

Reducing Medical Errors and “Never” Events: A Multi-Dimensional Challenge

Robert Chabon, MD, JD, MPH
Jack H. Olendar & Associates PC
Washington, DC

Robin Goldenberg, MD
Georgetown University’s School of Nursing and Health Policy
Washington, DC

Erling Hansen, Esquire
Alderman Devorsetz & Hora PLLC
Washington, DC

Brian Heller, PhD
Quadrus LLC
Washington, DC

Peter McGinn, PhD*
Leadership Impact
Vestal, NY

A recent Medicare policy change has brought into critical focus the fact that hospitals and medical staffs have failed to be effective in reducing medical errors. The Centers for Medicare and Medicaid Services (CMS) announced that it would no longer pay hospitals for the extra costs of treating injuries, infections, or other complications caused by preventable errors (never events).¹ The thesis of this paper is that the principal cause of the lack of success in reducing hospital errors is the often dysfunctional relationship between hospital administration and the medical staff. For hospital leaders at both the board and executive levels this bespeaks a need to find a solution that recognizes the problem’s legal, medical, financial, and operational dimensions.

Background

However challenging the new Medicare never event payment policy might be, it can in no way be viewed as a surprise. It is just the latest development in a story that has been unfolding for over fifteen years since Lucian Leape reported data from the second Harvard Medical Practice Study in 1991. Revisiting this issue in a recent issue of *Health Affairs*, Leape responded to the query, “Is hospital patient care becoming safer?”² He observed that some progress has been made, but that formidable barriers remain, including: inconsistencies in how doctors, nurses, and pharmacists learn; inadequate communication and team-building skills; poorly developed quality and safety curricula; lack of leadership among chief executive officers and hospital boards; physician



apathy; and absence of effective systems for accountability. Leape graded both federal and state governments with an F, “or at best a D- in providing incentives to get providers to focus on reducing errors and improving safety.”³

At the same time that hospitals are encountering this looming payment restriction from Medicare, they also are confronting the possibility of payment restrictions from commercial payors. Cigna, Aetna, Health Net, and Health Partners are among the payors that have indicated they are considering making non-payment for “never events” a standard part of their provider contracts.⁴

This issue lies squarely at the intersection of healthcare finance and patient safety. The stage is set—there is a significant market driven initiative that is forcing hospitals to find a way to work with their medical staffs to improve the quality of care provided.

Obstacles to Improving the Quality of Care

Notwithstanding the long-visible antecedents and the more recent financial imperatives, there are significant obstacles to hospitals and their medical staffs working together with common purpose to formulate strategies for successfully addressing the multidimensional problem of quality healthcare and patient safety. These obstacles include:

- The dysfunctionality of hospital-medical staff organizations;
- Poor physician attendance and participation in medical staff meetings;
- Weakening links between hospitals and medical staffs;
- Increased economic competition between hospitals and doctors;
- Financial issues such as compensation for call coverage;
- Physician shortages that affect hospitals' bargaining position in attempting to bring about changes;
- Insufficient clinical information technology;
- Medical education process and gaps; and
- Limitations of clinical knowledge/expertise on the part of administrators.

Underlying these obstacles is the reality that hospitals/hospital administrators and medical staffs/physicians often come from, and usually work in, different cultures that frequently result in only a grudging acceptance of one another.

The Solutions are Behavioral, Cultural, Legal, and Technological

The solutions to the poor relationship between hospital administration and the medical staff will not be found in one-shot, technological breakthroughs, although improvements in information technology are an important component of success. Coming to grips with the challenge of non-payment requires cultural change of a fundamental nature. Indeed, it demands a return to the social and professional cohesiveness of the medical staff of a much earlier day. However, that social and professional cohesiveness must be updated for the new economic, cultural, legal, and political environment in which hospitals and physicians find themselves today.

Effecting change will require a joint effort of hospital administration, medical staff leadership, legal counsel, and organizational development experts. Legal counsel will be essential in crafting new models that protect organizational and professional rights while encouraging cooperation without violating restrictions on referrals, kickbacks, and the like.

A multifaceted approach will include at least the following six components.

1. Reinvigoration of the Medical Staff Organization

The authors have observed that the medical staff organizations in many American hospitals have developed increasingly into institutional advocates for physicians rather than guardians of patient interests and quality control. Over time, attendance requirements have been allowed to lapse. Medical staff rules and regulations have been relaxed in response to increasing physician disinterest in, or alienation from, the hospital's concerns and priorities. In many organizations, the medical staff organization functions at just a fraction of its previous importance or influence in the lives



of physicians. To reinstate the traditional and legal role of the medical staff will require a careful revision of both bylaws and processes.

2. Building of Relationships

Physicians not only have become disinterested in hospital priorities and issues, but also display less solidarity among themselves professionally and socially than was previously the case. In some instances, this is driven by economic competition. In addition, changes such as prohibitions on extensions of "professional courtesy" have eroded physician group identity and lessened feelings of mutual obligation. Legal and regulatory demands paired with reimbursement constraints and increased financial expectations have reduced discretionary time for many physicians. Attention to relationship building has been a casualty of time pressures for physicians just as it has for many other professional groups such as attorneys and certified public accountants.

Hospitals need to take the lead in creating systems and structures that promote partnership activities. In addition, hospitals need to promote business and professional ventures that align incentives. Because many activities that would make good business sense elsewhere could potentially run afoul of anti-kickback and related legal restrictions in the healthcare setting, such plans need to be vetted by legal counsel.

