American Society of Anesthesiologists

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February 27, 2012

Inspector General Daniel R. Levinson
Office of Inspector General
Congressional and Regulatory Affairs
United States Department of Health and Human Services
Room 5541 Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Attention: OIG-120-N

Dear Mr. Levinson:

On behalf of the over 48,000 members of The American Society of Anesthesiologists (ASA), we appreciate the opportunity to submit comments in response to the Office of Inspector General (OIG) solicitation for Special Fraud Alerts. We firmly believe that the economic model, referred to as the "company model," is "fraudulent and abusive" to anesthesia providers and the patients for whom they provide high quality and safe care. We believe the best approach is to continue to have anesthesiologists working directly for a hospital, ambulatory surgery center (ASC) or if operating independently, anesthesiologists should be paid fairly for their service without having to unfairly remit their income to a facility under the "company model." The "company model" results in negative implications for a number of the criteria the OIG reviews when considering proposals, including but not limited to the following:

1) Decreasing the quality of services
2) Decreasing competition among health care providers
3) Increasing the potential overutilization of the health care services
4) Increasing the cost to Federal health care programs
5) Increasing the financial benefit to health care professionals or providers that may take into account their decisions whether to
    a) Order a health care item or service or
    b) Arrange for a referral of health care items or services to a particular practitioner or provider.

Our letter addresses each of these factors, along with supporting data of the volume and frequency of the conduct in question, to demonstrate the grave nature of the "company model."

In a letter from former ASA President Roger A. Moore, M.D., ASA first brought this to the attention of the OIG in 2008. Subsequently, we brought this issue to the attention of the OIG in letters dated February 24, 2011 and March 19, 2009. In those letters we illustrated our concerns that the "company model" potentially violates the Federal anti-kickback provisions of the Social Security Act (the Act) (section 1128B) and requested that the OIG issue a Special Advisory Bulletin providing guidance on the issue. The Social Security Act specifically states:

> whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Mr. Lewis Morris, Chief Counsel to the Inspector General, acknowledged receipt of ASA's letter in a letter ASA received on April 23, 2009. We followed with a subsequent letter dated June 16, 2010, reiterating our concerns and bringing to the attention of the OIG recent independent legal analyses that concluded the "company model" violates Federal law. We understand the enormous burden and workload of the OIG and applaud your important efforts to identify fraudulent activity within our Federal health care programs. We also believe this model fits within your current mission and hope our letter will convince you that it deserves expedited action.

As stated in ASA's previous letters, physician-owned facilities have been moving away from the traditional fee-for-service model and turning to the "company model" to increase their revenue stream for anesthesia services. Under the "company model", the referring physicians or their medical practices form a separate anesthesia company that they own. Typically, the referring physicians also own the facility where surgical/procedural and anesthesia services are provided, such as an ASC. Under this arrangement, the sole purpose of the anesthesia company is to provide anesthesia services to the referring physicians or the facility they own. Establishment of a separate anesthesia company permits the facility to bill for facility fees and anesthesia services fees through the same billing/administrative company. The referring physician owners of the facility and the anesthesia company then share in the profits generated by the facility fees and the anesthesia service fees. In other words, the referring physicians share in three revenue streams: (1) facility fee, (2) procedural fee and (3) anesthesia services fee.

Decreasing Quality of Services

As recognized leaders in patient safety, anesthesiologists pride themselves on providing the highest level of quality and safe patient care. ASA develops, modifies and updates evidence-based guidelines, statements and practice parameters to assist our members in keeping current with the latest science and best practices with respect to anesthesia care. As further evidence of our commitment to quality, ASA has launched a separate organization, the Anesthesia Quality Institute (AQI), with the primary mission of establishing a national anesthesia outcomes registry. AQI began collecting data in January 2010 with the intent that researchers, ASA and other interested parties will use the data to further enhance the science and practice of anesthesia.

The "company model" creates incentives and pressures that represent the complete antithesis of these strides in quality care provided by ASA and anesthesiologists. Because the referring physician has such a direct ownership stake in the anesthesia company, and thus the fees generated by anesthesia services, it is easy to see the pressures that could be exerted on anesthesia providers to administer inappropriate anesthesia services, against their clinical judgment. Faced with such pressure, and we

have anecdotal evidence this has in fact occurred, the anesthesia provider can be placed in a predicament – refuse to administer anesthesia and lose his/her job, or administer anesthesia. Obviously we would hope that all anesthesia providers would elect the former; however, the reality is that the referring physicians can likely find some unscrupulous providers willing to compromise their clinical judgment in order to secure gainful employment.

