internal rules regarding backups:

> Among the hospitals that had recently reviewed or updated their surgical policies, more than half require the primary attending surgeon to designate a backup surgeon if overlapping surgeries are scheduled. However, the policies of other hospitals were more vague, only requiring the primary attending surgeon to designate a backup surgeon should the need arise; for example, if the primary attending surgeon is not immediately available to return to the operating room.… Additionally, one hospitals' policy made no mention of backup surgical arrangements.

Id. at 13 & n.40. Similarly, the JLME Article observed that 12 of 19 hospitals "required that a backup attending be chosen in advance of the surgical procedure for any planned overlapping case." JLME Article at 70. Only 1 of those 12 required the backup to be designated at the time of the surgery was scheduled; the others "either did not specify when a backup attending was to be designated … or indicated a backup was only to be designated if the need arose." *Id*.

The conclusions in these two surveys have several profound implications for the allegations in this case. *First*, both studies indicate that hospitals updated their policies since 2015 and 2016.

[10] This information raises the question whether under the Complaint's theory that the "time out" is a "critical portion" of a surgery, the two hospitals that define "critical" as starting with a "skin incision" *per se* violate the *Medicare Claims Processing Manual* and are thus subject to potential FCA liability. In reality, these hospital policies demonstrate the danger and mistakenness of the Complaint's attempt to transform internal hospital policy into governing law for FCA purposes.

See SFC Staff Report 7 ("When the Committee began its investigation, less than half of the 20 teaching hospitals contacted had institution-wide policies outlining the requirements for concurrent or overlapping surgeries, and not all of those stipulated that concurrent surgeries were prohibited. During the course of the investigation, in order to be consistent with the revised ACS guidance, 17 of the 20 hospitals we contacted modified existing or created new hospital-wide policies specific to concurrent and overlapping surgeries."); JLME Article 71 ("[P]ublic scrutiny did appear to have a motivating effect on hospitals, with all responding hospitals that allowed OS having updated their policies since March 2016."). This demonstrates that hospitals are quite capable of forming responsible policies consistent with their experience and medical judgment, which is exactly what *Medicare Claims Processing Manual* permits.

Second, both reports demonstrate the dangers of elevating internal hospital policy into law for purposes of the FCA. Not only is that contrary to the statute, but it also prevents doctors with expert knowledge from working through medical debates and tailoring rules for their medical practices and its particular requirements. The JLME article (at 71) put it best when it describes the diverging definitions of "critical" portions of a surgery: "This diversity of this aspect of the policies likely reflects the controversial nature of critical portions and an unresolved debate about the relative merits of strict regulation versus surgeon judgment, and how patient safety, trainee education, and system efficiency will be influenced by strategies governing [overlapping surgeries.]"

Nevertheless, the government now seeks to insert itself into this ongoing medical debate—despite having no apparent expertise in the subject—and to elevate its own views over those of CMS, ACS, and hospitals throughout the country. The FCA does not countenance this kind of prosecutorial conduct. Because CMS leaves it to hospitals and their surgical teams to determine

what is best for patients in the context of overlapping surgeries, and because hospitals have acted appropriately when given that discretion, the FCA cannot be used to impose a particular set of regulations on overlapping simply because a relator or DOJ attorney believes he knows better.

One final point is worth mentioning here because it vividly illustrates the dangers of relying on the FCA, rather than CMS expertise or hospitals' own judgment, to police overlapping surgeries. The Complaint includes (at ¶¶ 150-154) several sensational (and legally-unnecessary) allegations about patient harm and the risks of overlapping surgeries. But the scientific evidence indicates otherwise. For example, the Senate Finance Committee Staff Report stated that "[b]oth CMS and Joint Commission told Committee staff that in conducting oversight activities, they have not noticed the practices of concurrent or overlapping surgeries as contributing in any particular way to patient harm." SFC Staff Report 6. Likewise, a Mayo Clinic study of overlapping surgeries "found no difference in the rates of postoperative complications or deaths within a month after surgery." Sharon Theimer, *Study of thousands of operations finds overlapping surgeries are safe for Mayo Clinic patients*, Mayo Clinic News Network (Dec. 1, 2016), https://newsnetwork.mayoclinic.org/discussion/study-of-thousands-of-operations-finds-overlapping-surgeries-are-safe-for-mayo-clinic-patients/. And a more recent survey published in the *Journal of the American Medical Association*—the most comprehensive study of the practice to date—concluded: "Among adults undergoing common operations, overlapping surgery was not significantly associated with differences in in-hospital mortality or postoperative complication rates."[11] Sun, E., et al., Association of Overlapping Surgery With Perioperative Outcomes, *Journal of the American Medical Association* (Feb. 26, 2019),

[11] This study did find that overlapping surgeries were "significantly associated with increased surgery length," but it observed that at least "some of this association may be attributable to confounding (ie, longer cases may be selected for overlapping scheduling)." *Id.*

https://jamanetwork.com/journals/jama/article-abstract/2725689. Faced with a choice between doctors and lawyers on as subject as important as patient safety, *amici* respectfully submit that the better course is to stick with the medicine. The Complaint, however, turns that sensible rule of thumb on its head.

Ultimately, there may well be a need to debate the many issues surrounding overlapping surgeries, including patient safety. But an FCA suit is not the place to resolve that debate. The FCA is not a mechanism for filling in regulatory blanks. Nor is it a tool for answering medical policy questions that experts at CMS, experienced surgeons at ACS, and hospitals themselves have not definitively solved. Because CMS billing guidance rightly defers to hospitals and surgeons with regard to overlapping surgeries, and because hospitals have permissibly adopted policies tailored to the needs of their patients and medical teams, there is "[n]othing in the text or history of the FCA" that should lead this Court "to conclude that Congress intended conduct such as [what is alleged in this case] to morph into an actionable fraud against the government." *United States ex rel. Spay v. CVS Caremark Corporation*, 875 F.3d 746, 765 (3d Cir. 2017).

CONCLUSION

For the reasons stated above and in Defendants' Motion to Dismiss, the Court should dismiss this case for failure to state a claim upon which relief can be granted.

Dated: November 1, 2021

/s/ Chad Golder

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CERTIFICATE OF SERVICE

Pursuant to Federal Rule of Civil Procedure 5(d)(1)(B), as amended, no certificate of service is necessary because this document is being filed with the Court's electronic system.

Dated: November 1, 2021

/s/ Chad Golder
Chad Golder