

HEALTH LAW UPDATE

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PHYSICIAN PROFILING

What is the Cost of Achieving Program Efficiency?

By Adil A. Daudi

In April of this year, the Government Accountability Office (hereinafter “GAO”) released a study in which it concluded that CMS has in place the tools to evaluate physicians’ practices for efficiency and could undertake a physician profiling system to compute efficiency measures as early as the summer of 2008.

This article examines the GAO report – including the circumstances that led to the report – and in particular its call for CMS to implement a “profiling system” to estimate and eliminate physician “inefficiency.” In addition, this article addresses the broader issue of using physician profiling as a twist from the pay-for-performance programs that are designed to reward physicians for keeping their patients healthier based on quality of care standards.

Background

The sustainability of the Medicare program has long been in doubt. In its 2006 Annual Report, the Medicare Trustees put the fate of the program in real terms, declaring that Medicare’s Hospital Insurance Trust Fund – which funds the Medicare Part A program – will be exhausted in 2018.¹ A direct consequence of this finding has been a continued effort for timely and effective action for reform.

The practice patterns of physicians has been the primary target for reform efforts due to the central role physicians play in the generation of health care

expenditures in total. Their services are estimated to account for twenty-percent of total health care expenditures, whereas their influence is estimated to account for up to ninety-percent of this spending.²

Recognizing, in part, the role physicians can play in controlling the rise in health care expenditures, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter “MMA”). The MMA called upon the GAO to study aspects of physician compensation, pertaining only to those physicians serving beneficiaries in traditional fee-for-service (hereinafter “FFS”) Medicare.³ Pursuant to the Congressional mandate, the GAO issued this report in April 2007 detailing its findings in this regard. The report compiled data from twelve metropolitan statistical areas to: (1) estimate the prevalence in Medicare physicians who are likely to practice medicine inefficiently, (2) examine physician-focused strategies used by public and private sector health care purchasers to encourage efficient medical care; and (3) examine the potential for CMS to profile physicians in traditional FFS Medicare for efficiency and use the results in ways that are similar to other purchasers that encourage efficiency.

GAO Report to Congress – The Case for Profiling

The GAO report is based on the premise that physicians play a central role in the consumption of

¹ See Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (Washington D.C.: May 1, 2006). Medicare Part A pays for inpatient hospital stays, skilled nursing facility care, hospice care, and some home health care. Part B finances physician, outpatient hospital, home health care, and other services.

² John M. Eisenberg, *Doctors’ Decisions and the Cost of Medical Care: The Reasons for Doctors’ Practice Patterns and Ways to Change Them*, Health Administration Press Perspectives (Ann Arbor, Mich.: 1986); Gail R. Wilensky and Louis F. Rossiter, “The Relative Importance of Physician-induced Demand in the Demand for Medical Care,” *Milbank Memorial Fund Quarterly: Health and Society*, 61(2): 252-277, spring 1983.

³ Pub. L. No. 108-173, § 953, 117 Stat. 2066, 2428.

healthcare services and the identification of “efficient” physicians is a positive move to curb rising health care costs. In its report, the GAO defines efficiency as “providing and ordering a level of services that is sufficient to meet a patient’s health care needs but not excessive, given the patient’s health status.”⁴

According to the GAO report, some public and private health care purchasers have initiated programs to identify “efficient” physicians and encourage patients to obtain care from these physicians.”⁵ The GAO report studied programs from commercial health plans, provider network trust funds managed by unions and government agencies. These programs were selected because they “profile” physicians explicitly to address efficiency – unlike other programs that assess quality only.

Physician profiling is a system where the practice pattern of a single physician or group is expressed as some measure of the use of resources and/or length of stay during a defined period for the population served. The resulting profile is then compared with a norm that is either based on practice or on standards.⁶ To inform its study, the GAO considered the experience of purchasers who regularly use efficiency profiling to evaluate physicians. To measure efficiency the GAO study, like similar studies from other purchasers, drew comparisons between actual spending for generalists physicians’ patients to the expected spending for those same patients, given their clinical and demographic characteristics.⁷ Generalist physicians profiled were classified as “practicing medicine inefficiently” based on data indicating that their Medicare practice included a percentage of overly expensive patients that was higher than would occur by chance for their area.

