

SENTINEL



Richard Month,
MD, FASA
PSA PRESIDENT

**...honored to lead
this Society through
perilous but
exciting times.**

President's Message

The most recent membership meeting of the Pennsylvania Society of Anesthesiologists marked a historic event, not so much for what happened, but for what didn't happen. This meeting marked the first time in our 58-year history that a membership meeting didn't end with a new President being elected. As I reflect on the first year of the first-ever two-year PSA presidential term, I find myself prouder than ever to be a member of this Society and honored to lead this Society through perilous but exciting times.

We've had one of the busiest years in PSA history these past 12 months. On the advocacy front, three major issues have filled our time:

1. **Department of Health Hospital Regulations:** In January, we met with the Department of Health several times, including a face-to-face meeting with Secretary Levine, to discuss concerning draft changes to the hospital regulations that would have permitted individual hospitals to allow independent practice of nurse anesthetists. We submitted extensive data describing both our patient care and legal concerns with that draft; we also provided an alternative model that could be an imperfect, but workable compromise. Based on public comments from the Department, we are hopeful that our compromise has been accepted.
2. **Anesthesia Supervision Legislation:** Senator Tom Killion (SB 697) and Representative Steven Mentzer (HB 1476) have sponsored PSA-supported legislation to place into statute the requirement for physician supervision of the provision of anesthesia care. At the time of writing, these bills remain in committee, but we hope they will see some movement in the very near future.
3. **Surprise Balance Billing:** PSA is a member of the Provider Coalition for Patient Access, a unified coalition of physician groups working toward the best possible solution for the balance billing issue. The Coalition is working closely with members of the Assembly to draft a bill that will treat physicians fairly while keeping patients out of the middle of reimbursement fights.

On the education front, PSA sponsored its first educational meeting in over a decade. The PSA Ultrasound Regional Anesthesia and POCUS course, held in Philadelphia on March 2, was a huge success and a testament to our hardworking

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SENTINEL NEWSLETTER

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President's Message

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Committee on Professional Education. The meeting was well-attended and well-evaluated by all who were there and was one of the few ultrasound meetings that included pediatric ultrasound-guided regional anesthesia training opportunities.

Our Committee on Anesthesia Practice was hard at work this year addressing concerns with the corporate practice of medicine, in response to a PSA-sponsored resolution to the PA Medical Society House of Delegates last year. We generated some excellent discussion, and members of our committee along with attorney John Hogan, Esq., wrote some excellent articles in the *Sentinel* about the changing interplay between business and medicine.

As I look back at our successes of the past year, I await the challenges and possibilities of the year to come. This year will bring the PSA's First Annual Educational Meeting on June 6 and 7, 2020, in Hershey. It will be an exciting new way for PSA to reach our members. Saturday will be a high-yield seminar providing up to 8 hours of CME, including the three Board-mandated hours of opioid education and three hours of patient-safety credit. Sunday will offer a hands-on Ultrasound workshop, again with both adult and pediatric training. I applaud the hard work of our Committee on Professional Education for creating such an incredible itinerary and I strongly encourage you to attend. Keep an eye out for registration information in the coming months.

In addition, the hospital regulations, anesthesia supervision legislation, and balance billing will continue to represent significant rapidly-moving and ever-changing targets. We will continue to work with stakeholders, legislators, and staff to protect the highest-quality Anesthesia care throughout the Commonwealth.

Finally, if there's anything I've learned in my first year as president, it is to expect the unexpected. PSA stands at the ready to address the next issue as it arises. As we move forward to the next year, I thank you, the members, for the trust you've placed in me. Leading this organization remains one of the highlights of my professional career. I am proud of what we've achieved in year one and am excited about the prospects of what year two will bring!

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EDITORIAL



Richard O'Flynn,
MD, FASA
EDITOR

What's In A Name?

Anesthesiologist

noun. (an-aes-the-si-ol-o-gist) An anesthesiologist is a doctor (MD or DO) who practices anesthesia.

Anesthesiologists are physicians specializing in perioperative care, developing anesthetic plans, and the administration of anesthetics.

In the last edition, I wrote about the increasing proliferation of doctoral degrees in hospitals and how this has the potential to confuse patients about who is caring for them. Now comes an even more disturbing and concerning issue. Recently, the Florida Board of Nursing unanimously agreed to allow a CRNA to officially use the title “nurse anesthesiologist.” The involved CRNA has for years identified himself to patients as a “nurse anesthesiologist.”

The justification used by the CRNA is that he is a “scientific expert on the art and science of anesthesia, not a technician or physician extender.” He states that it does not make sense to him that CRNAs who are “equally well trained in the specialty” are not called nurse anesthesiologists.



Scan Here
for more information
about the FL Ruling

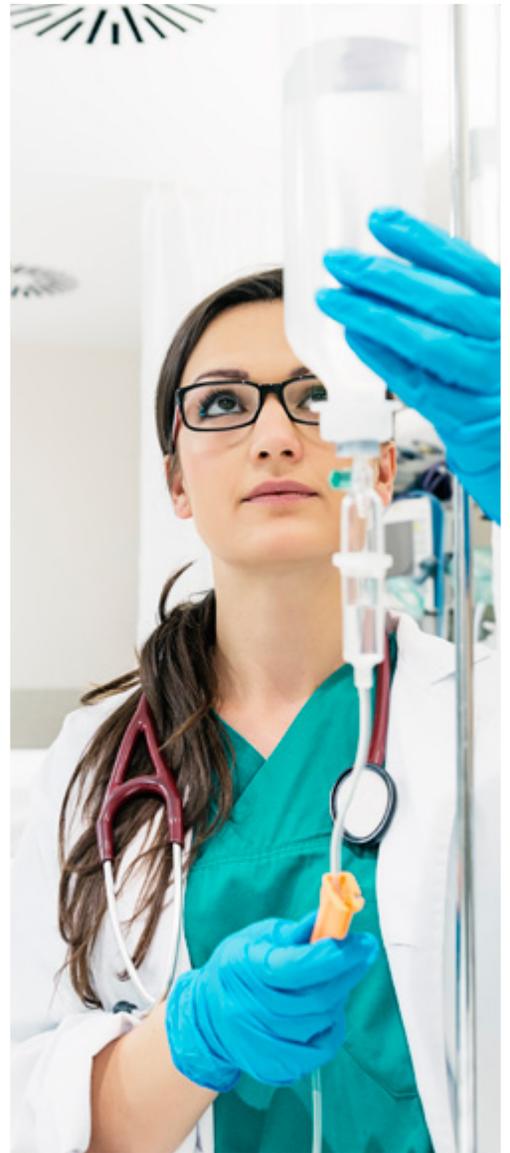
With the Board of Nursing ruling, he now has their blessing to continue using this title. While the ruling only applies to this one CRNA, it will obviously be used as a precedent for other Florida CRNAs to follow and it is reasonable to assume that the title will soon apply to all Florida CRNAs.

The New Hampshire Board of Nursing was the first nursing board in the nation to recognize the title of nurse anesthesiologist, which is permitted for use in personal or professional communications. Part of the Board of Nursing reasoning for the acceptance of the title nurse anesthesiologist was that in 1902, Dr. M.J. Seifert coined the term anesthesiology and defined it as “the science that treats the means and methods of producing various degrees of insensibility to pain with or without hypnosis. An anesthetist is a technician and an anesthesiologist is the specific authority on anesthesia and anesthetics.”



Scan Here
for more information
about the NH Ruling

They further state that the ASA acknowledges that over 50% of patients do not realize that anesthesiologists are physicians and have advocated for a more accurate description.... “physician anesthesiologist.” To the lay public this would appear to be an acknowledgement that there are other types of anesthesiologists. Have we become our own worst enemies by adding physician before anesthesiologist? Is the acceptance of the title nurse anesthesiologist by at least two state nursing boards foreboding of a coming national trend? Is this simply an attempt to further confuse patients and expand practice making physicians irrelevant? Does it even matter?



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What's in a Name?

