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Building a consistent approach across broad enterprises

an interview with
R. Brett Short

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Overlapping surgeries: Compounding regulatory requirements and risks

» In recent years, scrutiny of overlapping surgeries has increased considerably.
» Overlapping surgeries are relevant to both teaching and non-teaching institutions.
» Teaching institutions face unique risks due to Medicare payment requirements.
» Enforcement, including False Claims Act cases, is also escalating.
» Providers should examine their overlapping surgery policies, procedures, and controls.

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Overlapping surgeries—when one surgeon is responsible for two procedures that overlap in time—is a practice that has recently gained increased national attention from the media, patients, and government, among others. Many institutions throughout the country elect to permit the practice of overlapping surgeries to varying degrees, with significant differences in policies and processes. Although some view overlapping surgeries as an important vehicle for operating room efficiency, facilitating the ability of specialized surgeons to see more patients and promoting the progressive autonomy of residents in teaching institutions, those critical of the practice often argue that overlapping surgeries pose risks to patients and that informed consent processes do not adequately apprise patients of such practices.

The practice of overlapping surgeries presents a risk continuum with unique risks for different types of institutions. For example, overlapping surgeries present heightened risks for teaching hospitals, because those surgeries are governed by specific Medicare payment requirements. Although non-teaching institutions may currently face less risk from a payment perspective, those organizations must still consider other risks such as those related to informed consent, industry best practices, and reputational harm. Further, institutions that perform a high number of overlapping surgeries may find themselves higher on the risk continuum than organizations where overlapping surgeries are rare.


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This article is a follow-up to an article on overlapping surgeries that was published in *Compliance Today* in May 2016. This article aims to provide an overview of applicable authority for both teaching and non-teaching institutions, as well as explore compliance risks and recent enforcement developments. It will also discuss practical considerations and key questions to consider relevant to both the teaching and non-teaching contexts as you examine these

SNAPSHOT: KEY OVERLAPPING SURGERY TRENDS

- Enhanced regulatory and enforcement attention
- Significant media and public interest in topic
- Physicians (including anesthesiologists and residents) as whistleblowers
- Ability for examination of technical billing practices to snowball into quality of care and informed consent issues
- Complex and challenging area to assess controls and implement auditing
- Compliance strategies are not one size fits all

complex issues in light of increased scrutiny and expected enforcement activity.

Overview of overlapping surgery authorities

Overlapping surgeries may occur in the teaching setting (often with the assistance of resident surgeons) or the non-teaching setting. With respect to teaching settings, the Centers for Medicare & Medicaid Services (CMS or Medicare) regulations dictate certain requirements that must be followed for billing.[1] In the non-teaching context, Medicare regulations do not explicitly address overlapping surgeries, but call for providers to follow practices delineated by other applicable authorities, including industry groups such as the American College of Surgeons (ACS).[2]

In the teaching setting, Medicare requires that the teaching physician be present during all critical/key portions of both overlapping operations and personally document in the medical record that they were physically present during the critical/key portion(s) of both procedures.[3] Importantly, Medicare provides the teaching physician with the discretion to determine which part(s) of the procedure are key/critical. In addition, Medicare requires that if the teaching physician is *not* present during non-key/critical portions of the procedure, he/she must be immediately available to return to the procedure. If the teaching physician is not immediately available, he/she must arrange for another qualified surgeon to be immediately available to assist the resident in the first case, if the need arises. Notably, certain concepts in the Medicare authority do not have detailed definitions and appear to leave considerable discretion to the providers.

In April 2016, the American College of Surgeons updated its Statements on Principles (ACS Principles), which includes guidance regarding overlapping surgeries applicable to both the teaching and non-teaching setting.[4] The ACS Principles are very similar, although not identical, to the Medicare billing regulations for teaching surgeries. For instance, the ACS Principles define the term "concurrent" surgeries to mean two procedures under the same attending surgeon where the key/critical portions of both procedures overlap, and states that such practices are not appropriate. Medicare does not define concurrent surgeries but will not pay for such scenarios in the teaching setting because teaching surgeons are required to be present for the key/critical parts of all procedures. (We note that the May 2016 *Compliance Today* article uses the terms "concurrent" and "overlapping" interchangeably, but that such terms now have distinct meanings). The ACS Principles also address additional concepts, such as best practices for patient informed consent controls.