Role of CMS

The GAO study referenced those health care purchasers that link their physician evaluation results to a range of incentives to encourage efficiency. These include steering patients toward the most efficient providers to excluding physicians from the purchaser’s provider network because of inefficient

practice patterns. Commonly reported incentives include:

- Physician Education
- Publicly Designating Physicians Based on Efficiency or Quality
- Using Tiered Arrangements to Promote Efficiency
- Exclusion

The GAO report concludes that CMS has the tools to profile physicians for efficiency. Like its private health purchaser counterparts, CMS has the advantage of a repository of claims information to compute efficiency measures for physicians serving Medicare patients. However, CMS lacks the authority to use results in ways similar to the purchasers cited above and will require additional authority to use the results similarly. Ultimately, however, the GAO report recommends that given the contribution of physician spending in total, CMS should take immediate steps to develop a profiling system that identifies individual physicians with inefficient practice patterns and, seeking legislative change as necessary, use the results to improve the efficiency of care financed by Medicare.

Efficiency Profiling – Balancing Quality and Cost

The efficiency profiling program proposed by the GAO has been met with strong criticism from the American Medical Association and various physician specialty groups. The critics of such efficiency profiling programs cite that the profiling methodology is based on erroneous assumptions. In particular, that all products offered across specialties are the same and that differences in costs are attributable to differences in efficiency. For example, providers who have a high proportion of referrals for imaging or surgery and those charges per service exceed the averages set by the profiling criteria, the referring practitioner is held responsible. In addition, providers that care for the sickest patients will not “profile” well because those patients inherently require care at “inefficient” levels.

To be sure, quality measures, clinical guidelines and outcome measures should always factor into any profiling scheme. The critical determination in the success of a profiling scheme, however, will be whether it is administered properly. A poorly administered profiling system by CMS, that does not factor in quality measures, runs the risk that

⁴ MEDICARE FOCUS ON PHYSICIAN PRACTICE PATTERNS CAN LEAD TO GREATER PROGRAM EFFICIENCY, GOVERNMENT ACCOUNTABILITY OFFICE (April 2007).

⁵ *Id.*

⁶ See Zemenuk, Judith *et al.*, *What Effect Does Physician “Profiling” have on Inpatient Physician Satisfaction and Hospital Length of Stay?* (April 4, 2006).

⁷ For purposes of the GAO study “generalists” are physicians who described their specialty as general practice, internal medicine, or family practice.

physicians will opt to not take on patients with complicated issues. For other physicians, reimbursement cuts coupled with being examined through a profiling lens would encourage less participation in the Medicare program entirely.

Conclusion – Using Profiling Data “Efficiently”

As was recognized in the GAO report, profiling data can be used in a number of ways. The science of profiling, however, based on efficiency criteria requires good risk adjustment mechanisms and must be further developed. It is true CMS likely has the data and resources to profile physicians. However, CMS is in a better position to use efficiency data to

conduct educational outreach with physicians about efficiency, given how it has done so in the past regarding improper billing and fraud. To include financial incentives or deterrents to improve physicians’ performance on spending would not only require additional Congressional authority but would also require more accurate efficiency profiling programs. Providers should, nevertheless, be cognizant of CMS’ possible expansion into the efficiency profiling arena as a possible variation on the pay-for-performance model.

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OIG IS SUSPICIOUS OF HOSPITAL INVESTMENT IN AMBULATORY SURGERY CENTER

By: Veronica A. Marsich

On June 19, 2007 the Office of Inspector General (“OIG”) issued its most recent Advisory Opinion (No. 07-05) in which it declined to favorably review a proposed arrangement involving a hospital’s intent to purchase a 40% ownership interest in an ambulatory surgery center (ASC) then owned by seven physicians. Among health care attorneys, this advisory opinion created a significant buzz almost immediately upon posting. The concern among health care attorneys is not that the OIG continues to be generally suspicious of physician-hospital joint ventures. The OIG’s suspicion of physician-hospital joint ventures is long standing and well publicized. Rather, the concern stems from the OIG’s seemingly faulty analysis.

One of the issues that make this particular Advisory Opinion so troubling is the OIG’s somewhat illogical analysis of the importance of the “return on investment” of the physicians selling their interest in the ASC. Specifically, of the seven physician investors in the ASC, three orthopedic surgeons held 94% of the membership units. The proposed transaction involved the hospital buying its interest in the ASC exclusively from these orthopedic surgeons. In this regard, the OIG seems to have been particularly focused on the fact that the return on

investment received by the orthopedic surgeons for selling a portion of their shares in the ASC was greater than the price the surgeons had paid for their shares upon initial investment. Importantly, however, the requesting parties represented that the price the hospital was to pay for the membership units was “fair market value” and in fact logic would dictate that anytime owners of a successful surgery center are selling units in such a venture, those units will likely be worth more than they were when the investors initially opened the ASC and acquired their membership units. Had the hospital been unwilling to pay more for the units in the ASC than the original physician investors had paid, the OIG would have been able to argue that the hospital’s purchase price was not in fact fair market value because the units of the center were worth far more than they were when originally purchased.