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This year a bylaws amendment was submitted to the AANA to officially change the name to American Association of Nurse Anesthesiologists. The AANA created a task force to analyze the pros and cons of recognizing the title “nurse anesthesiologist.” Following the report, the AANA issued the following statement:

The AANA recognizes the following titles:

- Certified Registered Nurse Anesthetist
- CRNA
- Anesthetist

The AANA acknowledges additional descriptors for nurse anesthetists which include, but are not limited to, the following:

- Advanced Practice Registered Nurse
- Advanced Practice Provider
- Nurse Anesthesiologist
- Advanced Practice Professional

Regardless of the title or the descriptor being used, as a profession we believe it is time for the focus to be on the quality of healthcare provided and not the title of the healthcare provider.

Even with the official statement, there remains a group of CRNAs advocating for the AANA to change the organization name to American Association of Nurse Anesthesiologists. This group, called The Committee for the Proper Recognition of CRNAs (CPRC), started a go fund me page that had raised \$68,000 as of September 1. The group has two stated goals:

- To have the title of nurse anesthesiologist recognized by the AANA which was accomplished in the AANA statement
- To change the name of the AANA

While a change of this magnitude would most likely be years in the making, the simple fact that it is even being proposed indicates the seriousness of the issue. With the acceptance of the nurse anesthesiologist title, it appears to be pretty much a foregone conclusion that this action is going to be seen throughout the country especially as the push for independent practice rages on.

So, what is next?

Obviously, this needs to stay on the radar, but it may be hard to stem the tide. The arguments that are presented to the state nursing boards appear to the lay public to be sound on the surface, especially with the fact that the ASA advocated for the term “physician anesthesiologist.” Why the need to add physician before the word anesthesiologist if only a physician can be an anesthesiologist? While the intent was to clarify to the public that anesthesiologists are physicians, was this seen as an acknowledgement that there are, or could be, other classes of anesthesiologists? That appears to be the rationale that the nursing boards are taking to justify their actions. What will happen next if the trend continues to march across the country? Will the ASA become the ASPA...the American Society of Physician Anesthesiologists?



BUSINESS & MEDICINE

Fair and Balanced Views: The Pros and Cons of Selling Your Anesthesia Group



Mark Weiss, JD

The Mark F. Weiss Law Firm, a Professional Corporation

As my father used to say, “that’s why they make chocolate and vanilla ice cream.”

Translation from the slightly Bronx-inflected English: Different people make different choices. What you think is right for you in the context of a preference is right . . . for you. But it’s not necessarily right for someone else.

In no circumstance is that more true than in respect of the existential question du jour, should you sell your anesthesia group? [Note that the question is not binary, as in “sell or remain as we are;” there are multiple alternatives to a sale.]

Some authors provide a pointed answer to the question. In the Summer 2019 issue of *Sentinel*, Scott I. Winikoff, MD, an employee of one of the large multi-specialty aggregators, presented a sanguine paen to what he painted as the benefits of “joining” a regional/national anesthesia practice management company.

I suggest a more balanced approach for your consideration, one devoid of rainbows and unicorns, and with eyes wide open instead of eyes wide shut. That approach (and full disclosure) is based upon the fact that my own career is divided between my law practice,

in which I represent many completely independent anesthesia groups that have zero interest in ever selling, and in which I counsel many groups in respect of both sales and acquisitions; and my healthcare mergers and acquisitions advisory firm in which we actively seek the highest price and best deal terms for the sale of medical groups. So, it might be said that I have two horses in the race, and that they are sometimes running in opposite directions.

All Progress Starts With Telling The Truth

One certainly “joins” a club, the army, or a cult, but the sale of an anesthesia group is just that, a sale. That’s the cold hard fact no matter whether the buyer is a regional or national group, whether it’s closely held, funded through private equity, or publicly traded. A sale involves an exchange of value: your ownership transfers for money (and sometimes other consideration such as stock). Yes, you might, following the conclusion of the sale, become an employee of a large organization, but an employer-employee relationship doesn’t involve singing Kumbaya around the campfire. Rather, it involves employment contracts which end, sometimes abruptly.

And last, despite what Dr. Winikoff describes, it is not normally the case that the former owners of an anesthesia group become employed at a higher level of compensation following the closing of the transaction. That’s because the average anesthesia group has no assets other than contractual rights which result in cash flow that, after operating expenses, is nearly completely exhausted by way of distributions to its owner-physicians. All that such a group has to sell is a portion of that cash flow which is restated for valuation purposes as earnings. In other words, the EBITDA upon which the valuation is calculated consists of dollars taken away from funds otherwise available for distribution to those physicians who will soon be former owners.

Although it might, in a blue moon, be the case that the acquirer has significantly higher rate payer contracts driving higher compensation, it is likely not the case. As yummy as it sounds, you cannot have your cake and eat it too. So, make sure that the cake is particularly delicious.

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Fair and Balanced Views: The Pros and Cons of Selling Your Anesthesia Group

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Selling Puts Dollars, Potentially Lots of Them, in Your Pocket

But I certainly want to be fair and balanced, even, to the more jaded reader, if only because I represent sellers and, with my investment banker hat on, essentially broker sales, and there are certainly a myriad of reasons for some groups to sell. Most of those reasons are green and have pictures of Ben Franklin on them.

Even if the purchase price is, financially, simply prepayment of the present value of forgone future dollars, it is, to the extent that it is paid in cash, cash in your pocket at closing at capital gains rates. And, depending upon how the sale is structured, there may be other bites of the apple, additional payments, down the line.

However, the sale considerations are complex and multifactorial. At issue are not only the nature of the buyer and of its offer, even as it's maximized by way of an auction-like process among potential buyers, but also your nature qua seller and the nature of your group.

For example, the single shareholder of an anesthesia group with 50 employed anesthesiologists, to whom the entire purchase price would be paid, would certainly analyze a sale far differently than would one physician owner in a group of 50 anesthesiologists in which all 50 are equal partners.

Additionally, even in our 50 member equal partnership, some physicians, generally those who are closer to retirement, would evaluate a sale differently from those who are only a few years into practice. Your average 68-year-old owner who doesn't plan to practice for more than a few years past the sale, if even for that long, extracts true value. That might not be the case for your average 34-year-old owner who plans on practicing for another 30 years; his or her considerations are both monetary and based on considerations of the changed practice setting.

Selling Transfers Risk. True. But Not Always.

The notion of transferring risk isn't unique to the sale of anesthesia groups. If you were selling a manufacturing company, one of the benefits would be extracting your cash now and not being subject to the ongoing vagaries of various sorts of business and financial risk. In anesthesia group terms, risks range

from that of losing your major contracted hospital, to Medicare-for-all, to the economy crashing, and so on.

But some risk remains, and you must be cognizant of it.

Some entities in the market today are acquiring at very high valuations but paying millions of it in stock. To some, selling for part stock sounds sexy (tax free! . . . appreciation!) but, by definition, it comes prepackaged with risk. Certainly, it might appreciate, potentially by way of the subsequent sale of the entire anesthesia company to another entity, or to the public via an IPO. But stock might depreciate or even become worthless. And, bigger isn't always better. So-called efficiency isn't the same as efficacy. Large groups are no less immune to disasters such as losing hospital contracts than large ships are immune to sinking. Heard of the Titanic? Heard of Southeast Anesthesia Consultants?

Conclusion: "Sale" is Not an Event. It is a Process.

At its core, a "sale" is a process, not an event.

The process begins internally with an evaluation of both the "truths" of your situation and your interest in proceeding further. Some groups will never be interested in selling; it's not in their DNA or there's insufficient owner support. And, truth be told, some groups can never be sold.

It's not logical to simply be logical. Despite the fact that 10 out of 10 accountants would simultaneously yell "sell!," there are many reasons divorced from pure logic that influence the analysis. For example, is more freedom more important than more money? Is a lower sales price from "Company X" more valuable than a higher sales price from "Company Y"?