As such scenarios play out and less qualified providers are hired by referring physicians, quality of patient care will suffer dramatically. In an environment in which ASCs, despite the recommendations of the Medicare Payment Advisory Committee (MedPAC), are still not required to submit quality data to CMS, the quality of care could greatly diminish and no one would know until a catastrophic event occurred.

Decreasing Competition Among Health Care Providers

With the exception of major urban areas, most areas of the country have access to less than a handful of anesthesia practices from which they can obtain services. Due to the lack of OIG guidance on this matter, there are some anesthesia practices, anesthesia corporations and individual anesthesia providers, willing to take the legal risk and agree to serve under the "company model".

As supported by an ASA survey on the "company model" conducted from December 2010-January 2011, the vast majority of ASA members and their practices are rejecting these offers, seeking legal counsel or negotiating the potentially illegal terms out of the contract. At the same time, the ASA survey found that 125 of 308 (41%) responding anesthesia practices from across the country have been requested by an ASC and/or referring physician practice to adopt the "company model". Those 125 practices, representing 21 states, also reported multiple requests from multiple ASCs (n=332). Of the 332 requests reported in the survey, anesthesia practices lost a contract in at least 159 of those instances. These numbers were surprising and troubling to the ASA, but we believe, further underscore the urgency that guidance and clarity be provided on this economic model.

As the "company model" continues to increase in frequency, the eventual outcome is that those who reject contracts they believe to be illegal will be forced out of the competitive marketplace. Only those who concede to this illegal model will be left, and thus, competition will be decreased.

Further, according to the U.S. Government Accountability Office (GAO), Medicare pays anesthesiologists approximately 33% of their average commercial payment for the same anesthesia services. The rest of medicine receives from Medicare approximately 80-85% of their average commercial payments. There is no question that Medicare payment rates are not sustainable for anesthesia practices, particularly if the commercial payor mix declines over time. Given this economic reality, and assuming that the company model was somehow not illegal, it is clear that anesthesia practices cannot sustain themselves by also providing 40% or higher shares of anesthesia profits to other providers.

Increasing the Potential Overutilization of Health Care Services

Anesthesiologists often serve as "gatekeepers" to surgical procedures by performing pre-anesthesia evaluations that assess whether the patient is appropriate for the procedure and whether the proposed location for the procedure is appropriate (e.g., ASC, outpatient facility, inpatient admission, etc.).

The "company model" compromises this critical phase in the patient's perioperative care. The referring physician's direct financial interest in the anesthesia company creates the strong incentive to increase the utilization of anesthesia services and the depth of sedation to maximize anesthesia profits. Though there is no current registry or analysis being performed to determine with scientific precision whether ASCs that adopt the "company model" increase utilization of anesthesia services, ASA has heard from multiple sources that such ASCs have in fact increased from 45-60% utilization rates to nearly 100%.

Increasing the Cost to Federal Health Care Programs

CMS estimates that Medicare payments to ASCs in 2009 totaled $3.2 billion. This, of course, does not include the payments received by surgeons/proceduralists or anesthesia providers administering services under Medicare Part B. Data also show that at least 35% of procedures performed in ASCs are performed by gastroenterologists. The ASA survey conducted in December 2010-January 2011 demonstrated that the vast majority (66%) of specialties requesting this "company model" are gastroenterologists. Other specialties identified in the ASA survey as having requested anesthesiologists adopt the "company model" include orthopedics (9%), multi-specialty (12%) and other (13%), which includes the specialties of ophthalmology, plastics, urology, pulmonology, general surgery and neurology. Given the level of Federal health care payments and the volume of services provided to Medicare beneficiaries potentially under this economic model, there is significant opportunity to escalate the costs to Federal health care programs by the increased utilization of anesthesia services driven by referring physicians who profit from their ownership stake in the anesthesia company.

Increasing the Financial Benefit to Health Care Professionals or Providers that may take into account their decisions whether to order a health care item or service

For all of the reasons and explanations provided above, ASA believes that the "company model" further encourages referring physicians to consider financial incentives and motivations when deciding whether to order anesthesia services and at what level. The direct financial linkage to anesthesia service revenue is inappropriate and provides no clinical or administrative justification. The only rationale is financial.

ASA believes that the company model is a critical issue that should be addressed by the OIG through a Special Fraud Alert. The implications for Federal health care costs, the safety and quality of Medicare beneficiaries increasingly seeking services in ASCs, and the anti-kickback statute justify guidance from the OIG. As always, we welcome a conversation to discuss this issue further if the OIG would find it helpful. Please feel free to contact Jason Byrd, J.D., Director of Practice Management, Quality and Regulatory Affairs, in our Washington office via email (j.byrd@asawash.org) or phone (202-289-2222), with any questions or issues.

Sincerely,

Jerry A. Cohen, M.D.
President
American Society of Anesthesiologists