In addition, it is possible that states could have additional requirements relevant to overlapping or concurrent surgeries. For example, the Massachusetts Board of Registration in Medicine and associated agencies recently considered new regulations that would implement additional documentation requirements for instances when a surgeon is not present for part of an operation.[5]

The regulatory and enforcement spotlight on overlapping surgeries

Historically, overlapping surgery was not a concept that garnered significant public or enforcement attention. In the past, it appeared

that only the most egregious stories about surgeon presence (or non-presence) during surgeries, such as surgeons on the golf course during procedures, seemed to attract enforcement and media attention. However, that tide began to turn in 2015 as the media and government became more interested in the nuances of overlapping surgeries, and practices that had been common for years were suddenly challenged.

As described more fully in the May 2016 *Compliance Today* article, in the fall of 2015, *The Boston Globe* published a dramatic, in-depth investigative article regarding overlapping surgeries at Massachusetts General Hospital. *The Boston Globe* investigation captured the interest of the Senate Finance Committee, which sent comprehensive inquiries to 20 hospital systems throughout the country in February 2016, requesting detailed information on overlapping surgeries. As noted above, a few months later, in April 2016, the ACS updated its Statements on Principles.

On December 6, 2016, Senate Finance Committee (SFC) Chairman Orrin Hatch (R-Utah) and Ranking Member Ron Wyden (D-Oregon) issued a comprehensive Committee staff report regarding overlapping surgeries, titled "Concurrent and Overlapping Surgeries: Additional Measures Warranted" (Senate report).[6] The Senate report raises concerns regarding overlapping surgeries and concurrent surgeries, and encourages providers to develop policies that address such practices, as well as mechanisms to enforce such policies. In addition, the Senate report outlines example approaches to various aspects of overlapping surgeries taken by the providers probed by the SFC February 2016 inquiry. For example, the report outlines how providers take different approaches to defining key/critical portions of procedures, or designating immediately available surgeons. Ultimately, the Senate report appears to support fairly conservative approaches to overlapping surgeries, and it suggests providers consider controls that go well beyond the technical Medicare billing rules for teaching surgeries.

Although the SFC does not have direct enforcement authority of providers in this area, providers would be well advised to closely review the Senate report, because additional enforcement and regulatory activity is likely to follow. Indeed, the Senate report specifically addresses potential improper payments, stating that CMS has failed to routinely monitor teaching hospitals for compliance with applicable billing rules for overlapping surgery. The SFC recommends that the Department of Health and Human Services Office of Inspector General (OIG) evaluate current billing controls further and encourages CMS to review current billing rules for teaching institutions to determine if such requirements should be implemented for other non-teaching settings.

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In addition, although this article does not endeavor to cover all case law developments in this area, it is important to emphasize the uptick in recent enforcement activity:

- In January 2015, the Medical College of Wisconsin entered into a settlement agreement for $840,000 to settle False Claims Act (FCA) allegations that two of its teaching physicians improperly billed Medicare for

performing more than one neurosurgery at the same time.[7]

- In July 2016, the Department of Justice announced a $2.5 million settlement with the University of Pittsburgh Medical Center and related organizations to resolve FCA allegations in connection with a whistleblower lawsuit.[8] The lawsuit alleged certain neurosurgeons submitted claims for surgeries performed by other providers when those neurosurgeons did not participate to the degree necessary to bill for the claims.
- In 2016, a lawsuit filed by a former resident-turned-whistleblower against Advocate Medical Center was unsealed. The lawsuit alleged that Advocate falsely reported that no qualified surgical resident was available during surgical procedures, so they could bill for assistants, even though residents were available to assist.[9] Although the case does not directly address overlapping surgeries, it is relevant to teaching surgeries and provides an example of a whistleblower who is a former resident. Notably, the government declined to intervene in the case.
- In January 2017, Vanderbilt University settled a FCA suit for $6.5 million. The suit was brought by three physicians who alleged that Vanderbilt improperly billed for surgeries, such as when only residents were present for the key/critical portions of procedures. The government did not intervene in the case.
- In 2017, *The Seattle Times* published an investigative article on overlapping surgery practices at Swedish Health. In August 2017, the results of a state survey of Swedish Health–Cherry Hill were made public, exposing numerous patient safety issues, including issues related to surgery scheduling. CMS required Cherry Hill to implement a corrective action plan to continue participation in Medicare.[10]
- Dr. Lisa Wollman, an anesthesiologist at Massachusetts General Hospital (MGH) filed a *qui tam* lawsuit against MGH in connection with overlapping surgeries, administration of anesthesia, and informed consent practices. The government declined to intervene, and in March 2018, the case was dismissed on the grounds that Dr. Wollman's allegations did not meet pleading standards. Dr. Wollman is able to re-file an amended complaint, so the case could continue.[11]

As demonstrated above, the overlapping surgery enforcement landscape is expanding rapidly and gaining national attention. Although enforcement is currently focused on teaching institutions, it is possible that non-teaching institutions could experience scrutiny as well, such as in connection with informed consent or anesthesia administration practices.