If there's serious interest in pursuing a sale, bring on an advisory team early on in the process. Self-help is a non-fiction category, not an effective M&A strategy. Take the steps to groom your group for sale, to sort and sift potential buyers, to create an auction for the best deal, which, counterintuitively to many, is not necessarily the highest price. As in shopping for shoes, you're after the right fit, not just today's style.

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LEGAL UPDATE

Anesthesia Medical Necessity Fraud: Difference of Opinion or False Claim?



By: Charles I. Artz, Esq.

PSA General Counsel

Medical necessity in the practice of medicine is usually subjective. The physician determines what the patient needs given the patient's unique circumstances, conditions and diagnoses. It is a "judgment call," like balls and strikes in a major league baseball game. Using that analogy, one would think medical necessity is not subject to challenge and could never be the basis for fraud.

I have repeatedly argued that where a mere difference of opinion exists and a physician made a good faith effort to provide treatment in the context of the patient's presenting symptoms and diagnostic test results, it could never be fraud subject to the draconian sanctions under the federal False Claims Act ("FCA").

That changed over the years when cases were prosecuted against, for example, cardiologists who performed a stent procedure on any patient that had a heartbeat, and ophthalmologists who did cataract surgery on every patient with eyeballs and a little bit of cloudy vision.

Several federal court decisions held that a physician could not violate the FCA because a mere difference of opinion made it impossible for the physician to intentionally or recklessly violate federal health care program medical policies and billing rules. Three federal court cases published in the last several months, however, suggest the landscape is changing. This article will summarize those cases and provide some important guidance for PSA members.

The first case involved alleged anesthesia medical necessity fraud. In *U.S. ex rel. Wollman v. Massachusetts General Hospital*, the whistleblower was a treating anesthesiologist at Mass General. She alleged the defendants fraudulently billed Medicare and Medicaid for overlapping and concurrent surgeries in which a teaching physician performed two or three surgical procedures that required patients to be **under anesthesia at the same time**.

The whistleblower asserted that, in violation of Medicare regulations, teaching surgeons in Mass General's orthopedic surgery department routinely left patients who were undergoing surgery alone with residents and fellows in order to conduct concurrently scheduled surgeries, and they did so without identifying another qualified teaching physician who would be immediately available in the event of an emergency and without keeping proper records. The whistleblower contends this practice resulted in patients being **under anesthesia for extended, medically unnecessary periods**.

Mass General and the other defendants filed a Motion to Dismiss. The court refused to grant the Motion to Dismiss, and will allow the fraud case to continue. With respect to the anesthesia alleged fraud, the court held as follows:

1. Medicare reimburses anesthesia practitioners for "anesthesia time," which is defined as "the period during which an anesthesia practitioner is present with the patient."
2. Anesthesia time "starts when the anesthesia practitioner begins to prepare the patient for the anesthesia services in the operating room or an equivalent area and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the patient, that is, when the patient may be placed safely under post-operative care."
3. Medicare excludes from coverage any claims for procedures that are not reasonable and necessary for the diagnosis or treatment of illness and injury.
4. The defendants may have violated the Medicare billing rules and submitted false claims to Medicare because the surgical practices **resulted in medically unnecessary prolonged anesthesia**.

This is the first False Claims Act case I have seen

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BUSINESS & MEDICINE

An Update on the ‘Company Model’ and Other Anesthesia Kickback Schemes



Mark Weiss, JD

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Kickbacks in healthcare are rarely (but not never) as blatant as an envelope of cash passed under the table. But they do exist in many forms and settings.

When asked why he robbed banks, the notorious criminal Willie Sutton reputedly responded, “Because that’s where the money is.” Referring physicians, quite often but not always the owners of facilities, and facilities themselves, might seek a share of anesthesia fees for the same reason. But instead of using a gun, they turn to less violent but still violative devices, one of which is the so-called “company model” of anesthesia services. Others include questionable management services deals and expense-shifting arrangements.

Warning: Unlike a bank robbery, the compliance issues cut both ways. The intentional submission to kickback demands is a crime. So, too, are schemes in which anesthesia providers propose kickbacks to obtain referrals.

The Key Compliance Issue

The federal anti-kickback statute (AKS) prohibits the offer of, demand for, payment of, or acceptance of any remuneration for referrals of patients whose care is covered by federal healthcare programs such as Medicare, Medicaid and Tricare (among many others).

There are exceptions, known as “safe harbors,” that describe certain arrangements not subject to the AKS because they are unlikely to result in fraud or abuse. The ability to fit within a safe harbor is voluntary. In other words, the failure to qualify for a safe harbor is not fatal for the parties to the arrangement; rather, a detailed analysis of the statute itself and of the facts of the deal is then required.

The specialized body of knowledge mandates both self-regulation of the profession and a fiduciary relationship to patients.

Company Model Arrangements

In its most direct form, the company model involves the formation, by the surgeon-owners of an ambulatory surgery center (ASC), of an anesthesia services company to provide all of the anesthesia services for the center.

In the typical scenario, prior to the formation of the company, all anesthesia services were provided by anesthesiologists, alone or in concert with CRNAs, either for their separate accounts or for the account of their anesthesia group. After the formation of the company, the anesthesiologists and CRNAs are employed or subcontracted by the company, with a significant share of the anesthesia fee being redirected to the company model’s owners, the surgeons.

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There are other variants of the model, such as that in which the facility itself directly employs the anesthesia providers or controls the company that, in turn, employs them. However, for purposes of this discussion, the issues are relatively the same. For that reason, we’ll use the surgeon-owned “anesthesia company” as the avatar for a company model scheme.

Broad OIG Guidance

Two fraud alerts issued by the Office of Inspector General (OIG) of the Department of Health and Human Services, the agency charged with regulating and enforcing the AKS, are applicable to the analysis of company model deals: Its 1989 Special Fraud Alert on Joint Venture Arrangements, which was republished in 1994, and a 2003 Special Advisory Bulletin on Contractual Joint Ventures.

Note that the term “joint venture,” as used by the OIG in the alerts, is not limited to the creation of a legal entity; rather, it covers any arrangement, whether contractual or involving a new legal entity, between parties in a position to refer business and those providing items or services for which Medicare or Medicaid pays.

Although each alert illustrates the OIG’s regulatory posture, the 2003 Special Advisory Bulletin is particularly on point in connection with analyzing company model structures. In it, the OIG focuses on arrangements in which a healthcare provider in an initial line of business (for example, a surgeon) expands into a related business (such as anesthesiology) by contracting with an existing provider of the item or service (anesthesiologists or CRNAs) to provide the new item or service to the owner’s existing patient population.

The 2003 Special Bulletin lists some of the common elements of these problematic structures in general. Neither of the alerts are anesthesia-specific (or, for that matter, specific to any medical specialty). In the points that follow, I have substituted words such as “surgeon” and “anesthesiologist,” all in brackets, for the broader terms used by the OIG.

The surgeon expands into [an anesthesia business] that is dependent on direct or indirect referrals

from, or on other business generated by, the owner’s existing business [such as the surgeon’s practice or ASC].

The surgeon does not operate the [anesthesia] business-the [anesthesiologist] does-and does not commit substantial funds or human resources to it.

Absent participation in the joint venture, the [anesthesiologist] would be a competitor [of the surgeon’s anesthesia company]. providing services, billing and collecting [for the anesthesiologist’s own benefit].

The [surgeon] and the [anesthesiologist] share in the economic benefit of the [surgeon’s] new [anesthesia] business.

The aggregate payments to the [surgeon] vary based on the [surgeon’s] referrals to the new [anesthesia] business.

Advisory Opinion 12-06

The OIG’s first direct pronouncement on the propriety of the company model came in June 2012, when it issued Advisory Opinion 12-06. The anesthesia group requesting the opinion presented two alternative proposed scenarios, one a management fee deal and the other a company model structure

In the proposed company model structure, the surgeons, or their ASC, would set up an anesthesia company to hold the exclusive anesthesia contract at the ASC. The anesthesia company would engage the anesthesia group at a negotiated rate as an independent contractor to provide the actual anesthesia care and certain related services. The anesthesia company would retain any profit.