In addition to this flawed fair market value analysis put forth by the OIG, the OIG also cited concern over the fact that the hospital was purchasing its investment interest in the ASC exclusively from the three orthopedic physicians and not from either the ASC directly or from all of the physicians in proportion to their ownership interest. The OIG seemed to view this as an indication that hospital intended its investment

in the ASC to directly benefit the orthopedic surgeons to the exclusion of the other physicians. The OIG had concern that this was designed to somehow serve as a reward for past or future referrals by the orthopedic surgeons to the hospital. Again, the OIG's analysis seems suspect given that there are a number of variations by which the parties could have accomplished the same goal by, for example, having the ASC simply buy back a certain number of shares from the orthopedic surgeon physicians and then sell those shares directly to the hospital.

For a health care attorney, what makes the OIG Advisory Opinion particularly troubling is that it appears the OIG simply did not like the transaction and did not want to give it any level of approval. The OIG created various, arguably, artificial justifications for disapproving of the transaction. These justifications, if left unclarified by the OIG through

some future communication, could ultimately result in a number of fairly common practices in the ASC industry and the health care industry generally, in the context of hospital-physician transactions, being called into question. Hospital executives, physicians and the attorneys who counsel them will need to pay close attention to future communications from the OIG with respect to similar joint ventures to monitor whether the OIG truly intended to take us down this path or whether this Advisory Opinion merely represents a momentary lapse in good judgment.

Veronica A. Marsich represents physician groups, hospitals and health care providers of all types in general health, transactional and regulatory matters. She can be reached directly at vmarsich@shrr.com or 734.913.6662.

CMS ATTEMPTS TO GUIDE PROVIDERS IN NAVIGATING RESTRAINT AND SECLUSION REQUIREMENTS

By Billee Lightvoet Ward

On May 18, 2007, CMS held an Open Door Forum to discuss hospital obligations relating to restraints and seclusion.⁸ This came on the heels of revisions to the Conditions of Participation for Patients' Rights ("COP") which went into effect on January 8, 2007 and significantly altered the requirements for use of restraints and seclusion. During the Forum, CMS representatives highlighted some of the more significant changes in the COP and attempted to provide clarification in response to providers' questions. This article provides a brief overview of the new COP and the points of clarification offered by CMS.

⁸ CMS describes an Open Door Forum as "an opportunity for live dialogue between CMS and the provider community at large, in order to understand and then help find solutions to contemporary program issues." See Centers for Medicare and Medicaid Services, *Open Door Forums Overview*, (visited June 21, 2007), available at http://www.cms.hhs.gov/OpenDoorForums/01_Overview.asp#TopOfPage.

New Standard 482.13(e) Restraint or Seclusion

The revised COP combine the previous requirements of §482.13(e) Acute Medical and Surgical Care with those at §482.13(f) Behavior Management, resulting in a single Standard 482.13(e) Restraint or Seclusion which applies to the use of restraint or seclusion in any treatment setting within the hospital. The new COP retain many of the general principles of the former rule, including requirements that restraint or seclusion be used only when less restrictive interventions have been determined to be ineffective and only in accordance with the order of a physician or other licensed independent practitioner. Furthermore, orders for restraint or seclusion may not be written as a standing or PRN order and must be discontinued at the earliest possible time. Notable changes in the new Rule include revised definitions of restraint and seclusion, heightened requirements for restraint or seclusion used in the management of violent or self-destructive behavior, and specified documentation and death reporting requirements.

A restraint under the new COP is defined as “any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient’s behavior or restrict the patient’s freedom of movement and is not a standard treatment or dosage for the patient’s condition.” See 42 CFR 482.13(e)(1)(i). Included in the new definition are examples of what is *not* considered a restraint. Specifically, §482.13(e)(1)(C) states:

A restraint does not include devices, such as orthopaedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

Hospitals should be cautious not to interpret these examples as bright line exceptions to the Rule in every instance. For example, although side rails are often used to protect a patient from falling out of bed, side rails may also be used as a behavioral intervention. In the latter instance, side rails would qualify as a restraint and may be used only in accordance with the Rule. Whether a device or other intervention qualifies as a restraint depends on the provider’s intent. As always, providers should maintain appropriate documentation to support the purpose for which any restrictive device or intervention is used along with the clinical justification for such use.