Finally, we note that, historically, there were not many clinical studies analyzing overlapping surgeries and associated outcomes. However, the increased public focus on this issue has spurred academic interest, and a number of journal articles have been published on the topic recently, both supporting and questioning overlapping surgeries. Accordingly, providers would be well advised to continue to monitor this developing area.

Practical considerations for compliance professionals

In light of the evolving landscape of overlapping surgeries, compliance professionals in both teaching and non-teaching settings would be well advised to refine or develop policies, processes, and controls. However, there is no one-size-fits-all roadmap or approach. Below we outline questions that providers may wish to consider as they evaluate competing dynamics relevant to this complex and challenging issue.

For all institutions

- Are current policies and procedures compliant with applicable authority and ACS guidelines?
- Is the employment status of physicians (i.e., employed or not employed by the hospital) taken into consideration?
- Are various stakeholders (e.g., surgeons, leadership, risk management) appropriately involved in potential changes to policies and processes involving overlapping surgeries?
- What are the practical impacts of changes to policies, such as impacts on the cadence of surgeon practice, patient wait times, and operating suite efficiency?
- Does my institution's electronic medical record system facilitate documentation consistent with current policies and applicable authority?
- Does my institution's surgery scheduling system permit scheduling of overlapping procedures, and are there any specific controls around that process?
- How would my institution respond to a similar inquiry from the Senate Finance Committee?
- What controls does my organization have in place?
- Is my institution prepared to respond to information requests from the media or patients?
- Are current informed consent forms and protocols adequate?
- Does my institution have a plan to monitor for additional overlapping surgery developments and enforcement trends?

Additional considerations for teaching institutions

- Are current policies and procedures compliant with Medicare payment requirements?
- Is my institution prepared for a government audit, such as a claims review of Medicare billing requirements?
- Would my institution benefit from an internal audit of historical claims? If discrepancies are found, how does that implicate potential obligations under the 60-Day Rule to refund and report Medicare overpayments?
- Has my institution collaborated with other relevant organizations such as the medical school?
- Would my institution be prepared to defend a *qui tam* lawsuit?

These questions are challenging and this list is not exhaustive. Each institution would be well advised take an individualized and tailored approach to addressing these issues. In addition, providers should continue to closely follow industry developments regarding overlapping surgeries, as it appears likely that further scrutiny and enforcement actions may be on the horizon.

1. See 42 CFR § 415.172—Physician fee schedule payment for services of teaching physicians.
2. CMS: State Operations Manual: Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (revised November 2015), Section A-0940. Available at http://go.cms.gov/2CSTd2R
3. CMS: Medicare Claims Processing Manual, Chapter 12, Section 100.1.2. Available at https://go.cms.gov/2N29UyQ
4. American College of Surgeons: Statements on Principles. April 12, 2016. Available at http://bit.ly/2tA57wp
5. Jenn Abelson and Jonathan Saltzman: "State acts on simultaneous surgeries" *The Boston Globe*, January 7, 2016. Available at http://bit.ly/25NGQ26
6. Staff of Senate Finance Committee, 114th Congress: "Concurrent and Overlapping Surgeries: Additional Measures Warranted" December 6, 2016. Available at http://bit.ly/2nfYqyO
7. Department of Justice, Eastern District of Wisconsin, press release: "Medical College of Wisconsin, Inc. Pays $840,000 to Settle Alleged False Claims for Neurosurgeries" January 9, 2015. Available at http://bit.ly/2lFalCQ
8. Department of Justice, Western District of Pennsylvania, press release: "False Claims Act Violation by UPMC Resolved for $2.5 Million" July 27, 2016. Available at http://bit.ly/2lCEGSo
9. *U.S. ex rel. Ailabouni et al. v. Advocate Health and Hospitals Corp. et al.*, No. 1:2013cv01826 (N.D. Ill.).
10. Mike Baker: "Investigators find 'numerous' issues related to patient safety at Swedish's Cherry Hill site" *The Seattle Times*; August 10, 2017. Available at http://bit.ly/2yM505X
11. *United States ex rel. Wollman v. The General Hospital Corporation et al.*, No. 1:15-cv-11890-ADB (Mar. 30, 2018 D. Mass).