In its Opinion 12-06, the OIG stated that no safe harbor was available in respect of the distributions that the surgeons would receive from their anesthesia company. The ASC investment safe harbor does not apply to protect distributions of anesthesia profits.

Even if the safe harbor for payment to employees applied, or if the safe harbor for personal services contracts applied, those safe harbors would protect payments to the anesthesiologists. But they would

An Update on the ‘Company Model’ and Other Anesthesia Kickback Schemes

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not apply to the company model profits that would be distributed to the surgeons, and such remuneration would be prohibited under the AKS if one purpose of the remuneration is to generate or reward referrals for anesthesia services.

Because, as mentioned above, the failure to qualify for a safe harbor does not automatically render an arrangement a violation of the AKS, the OIG then turned to an analysis pursuant to the 2003 Special Advisory Bulletin and found that the physician- owners of the proposed company model entity would be in almost the exact same position as the suspect joint venture described in the bulletin: that is, in a position to receive indirectly what they cannot legally receive directly—a share of the anesthesiologists’ fees in return for referrals.

Therefore, the OIG stated that the proposed company model venture could potentially generate prohibited remuneration under the AKS, and the OIG potentially could impose administrative sanctions on the requester. In other words, the OIG declined to approve the arrangement.

Advisory Opinion 13-15

On November 12, 2013, the OIG released Advisory Opinion 13-15 dealing with a situation closely akin to a “company model” deal. [Note to reader: In full disclosure, the author was counsel to the anesthesia group in its request for Advisory Opinion 13-15.]

Underlying 13-15 was a proposed arrangement whereby a psychiatry group performing electroconvulsive therapy (ECT) procedures at a hospital would capture the difference between the amount it collected for anesthesia for ECT patients and the per diem rate it would pay to the anesthesia provider.

Initially, an anesthesia group held the exclusive contact to provide all anesthesia services at a hospital (Hospital). Then, in late 2010, a psychiatry group with a practice centering on performing ECT procedures relocated to the Hospital. “Dr. X,” board certified in both psychiatry and anesthesiology, is one of the psychiatry group’s owners.

In 2011, the anesthesia group began negotiating with

the Hospital for the renewal of its exclusive contract. The Hospital demanded an initial carve out: Dr. X would be allowed to independently provide anesthesia services to ECT patients.

The following year, when negotiating the 2012 renewal, the hospital demanded amendments to the carve out provision: v Dr. X would be allowed to provide anesthesia services to ECT patients and the anesthesia group would be required to provide coverage for Dr. X

c, Pursuant to what was called the “Additional Anesthesiologist Provision,” the psychiatry group would determine if an additional anesthesiologist was needed for ECT anesthesia. If so, the anesthesia group would negotiate to provide those services. If the anesthesia group and the psychiatry group did not come to terms, then the psychiatry group or Dr. X could contract with an additional anesthesiologist.

Subsequently, the psychiatry group informed the anesthesia group that an additional anesthesiologist was needed. The parties began negotiating. Under the proposed arrangement presented to the OIG, the anesthesia group and the psychiatry group would enter into a contract pursuant to which the anesthesia group would provide the additional ECT anesthesia services. The anesthesia group would reassign to the psychiatry group its right to bill and collect for the services. The psychiatry group would pay the anesthesia group a per diem rate. The psychiatry group would retain the difference between the amount collected and the per diem rate.

OIG’s Analysis

The OIG has stated on numerous occasions that the opportunity to generate a fee could constitute illegal remuneration under the AKS even if no payment is made for a referral. Under the proposed arrangement, the psychiatry group would have the opportunity to generate a fee equal to the difference between the amount it would bill and collect and the per diem rate paid to the anesthesiologists.

The OIG found that the proposed arrangement would not qualify for protection under the AKS’s safe harbor for personal services and management contracts. That safe harbor protects only payments made by a principal (here, the psychiatry group) to an agent

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(here, the anesthesia group); no safe harbor would protect the remuneration the anesthesia group would provide to the psychiatry group by way of the discount between the per diem rate their group would receive and the amount that the psychiatry group would actually collect.

Because failure to comply with a safe harbor does not render an arrangement per se illegal, the OIG then analyzed whether, given the facts, the proposed arrangement would pose no more than a minimal risk under the AKS.

The OIG flatly stated that “the proposed arrangement appears to be designed to permit the psychiatry group to do indirectly what it cannot do directly; that is, to receive compensation, in the form of a portion of the anesthesia group’s revenues, in return for the psychiatry group’s referrals of patients to the anesthesia group for anesthesia services.”

The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the AKS and that the OIG could impose administrative sanctions in connection with the proposed arrangement. In other words, the OIG declined to approve the arrangement.

Advisory Opinion 13-15 demonstrates a fact lost to many when discussing company model deals: they generally do not fit into an available safe harbor—either the personal services and management contract safe harbor or the employee safe harbor. Not only is this because payment is not set in advance and will vary with the value or volume of referrals, but even more fundamentally, because those safe harbors apply only to payments from the principal to the agent, |not to payments, that is, remuneration, from the agent to the principal. In 13-15, the discount that permits the referral source to profit from the arrangement is remuneration to the principal.

Second, although failure to fit within a safe harbor is not ipso facto fatal, the OIG has again illustrated that being put in a position to profit from one’s referrals raises significant concerns of prohibited remuneration—that is, of violation of the AKS. Note that payment of so-called “fair market value,” the supposed holy grail of anti-kickback analysis, is not a panacea. Deals that place the referral maker in

the position of profiting from its referrals are highly suspicious even in the face of valuation studies and valuation opinions.

The Bottom Line on the Company Model

The term “company model” is an industry descriptor of certain types of arrangements. It’s not the case that any specific law or regulation makes, in blanket fashion, company model deals illegal.

In similar fashion, although they give great insight into the minds of the federal enforcers of the AKS, that is, of the OIG, advisory opinions themselves are binding only on the specific requestor. As such, courts do not defer to the opinions as creating any sort of precedent. The AKS is a criminal statute, and, as such, intent to provide/accept remuneration to induce referrals must be proven. That means that the analysis is highly fact-specific.

In similar fashion, when an alleged company model scheme underlies a federal False Claims Act (i.e., whistleblower) lawsuit, specific facts relating to the kickback-tainted claims for payment must be pleaded with particularity, although there is some variance among the federal court circuits as to the required degree.

For example, in 2017, the False Claims action brought by the Florida Society of Anesthesiologists against a number of surgeons and facilities based on allegations of company model arrangements (U.S. ex rel.

Florida Society of Anesthesiologists v. Chaudhry) was dismissed after the Florida Society failed three times to plead sufficient facts to withstand the defendants’ attack on its pleadings.

The bottom line is that each arrangement within the rubric of the company model must be scrutinized extremely carefully. The “chance” of criminal conviction, or of civil judgment on the False Claims front, may be low, but the criminal penalties (jail time, civil monetary penalties, exclusion from participation in federal healthcare programs) and trebled civil damages judgments are high. Low odds times high penalties equal high risk.

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An Update on the ‘Company Model’ and Other Anesthesia Kickback Schemes

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Management Services/Expense- Shifting Arrangements

Let’s turn to another category of often-seen, highly questionable arrangements: the imposition of management fees or other expenses on the anesthesia providers, or, as illustrated by the return, below, to Advisory Opinion 12-06, to the proposed offer to pay such fees.

Back to Advisory Opinion 12-06

As you’ll recall from the discussion above, the anesthesia group requesting Advisory Opinion 12-06 presented a second scenario, one involving a management fee arrangement. In that arrangement, the anesthesiologists would not meld into a company model structure. Instead, the existing anesthesia group would continue to serve as the ASC’s exclusive provider of anesthesia services. And accordingly, the group would continue to bill and collect for its own account.

However, the group would begin paying the ASCs for “management services,” including preoperative nursing assessments; adequate space for all of the group’s physicians, including their personal effects; adequate space for the group’s physicians’ materials, including documentation and records; and assistance with transferring billing documentation to the group’s billing office.