“Seclusion” is defined at 482.13(e)(1)(ii) as “the involuntary confinement of a patient *alone* in a room or area from which the patient is physically prevented from leaving. Seclusion *may only be used for the management of violent or self-destructive behavior.*” [Emphasis added]. If either restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient or others, hospitals are required to conduct a face-to-face evaluation of the patient within one hour of the time the restraint or seclusion was initiated. CMS has attempted to alleviate the potential burden of this one-hour requirement by allowing the evaluation to be performed by a physician or other

licensed independent practitioner, or by a Registered Nurse (“RN”) or Physician’s Assistant (“PA”) who is appropriately trained. If an RN or PA performs the evaluation, he or she must consult the attending physician as soon as possible after the evaluation is completed. Documentation of the face-to-face evaluation must be maintained in addition to other minimum documentation requirements now set forth explicitly in the Rule.

New Standard 482.13(f) Restraint or Seclusion: Staff Training Requirements

The former Behavior Management standards have been replaced by an entirely new Standard §482.13(f): Staff Training Requirements. This Standard requires hospitals to train all staff members who will be involved in any of the following activities: i) application of restraints; ii) implementation of seclusion; iii) monitoring, assessment, and providing care for a patient in restraint or seclusion. Before performing any of the listed activities, staff members must undergo appropriate training and be able to demonstrate competency in the relevant activities. See 42 CFR 482.13(f)(1). The new Rule outlines minimum content requirements for training and minimum qualifications for individuals providing staff training. Demonstration of competency is a notable change and will likely require amendments to hospital policies and procedures. Staff members must be trained as part of orientation and periodically thereafter consistent with hospital policy, and completion of the requisite training and demonstrated competency must be documented in each staff member’s personnel file.

New Standard 482.13(g) Standard: Death Reporting Requirements

The new Rule expands the incidents of death that must be reported to CMS. Under the previous COP, hospitals were required to report any death occurring while the patient was in restraint or seclusion, and any instance of death where it was reasonable to assume that the death resulted from restraint or seclusion. The new Rule limits the “reasonable to assume” deaths to those occurring within 1 week after the restraint or seclusion is ceased, but expands the incidents of reportable deaths overall. As of January 8, 2007, hospitals must report the following incidents of death:

- (i) Each death that occurs while a patient is in restraint or seclusion;

- (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; and
- (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement of seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

42 CFR 482.13(g)(1). As outlined in subsections (ii) and (iii) above, the range of reportable deaths under this new Standard are much broader than the previous COP and encompass deaths that may be wholly unrelated to the use of restraint or seclusion. Reports under this Standard must be made by telephone no later than the close of business the next business day following knowledge of the patient's death. *Id* at 482.13(g)(2). Additionally, CMS now requires that the date and time of the report be documented in the patient's medical record. *Id* at 482.13(g)(3).

During the Open Door Forum, CMS acknowledged the fact that hospitals may not be aware of all deaths required to be reported under the new COP. For instance, if a patient is discharged a day or two following removal from restraints, and passes away within the one week window under the Rule, the hospital may have no reason to know of the discharged patient's death and, correspondingly, may not have the information necessary to make a report. If the hospital is aware of the patient's death, it must determine whether the "reasonable to assume" element in subsection (iii) above is met. Death reports under the Rule must be directed to the applicable CMS Regional Office and, depending on the circumstances, state reporting requirements may also apply.

Informal Guidance

Providers continue to raise questions and concerns over the new COP. CMS offered the following specific points of clarification during the Open Door Forum:

- The hospital COP do not apply to Critical Access Hospitals unless they have a Distinct Part Unit (DPU). In that case, the COP apply to the DPU.

- Mitts, whether used on pediatric or adult patients, are not a restraint unless they are tied down or pinned down.
- Relevant clinical protocols are allowable if approved by the Medical Staff, but they do not obviate the need for a physician order and overall compliance with the COP.
- Risk of a patient's self-extubation does not constitute violent or self-destructive behavior for purposes of the COP.
- A physical hold to prevent a patient from leaving against medical advice is a restraint.
- A new order is not required to place a patient in seclusion after releasing him/her for eating or toileting.
- A new order is required to place a patient in seclusion after releasing him/her on a trial basis.