Although both Medicare and private payers set their reimbursement to the ASCs taking into account the expenses of the type included within the management fee, the ASCs would continue to bill Medicare and private payers in the same amount as currently billed. The management fee would be at fair market value and determined on a per patient basis. No management fee would be charged in connection with federal healthcare program patients.

Consistent with its longstanding viewpoint, the OIG found that carving out federally-funded patients was ineffective to remove the proposed arrangement from within the purview of the AKS, because the payment of the fee in connection with private payers would influence the decision to refer all cases, thereby not reducing the risk that their payment is made to induce the referral of the federally-funded ones.

The OIG stated that the AKS seeks to ensure that referrals will be based on sound medical judgment, and competition for business based on quality and convenience, instead of paying for referrals. But

under the management fee proposal, the ASCs would be paid twice for the same services: by Medicare or by the private payer via the facility fee, and then also by the anesthesiologists via the management fee. That double payment could unduly influence the ASCs to select the requestor as the ASCs’ exclusive provider of anesthesia services. Therefore, the OIG concluded that the management fee arrangement could potentially generate prohibited remuneration under the AKS, and that the OIG potentially could impose administrative sanctions on the requestor.

Sweet Dreams

In August 2016, the U.S. Attorney for the Middle District of Georgia, joined by Georgia’s Attorney General, announced a civil settlement with a series of anesthesia businesses collectively known as Sweet Dreams Nurse Anesthesia (Sweet Dreams).

In that settlement, Sweet Dreams agreed to pay \$1,034,416 to the U.S. government and \$12,078.79 to the State of Georgia to resolve allegations that it violated (due to underlying AKS violations) the False Claims Act and the Georgia False Medicaid Claims Act.

Sweet Dreams was alleged to have entered into arrangements with ASCs to provide the facilities with free anesthesia drugs in exchange for exclusive anesthesia agreements. Like the elements of the “management services” that the requestor anesthesia group proposed to provide to the surgery center in Advisory Opinion 12-06, anesthesia drugs are a part of the expenses covered by the facility fees paid by Medicare, Medicaid and other payers.

By either providing the drugs itself, or reimbursing the ASCs for the cost of drugs, an anesthesia group puts itself in the position of providing what is essentially double payment to the ASC: once from the anesthesia group and once from Medicare or the other payer. That double payment could unduly influence the ASC to select the group as the ASC’s provider.

The allegations announced in connection with the Sweet Dreams settlement were, for the most part, similar to commonly observed kickback demand/offer situations: the demand or offer to provide personnel to work in the ASC, the provision of drugs, the provision of supplies, the provision of anesthesia machines and so on. However, another allegation may be one of a

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An Update on the ‘Company Model’ and Other Anesthesia Kickback Schemes

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kind: That they agreed, through an affiliate, to fund the construction of an ASC in exchange for contracts as the exclusive anesthesia provider at that and a number of other ASCs.

Southern Crescent Anesthesiology

We’ve all probably seen them: unpaid medical directorships. Yes, sometimes they’re demanded by a facility, from ASCs to hospitals, as a part of the “deal” for an exclusive contract. And sometimes they’re offered by the anesthesia group to induce the facility to choose it as the exclusive provider.

But free isn’t always free. Sometimes it costs millions, as in the 2018 settlement of allegations that CRNA David LaGuardia (LaGuardia) and his anesthesia entities Southern Crescent Anesthesiology, PC (SCA) and Sentry Anesthesia Management, LLC (Sentry) provided a free medical director to an ASC.

The portion of the settlement allocated to the free directorship wasn’t specifically disclosed, because it was part of an overall \$3.2 million settlement paid to the federal government by a medical practice (Georgia Bone & Joint), an ASC (Southern Bone & Joint, aka Summit Orthopaedic Surgery Center) and La Guardia, SCA and Sentry that also resolved allegations that Georgia Bone & Joint and LaGuardia submitted false claims to Medicare for non-FDA approved prescription drugs purchased outside the U.S.

The Bottom Line on Management Services/Expense-Shifting Arrangements

Although on the first level, they might appear to be commercially reasonable, arrangements by which anesthesia groups provide anything of value to or for a facility in connection with the right to provide services to patients is fraught with AKS danger. This is true whether the items or services are demanded by the facility or a surgeon ... or offered by the anesthesia group. Same issue. Same bottom line. Same potential crime.

Just as in connection with the company model arrangements discussed above, the legal issues are highly complex and involve compliance with a criminal law statute, the AKS. Anyone confronted by, or designing, an arrangement that potentially violates the AKS must obtain counsel well versed in the issues.

At least one highly competitive residency program is now owned by a venture capital firm where compensation during training is provided mainly in the form of “loans”.

Last, but not least, in answer to the question I suspect lurks in the minds of readers (“How will I ever get caught?”), it pays to know that many cases come to light as the result of whistleblowers, whether actual whistleblowers under the FCA or just those who “drop the dime” by contacting the OIG or other federal or state authorities to report what they think might be a crime. You have to pay attention to the fact that many whistleblowers are insiders, including physicians and medical group or facility employees.

Whistleblower Adam Nauss, who worked with Sweet Dreams for several years, received a portion of the settlement. So, too, did whistleblower Sharon Kopko, the former practice administrator at Georgia Bone & Joint and Summit Surgery Center.

Picture each of your employees and colleagues with a whistle around their neck.

Mark F. Weiss, JD, is an attorney who specializes in the business and legal issues affecting physicians and physician groups on a national basis. He served as a clinical assistant professor of anesthesiology at USC Keck School of Medicine and practices with the Mark F. Weiss Law Firm, a firm with offices in Dallas, Texas and Los Angeles and Santa Barbara, California, representing clients across the country. He can be reached by email at markweiss@advisorylawgroup.com.

Anesthesia Medical Necessity Fraud: Difference of Opinion or False Claim?

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involving allegations of fraudulent anesthesia services in terms of medical necessity noncompliance.

Two other federal court decisions holding physicians can be liable under the FCA for medical necessity violations are also important to consider. In U.S. ex rel. Tra v. Fesen/Hutchinson Clinic, a whistleblower (who worked as a clinical oncology pharmacist at the medical oncology clinic) filed an FCA lawsuit alleging that a physician and the clinic violated the FCA by submitting medically unnecessary claims to Medicare and TRICARE.

In U.S. ex rel. Dildine v. Pandya, the former office manager of an ophthalmology practice filed a whistleblower lawsuit under the FCA against the ophthalmologist and the ophthalmology practice. The alleged false claims involved surgical and laser procedures, diagnostic tests, and office visits.

The federal courts' important legal holdings can be summarized as follows:

1. Medical necessity fraud can be asserted under the "express false certification" FCA theory based upon the following:

- The Medicare Act, which vaguely defines medical necessity as "services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member";
- The Medicare Manual, which states that drugs are covered only if they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- The Medicare documentation standards, which require medical records to confirm medical necessity;
- The CMS-1500 Form, which requires physicians to certify that "the services on this form are medically necessary";
- The Medicare Contractor's Local Coverage Determination, which states that drugs must be used as set forth in certain compendia ratings; and
- The practice's own policies which stated that they would follow Medicare guidelines.

2. Medical necessity fraud is a viable claim under the "express false certification" theory because of the certification statement contained on the back of the CMS-1500 Form.

3. Failure to provide medically necessary treatment was material to the government's decision to pay the claims. Materiality was established because the physician treated patients with medications that were not medically appropriate based upon the compendia and standard industry practices, and because some patients were treated too long. **Editorial note: The court relied on the Medicare Manual, LCDs and industry guidelines to establish medical necessity fraud even though they are not "the law."**

4. The court held that a physician's certification to the government that a procedure is reasonable and necessary is false under the FCA if the procedure was not reasonable and necessary under the government's definition of that phrase. **Editorial note: In that case, the provider performed a high number of procedures; the procedures violated industry and hospital guidelines; other physicians objected to the practice; audits showed that the guidelines were violated; and the provider represented that they were performed on other indications, none of which constitute the government's legally binding definition of medical necessity.**

5. The U.S. ex rel. Tra case did not involve a subjective difference of medical opinion, which another federal court found to be not actionable under the FCA.

6. The government relied on Medicare National Coverage Determinations ("NCDs") to establish medical necessity violations. The U.S. Department of Justice recently published a document prohibiting DOJ litigators from using such "sub-regulatory" guidelines to establish civil fraud liability. Nevertheless, the federal court held that it doesn't matter that the government failed to adequately define "reasonable and necessary," and no other case law was cited to support the exclusion of a Medicare NCD. Instead, the court held that NCDs can be considered substantive rules to establish fraud, and the physician cannot avoid liability by merely contending that NCDs are nonbinding as a matter of law.

7. The court also stated: "Moreover, based on the language of the DOJ Memorandum itself, the court cannot conclude that the DOJ Memorandum precludes these claims." Editorial note: It is remarkable that a federal court judge would allow use of nonbinding, sub-regulatory guidance to establish potential fraud liability when the DOJ litigators themselves are not supposed to do so.

8. A physician's latitude in medical judgment does not nullify the allegations of false claims.

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From the ASA Committee on Practice Management

The American Society of Anesthesiologists offers a Residents & Fellows Track at PRACTICE MANAGEMENT 2020, being held January 17-19, 2020 in Las Vegas, NV. This program provides foundational concepts in practice management, which will help residents and fellows excel at non-clinical demands unique to operating a practice. In order to encourage resident participation, the ASA offers a scholarship award to interested residents.

Scholarship Nominations - The ASA Committee on Practice Management, which oversees program planning for PRACTICE MANAGEMENT 2020, will sponsor 10 residents through the ASA Emerging Leaders Scholarship Program. Nominations will be accepted through October 31. Nominations are made by program directors and should be accompanied by two letters of recommendation, a CV, and

an essay of 500 words or less from each applicant describing their interest in practice management and leadership. All materials can be emailed to residentcomponent@asahq.org. The ASA Committee on Practice Management will award 10 scholarships of \$1000 each toward the cost of attending this program. Interested residents should discuss this program with their program directors.

The future of our specialty depends on the next generation of physicians who have the potential to develop into talented anesthesiologists with an expanded skill set as a physician leader.

For more information, please visit <https://www.asahq.org/practicemanagement>.

Anesthesia Medical Necessity Fraud: Difference of Opinion or False Claim?

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As this article was being finalized for publication, the 11th Circuit U.S. Court of Appeals issued an extremely well-reasoned, lengthy decision on this precise subject. The court made the following important holdings:

1. **Objective falsity** must be proven in order to violate the FCA.
2. Where there is only a **reasonable disagreement or difference of opinion** between medical experts as to the medical necessity of services ordered or rendered, with no other evidence to prove falsity of the assessment, objective falsity was not proven.
3. Objective falsity can be shown in a variety of ways. If a physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before ordering or performing services, his ill-formed "clinical judgment" reflects an objective falsehood. The same is true if a physician did not, in fact, subjectively believe that his patient needed the service.
4. A reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own to suggest that those judgments – or any claims based on them – are false under the FCA.
5. A properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong.

Although the Court of Appeals sent the case back for additional consideration by the trial court, the foregoing analysis and holding provides hope for a reasonable approach to allegations of medical necessity fraud asserted by the federal government and the whistleblowers.

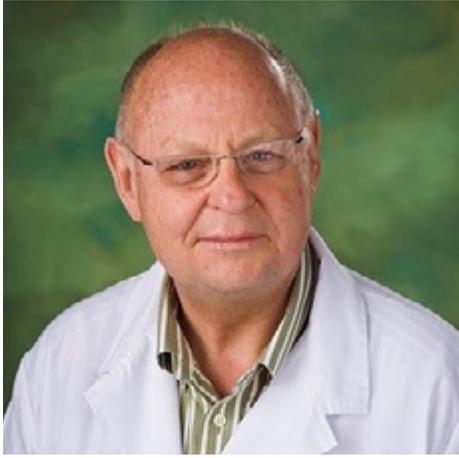
Even in light of the favorable ruling, the compliance points for PSA members from these decisions are clear:

1. In determining the medical necessity of claims submitted to Medicare and federal health care programs, National Coverage Determinations, the Medicare contractor's Local Coverage Determinations and industry guidelines or standards defining the parameters of medical necessity should be reviewed for every procedure billed, and used to determine whether claims submitted for those procedures were medically necessary.
2. Diagnostic testing data should be audited to ensure patients who receive surgical or other procedures (such as pain management procedures) have established complaints and objective impairments to justify the procedure.

PSA members in private practice should include medical necessity analysis in the context of internal audits and make every effort to provide treatment and services within the confines of the applicable third party payor's medical policies.

Z-PAC Update

There is no bad publicity



Craig Muetterties, MD

Have you ever done something that you did not want publicized? Something you told all your friends that you would NEVER do? I have a confession to make; I just committed that sin.

You see, my wife is a closet photographer. Her phone holds images of every person, place and item in our lives. In contrast, I rarely use my phone's camera. Well, I did capture that image of her napping with arms folded across her chest that looked like a scene from a funeral home. She thinks I deleted that one. I didn't.

This brings me to my confession. I committed to a monthly payment program to get her a new phone with a phenomenal camera. I swore I would never get involved in a subscription plan but it seemed so painless. It could be perfect restitution for taking (and keeping) that photo of her!

You may be asking yourself why I share this with you. As I was wringing my hands over this purchase, I found that I had already committed to a number of "subscription based" services. I pay for cloud-based storage, streaming internet services and online news. Oh, I almost forgot the monthly payment for my wife's massage, possibly made as payment for that photo. Subscription services work because it is less painful to write a check for \$83.34 every month than to make the identical payment of \$1,000.00 once.

Z-PAC is facing a critical shortage of funds at a time when our Society is dealing with a number of serious

issues. As I write this, contributions have fallen to about half the level for a typical year while the output of funds has nearly doubled.

We need your participation. I suggest you look at your monthly subscription expenditures, cut the ones you don't need, and contribute your savings to the PAC.

As for me, I found a monthly \$65.00 payment to a sports massage that I gave my wife as a gift years ago. When I asked her about it she commented that she hadn't used it in months.... only \$18.34 to go for me!

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PAIN MANAGEMENT IN PENNSYLVANIA - MOVING FORWARD

Cell Phones in the Operating Room



Gary Okum, MD

Professor Emeritus of Clinical Anesthesiology,
Perioperative Medicine & Surgery
Drexel University of Medicine

Certain technologies have been described as transformational. Until roughly 200 years ago, a man spent his entire life in a village. Day to day, he grew his own food, met mainly fellow villagers and retired shortly after dusk. Now, we have friends on other continents and can visit them in a matter of hours. We can have virtually anything delivered to our doorstep the same day, often by drone. We have our choice of nearly a dozen late night comedy shows in “stunning HD” and we go to the post office only to make sure we do not see our picture posted.

While personal digital assistants such as the Palm Pilot and Research in Motion’s Blackberry products enjoyed widespread use early this century, the “smartphone” era began in earnest in 2007 with the rollout of the very first iPhone by Apple. Google, Samsung, Microsoft and other entrants flooded the market and very quickly, virtually every adult and most children had access to one of these devices. Now, not only could one access e-mail and surf hypertext pages on the internet, but also any site could be accessed at high speed. If that weren’t enough, scores of mini-programs called apps were created offering everything from tomorrow’s weather to a twenty minute fling in a hotel room in Moscow. While perhaps not as exciting as 20 minutes in Moscow (who am I to judge?), scores of useful medical applications have been introduced over 12 years.

With few limits, the world is almost literally at our fingertips. However, when these devices were first introduced, the revolution stopped at the front door of your favorite hospital. Cell phone use was strictly prohibited due to fear of interference with medical devices including, but not limited to, ventilators. These fears have largely been debunked. However, at least in the hospital with which I am most familiar, some of the proscriptive placards persist as “period pieces.” So now that we can use our smart phones in the hospital in general and the operating room in specific, the question to be answered is should we use them?