These clarifications should not be taken as absolute in all circumstances. The Open Door Forum served, most notably, to confirm what has always been the case in relation to restraints and seclusion: it is the provider's *documented* intent that will determine whether an intervention is considered restraint or seclusion. Furthermore, it is important to note that the guidance provided by CMS through the Open Door Forum is informal and not authoritative. Providers should continue to consult legal counsel to ensure ongoing compliance with the new requirements.

Conclusion

Compliance with the new COP in the use of restraint or seclusion will continue to be an issue of documentation. Hospital providers should maintain detailed records documenting all aspects of care in the use of restraint or seclusion, and evidencing compliance with the various requirements under the Rule. Such documentation should include the use of restraint or seclusion; the clinical justification for such use; the patient's behavior, conditions, and symptoms; interventions utilized including the use of interventions that are less restrictive than restraint or seclusion; the patient's response to such interventions; continuous observation of all patients in seclusion or restraint; and all applicable documentation requirements specified in the Rule.

As a result of the new COP, hospitals will need to develop new policies or update their existing policies to comply with the standards governing face-to-face monitoring, training and demonstrated competency, reportable deaths, and other obligations. In doing so,

it is important to note that mental health providers such as hospital psychiatric units are subject not only to federal regulation, but also to recipient rights provisions of the Michigan Mental Health Code and related administrative rules. Attention must be paid to all applicable legal authorities when establishing processes and revising hospital policies and procedures.

If you have any questions regarding the new COP for Restraint or Seclusion, or would like us to review your

policies or procedures, please contact a member of our Health Care Team.

Billee Lightvoet Ward represents hospitals, physician practices, and other health care providers in general health law matters. She specializes in regulatory and transactional matters involving health care contracting, corporate compliance, clinical research, release of protected health information, fraud and abuse, and behavioral health. She can be reached directly at bward@shrr.com or 616.458.5454.

Who is Dave Vinocur?



Dave Vinocur, shareholder in Smith Haughey's Traverse City office, enjoys the practice of health law because it allows him to work at the intersection of science and social policy.

An experienced health care attorney and malpractice litigator, Dave has a special interest in behavioral

health. He enjoys helping clients, which include facilities with and without inpatient psychiatric units, solve organizational and case-specific issues that have behavioral health components. Dave's expertise includes risk management of specific clinical behavioral health emergencies, Medicaid and Mental Health Code compliance, clinical documentation, recipient rights, managed care contracting, EMTALA, use and disclosure of confidential health information, credentialing, legal proceedings under the Mental Health Code, guardianships, surrogate decision-making, clinical policies and procedures and inter-agency operating agreements.

Currently, Dave has a number of clients who, with his assistance, are attempting to reduce their compliance, EMTALA and professional liability risk by formalizing (through the adoption of written

protocols) the respective roles and responsibilities of CMHSPs and hospitals in the diagnosis and treatment of patients who present to the emergency department with psychiatric issues. He is also helping a client prepare for the federalization of Medicaid fraud and abuse enforcement by more closely integrating its quality assurance and compliance operations. Dave feels strongly that the best attorneys never forget they are also counselors.

A practicing attorney for 30 years, Dave helped start SHRR's Traverse City office in 1990 and was the first SHRR attorney to specialize in health care law. He served as in-house counsel to Northern Lakes Community Mental Health Authority from 1999 through 2006, rejoining SHRR in January 2007.

Dave received his Bachelor of Arts from Yale University, and his Juris Doctor from Syracuse University College of Law. A member of the State Bar of Michigan, the American Health Lawyers Association, the Health Care Compliance Association, and the Munson Medical Center Bioethics Resource Committee, Dave resides near Traverse City with his wife Barbara, a social worker, and a couple of dogs. His interests include travel, politics, history, cigars and fly fishing.

NEWS & SUCCESS

Two of Smith Haughey health law attorneys presented at the recent annual meeting for the Michigan Society of Healthcare Risk Management (MSHRM). **Richard Kraus'** presentation was titled "Criminal Actions Against Licensure" and **Veronica Marsich's** presentation was titled "How to Respond When the Feds Show Up."

Cara Nieboer has completed her first semester as an adjunct professor of Health Law and Ethics at Grand Valley State University. **Bill Jewell** is also an adjunct professor at the university.

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