Of course, in 2019 it is almost impossible to make a statement that cell phones should not be used. In many hospitals, cellular phones have supplanted the once ubiquitous pager as the primary means of communicating changes in the daily schedule and seeking help in an emergency. Gone is the one- to two-minute pager lag common at busy times of the day. The internet can be used to access drug information and to refresh one’s memory on rarely seen conditions.

The electronic medical record can be accessed, and pictures can be taken of important or unexpected findings. Emergency procedures can immediately be accessed and the risk of miscalculating a drug dose can almost be eliminated. Since today’s surgeons often do their best work in the dark, the flash included as part of the built-in camera can serve as an immediate source of “under the drapes” illumination without interfering with the surgeon’s ability to operate. Of course, the many music apps available can feed external speakers with music to soothe the jangled nerves of the most obstreperous surgeon.

So, with all that the smartphone does to enhance our ability to care for our patients, the case for its usage in the operating suite seems open and shut, right? Well, not so fast. There are some serious issues presented by these devices. For starters, in a world where we are being advised to change our masks as many as 60 times per day, we bring to the operating room, for reference purposes, the same smartphone that we use while walking the dog. There are no universally accepted guidelines for the disinfection of smartphones. As a matter of fact, most of the compounds potentially used to disinfect are specifically discouraged by the cell phone manufacturers. Since we tend to use our devices in closer proximity to the patient

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Cell Phones in the Operating Room

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than a stationary landline phone, there is at least the theoretical risk that the device could become a nidus of infection. Of course, it is up to the physician to weigh the potential risk of infection versus the benefit of instant availability of life saving information or Beatles music. I don't think the weight of evidence will come down in favor of a ban of these devices, but there is at least some food for thought here.

Hardly a day goes by without mention in the mainstream media of the perils inherent in telephone conversation and/or texting while driving. It's clear that one cannot maintain the level of vigilance required to drive a car while engulfed in intense conversation or, heaven forbid, while typing. While there are no median strips or guardrails in the typical operating room, there are certainly enough tasks requiring constant vigilance to keep an anesthesia provider busy. Texting the significant other to bring home fried chicken could divert significant cerebral "bandwidth" from several tasks requiring attentiveness, including monitoring vital signs and the surgical field, communicating with the surgeon, checking lab values, documenting care in the electronic record and preparing medication.

While much ink has been spent on the controversy of limited reading in the operating room, most evidence suggests that texting, and certainly phone conversations, are much more "attention draining" than reading. Studies in simulators show demonstrable increases in error rates with the introduction of even minimal distractions. Anesthesiology is frequently compared to aviation, and in commercial aviation, there is the "sterile cockpit" rule. When the aircraft is below 10,000 feet including, there can be no conversation between crew members that is not pertinent to the conduct of the flight. The so-called "black box" continuously records cockpit conversations. There is no "black box" in the operating room. However, even though cell phone conversations are not recorded, the phone carriers maintain an accurate record of the time of texts and time and length of any calls. Not only is there a record of the time text messages are sent, but the messages could also be subject to discovery. The implications in a legal proceeding stemming from an adverse outcome are obvious.

Given the many benefits of smartphones in the operating room tempered by real potential for harm, what are sensible guidelines for their usage?

1. It is best to avoid patient contact after cell phone usage until gloves have been changed, and the cell phone should not be allowed to rest on any surface in direct contact with the patient.
2. Due to the potential risk of electromagnetic interference with monitors, ventilators and pacemakers, it is best to keep smartphones at least 1 meter away from ventilators and monitors and at least 10 cm away from pacemaker/defibrillator generators. The higher the frequency used by the phone, the less distance must be maintained between the phone and medical devices. The evolution of cell phone service is away from the 800MHz band toward bands in the GHz range, so there is much less risk with LTE and 4G service than with the older 3G service.
3. Use of mobile phones by those actively caring for a patient should be limited to activities necessary for care of that patient, and cautiously for other medically related issues such as consultation on the ensuing patient or management issues with a previous patient.
4. Information relating to the use of a cell phone and perhaps the information shared on the phone itself may be discoverable in court, so appropriate judgment should be exercised to minimize distracting behavior that may form the basis for medicolegal action.
5. The HIPAA act of 1996 sets very strict limits on the sharing of protected health information (PHI). Sharing of PHI and images is governed under HIPAA, and this must always be borne in mind when texting or storing data and images on the mobile device.

The "cat is out of the bag" as far as mobile devices in hospitals, and they do have the ability to save lives. It is up to us as practitioners to be the final arbiters of the proper balance between added patient safety and potential to violate the first law of medicine -- *primum non nocere*, first do no harm.

So was Michael Porter Correct?

Revisiting His Thoughts Three Years Later with Clinical Correlations



Joseph F. Answine, MD, FASA

We were surprised and somewhat taken aback by the 2016 ASA annual meeting keynote address by Harvard Business School professor, Michael Porter, MD, PhD. To suggest that we should give up the fight to maintain intra-operative supervision of anesthesia care, and to concentrate on other peri-operative pursuits to sustain our relevance and viability created nothing less than a hailstorm of criticism and concern. My business background daughter, Amber, sitting in the audience with me, may have been the only person present in agreement with his assessment and recommendations. We co-authored a *Sentinel* article outlining what we did and did not agree on pertaining to the subject (Answine, J.F., Answine, A.E. Is Michael Porter Correct? *Sentinel*, Winter, 2016.).

We are now three years from the shock and awe left in the aftermath of the lecture. We obviously have not given up the fight to maintain supervision during anesthesia care – nor should we – but have we accepted the suggestions and advice of the expert economist? In my practice, we have. Below are two clinical scenarios demonstrating advancement in our role as peri-operative physicians at the grassroots level.

Our institution has asked the department of Anesthesiology to assist with enhanced patient recovery and resident and student education. These are two daunting tasks for an exceptionally busy anesthesia practice covering multiple hospitals and ambulatory centers. What's more is that we are a physician-owned practice that was offered no financial compensation for

the added workload. Many of my colleagues said “absolutely not” because there is no financial gain for the increased work – work that is relatively foreign to those experts in intra-operative care. But, as a group, we accepted the requests and the challenge.

First, we developed a proactive daily teaching program for trainees. The trainees are anesthesia residents and SRNAs from nearby teaching programs as well as residents from other specialties, such as Emergency Medicine, Surgery, Family Medicine, Internal Medicine and Podiatry, within our institution. It was considered onerous for many within the department and not all agreed to participate; however, significant effort was put into advancing anesthesia education, including pre-operative discussions, creation of care plans, hands-on intra-operative care and didactics. We volunteered our time for inter-departmental committees and gave lectures on various aspects of peri-operative care to providers in other medical specialties, administration and nursing. Very quickly, the work was noticed by other departments and the hospital administration. We were praised for it and the department was even granted paid administrative time to continue to advance anesthesia education.

However, much more work has been required and much more anguish has been produced to advance the enhanced recovery (ERAS) program within our institution. The program was initiated with even less early enthusiasm than the educational pursuits. It has involved years of meetings, curbside discussions, lectures, rollouts, re-rollouts, and arm-twisting to get to where we are today. So, where are we? There are many anesthesiologists, surgeons, surgical specialties, nurse managers and individuals within administration that have bought into the program. There is an optimization clinic with increasing utilization. And, there are improved patient outcomes. Most importantly, all are quite happy having anesthesiology take the lead. For good or bad, we are the go-to people for questions, suggestions, problems and concerns. All-in-all, progress has been made, patients have benefited, and administration has noticed the efforts and progress.

Now three years from the thought-provoking lecture, I assume the above scenarios are exactly what Michael Porter suggested we do. We are still diligent in our efforts to keep anesthesiologist supervision as the norm. Yet I, and I am sure a few more anesthesia brethren, have now accepted the notion that our future, our viability and our relevance is as peri-operative physicians contributing to advancing anesthesia knowledge, as well as patient care – a few weeks prior to surgery and, at the least, days after the patient is discharged from recovery.



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Breathing circuits are the conduit to deliver oxygen and anesthetic gases from the anesthesia machine to the patient. An important safety requirement for any breathing circuit is that it should avoid rebreathing of exhaled carbon dioxide (CO₂). In the semi-open circuits, as classified by Mapleson, this is achieved by ensuring adequate fresh gas flow, while in the circle system the exhaled CO₂ is absorbed by an absorbent.

Historic perspective

The concept of a rebreathing circuit with absorption of the exhaled carbon dioxide was first advocated by Dennis Jackson, in 1914. In 1922, Ralph Waters introduced the use of soda lime into clinical anesthesia and the circle system with flow-directing valves was devised by Brian Sword in 1926.

The popularity of circle system started declining in 1950s as cyclopropane gradually fell out of use with the introduction of halothane. Accurately calibrated vaporizers allowed the delivery, in high-flow circuits, of agent concentrations which would produce the required level of anesthesia. However, interest was rekindled in the use of the circle system as a practical way to reduce environmental pollution by economical use of inhalational anesthetics.

Construction

The presence of unidirectional valves ensures the passage of gases in a circular fashion and hence the name. The essential components of the circle system are shown in Figure 1.

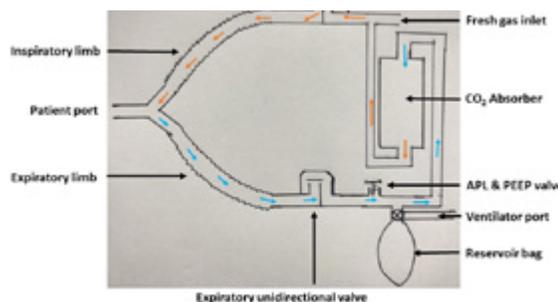


Figure 1: A schematic diagram of the circle system

- Inspiratory and expiratory unidirectional valves
- Corrugated tubes with a Y-piece
- Reservoir Bag
- Inlet for the fresh gas flow (FGF)
- Canister containing CO₂ absorbent
- Adjustable Pressure Limiting (APL) valve

Modern anesthesia workstations have in addition the airway pressure gauge, the oxygen analyzer, the positive end-expiratory pressure (PEEP) valve, the bacterial filter and the attachment for the ventilator and the scavenging system.

However, to ensure that the exhaled gases pass through the soda lime canister before returning to the patient and thus avoid rebreathing of exhaled CO₂, Eger suggested three essential rules in the construction of the circle system. (Figure 2)

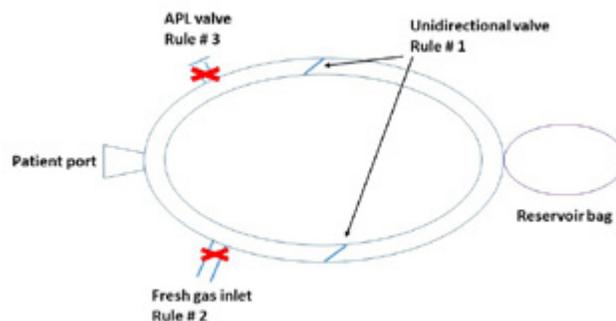


Figure 2: A schematic diagram of the circle system

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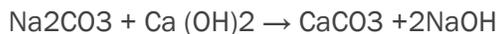
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1. A unidirectional valve must be present between the patient and the reservoir bag on the inspiratory and the expiratory limb of the circuit.
2. The fresh gas inflow must not enter the circuit between the patient and the expiratory unidirectional valve.
3. The pressure relief valve must not be located between the patient and the inspiratory unidirectional valve.

Every breathing circuit has a section from where the exhaled gases has the potential to be rebreathed and this segment is known as the 'dead space.' In a circle system this extends from the Y-piece between the expiratory and the inspiratory limbs to the patient port. If any of the rules suggested by Eger are not fulfilled, the segment of the circuit between the patient and the reservoir (rule #1), FGF inlet (rule #2) or the APL valve (rule #3) will act as dead space and result in rebreathing. Addition of the capnography adapter adds to the dead space which could be significant when the circle system is used for a neonate.

CO₂ absorption

CO₂ combines with water to form carbonic acid [H₂CO₃], which is then neutralized by a strong alkali. Calcium hydroxide [Ca (OH)₂] is the main component of soda lime as it combines with CO₂ to form calcium carbonate [CaCO₃], which is an insoluble precipitate. However, this reaction needs an activator like sodium hydroxide [NaOH] or potassium hydroxide [KOH].



Although, NaOH is regenerated, Ca(OH)₂ is irrecoverably converted to CaCO₃. The absorptive capacity of soda lime is 26L of CO₂ per 100 gm of absorbent. Ethyl chloride, an indicator added to soda lime, turns from colorless to violet when the capacity of the soda lime to absorb CO₂ is exhausted. The size of the absorptive granules is a compromise between resistance to airflow and the absorptive efficiency. The granular size is between 4-8 mesh. Mesh refers to the number of openings per linear inch in a sieve through which the granular particles can pass. Small amounts of silica and kieselguhr are added to provide hardness to the granules to reduce dust formation.

Interactions of inhaled anesthetics with absorbents

Sevoflurane in the presence of a strong alkali can degrade into penta-fluoro-isopropenyl fluoro-methyl

ether, also known as Compound A. In rats, compound A has been shown to be lethal at 130-340 ppm (parts per million) and cause renal injury at 25-50 ppm, but the levels at which toxicity occurs in humans is not known. Compound A concentrations of 25-50 ppm are present during normal clinical practice. Sevoflurane degradation is enhanced by higher absorbent temperature, higher sevoflurane concentration, low fresh gas flow (FGF) and desiccated CO₂ absorbents (especially with potassium hydroxide containing absorbents e.g. Baralyme). Sevoflurane package insert recommends a FGF of 2L/min and to limit a FGF at 1 L/min to 2 MAC-hours.

Desiccated soda lime can degrade inhaled anesthetics to form clinically significant concentrations of carbon monoxide (CO) and formaldehyde. This is more so with desflurane and Isoflurane compared to sevoflurane. The CO production is increased with a higher concentration of anesthetic given over a long duration and at low FGF as it prolongs the contact between the absorbent and the anesthetic. Therefore, it is prudent to turn off the gas flow when the machine is not in use as the passage of oxygen over a long time period could dry the soda lime.

Advantages of the circle system

1. The ability to use a low FGF. Recirculation of anesthetic gases has both economic and environmental benefits.
2. Conservation of body temperature by warming and humidifying the inspiratory gases.
3. The circle system can be used for adult and pediatric subjects during spontaneous and controlled ventilation. This universality reduces error.
4. Ease of using a ventilator and the scavenging system.

Disadvantages of the circle system

1. Multiple components and connections has the potential for leaks.
2. If either of the unidirectional valve is stuck in an open position the dead space would extend to the whole limb on that side. Improved design of the unidirectional valves has reduced the incidence of this malfunction.
3. Interaction of inhaled anesthetics with the absorbent.

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4. The compliance of the corrugated tube may reduce the tidal volume delivered. Therefore, it is advisable to use thinner, less compliant tubing while anesthetizing neonates.

In modern anesthesia workstations the 'self-test' includes the integrity of the circle system. It essentially checks for leaks and patency.

Practical Points

The volume of the various components of the circle system can add up to about 8L. Therefore, at the start of the anesthetic, the FGF should be kept high to replace the existing air with the delivered concentration of the anesthetic in order to hasten induction. Similarly, at the end of the anesthetic displacing the anesthetic vapor from the inhaled gas mixture by flushing the circuit with high flow of oxygen will hasten the recovery. During maintenance of anesthesia when the tissue anesthetic concentration is approaching the limit and the uptake of anesthetic is minimal the FGF can be reduced to account for patient's oxygen consumption and gas leakage from the circuit.

The circle system is the most commonly used breathing circuit during anesthesia and therefore understanding its functioning and limitations is crucial for any anesthesiologist.

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