3. Involving Physicians in Strategic and Operational Planning

In order to break down walls, build trust, and align incentives, hospitals should increase physician participation in planning—and in many cases reward physicians for their efforts both through direct compensation (consistent with legal and regulatory constraints) and through greater input in the hospital's investment decisions. Because there are inherent conflicts of interest in this approach, this effort needs careful organization and oversight. Moreover, in not-for-profit hospitals, additional safeguards will be required to protect against private inurement and other jeopardy to tax-exempt status. Nevertheless, rebuilding medical staff relationships and creating partnerships that are essential for true quality improvement will involve meaningful physician participation in capital projects, information technology, and service line planning.

4. Facilitating Best Practices

The success of the Institute for Healthcare Improvement's 100,000 Lives Campaign⁵ and the CMS "Core Measures" initiative⁶ both point to the practical value of identifying, promoting, and tracking best practices. This road, however, is not without its bumps. In this same timeframe, researchers at Johns Hopkins University published the results of a program in certain Michigan hospitals that instituted a simple five-step checklist designed to prevent infections by reminding doctors to wash their hands and don a sterile gown and gloves before putting large intravenous lines into patients. Although the results were reportedly "stunning," and "the program saved more than 1,500 lives and nearly \$200 million,"⁷ the federal Office for Human Research Protections temporarily shut the program down because, by introducing a checklist and tracking the results without written, informed consent from each patient and healthcare provider, Johns Hopkins researchers had violated scientific ethics regulations.⁸ Therefore, while hospitals will find "best practices" and checklists to be two of the most effective tools for addressing quality control problems, legal counsel will be essential in order to address potential regulatory obstacles with implementing these tools.

5. Assisting with the Evaluation and Implementation of New Income Streams

The government has attempted to limit business partnerships between hospitals and physicians in order to prevent hospitals or doctors from using economic incentives that are not in the best interests of patient care or of those paying for patient care. Although this has had the presumptive benefit of minimizing such practices as payment for referrals, it also has prohibited many opportunities that would exist in other business ventures for collaboration between partners. The opportunities for gain-sharing, for example, have been constrained within the relatively limited activities supported by safe-harbor rules and occasional private letter rulings.

Any joint ventures between hospitals and medical staff need to steer through a minefield of regulations, and this often gives

rise to the need for creating cumbersome planning and ownership mechanisms. The intentions are to build partnership and mutual commitment towards common goals (including improved quality), and to increase physician income streams so that they can more easily afford to participate in voluntary medical staff activities. Therefore, it is necessary to construct relationships that are not so complex that those goals get lost in constructing firewalls and barriers that communicate caution and distrust rather than partnership.

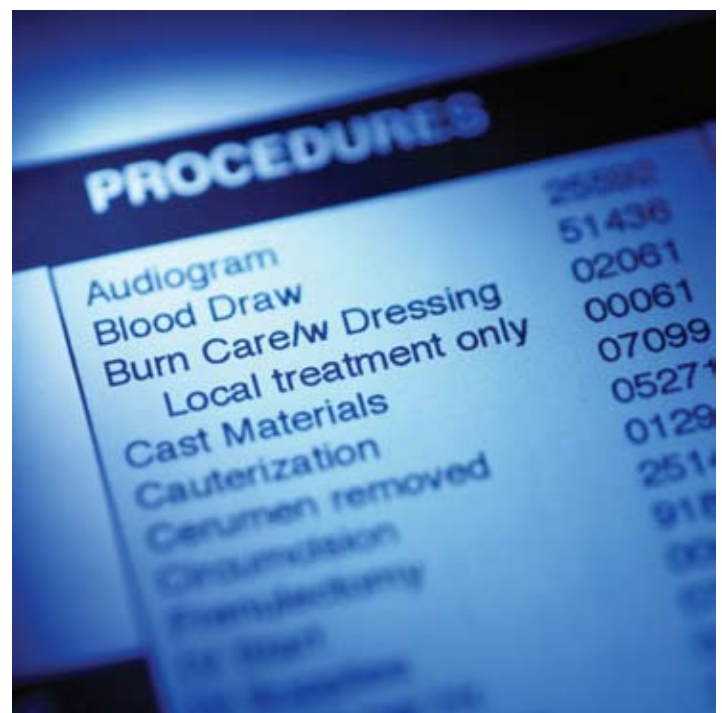
6. Assisting Hospital Departments in Creating Complication and Surveillance Mechanisms

The demands of the new CMS payment policy directive will require improvements in at least five major hospital departments and will put stress on working together effectively across departmental lines. Because of historical and practical factors, such improvement may be more difficult than it first appears. Involved departments will include at a minimum: Nursing, the Medical Staff Office, Quality, Information Services, and Billing. As previously noted, legal counsel will also be indispensable.

Legal Issues and Liability Concerns

In addition to the formidable barriers that must be overcome to bring hospitals and their medical staffs together to address issues of patient safety and medical error, there are significant potential liability concerns that may arise from the new CMS payment plan and from similar state and commercial plans.

Not all of the qualifying "preventable" complications selected by CMS are comparable in terms of their preventability, nor are they entirely within the control of the hospital or its medical staff. It is without question that instruments or sponges left behind after surgery should be never events. However, current best efforts





may not entirely prevent vascular infections from catheter use, for example. Similarly, the amount of effort and expense required to prevent the formation of pressure ulcers is far greater than that required to avoid retained instruments. This alone could lead hospitals to alter admission policies and practices. The aspect of the Medicare never event payment policy change requiring hospitals to report Present on Admission Indicators may make it inevitable.

We suspect that plaintiff's attorneys may well argue that never events should be viewed as *res ipsa* occurrences or, at the least, that they should always be viewed as representing below standard care. This would appear to be an excellent example of the law of unintended consequences as "the mere designation of never events will likely result in both more numerous and more valuable plaintiffs' verdicts nationwide."⁹

Some sets of these never events, for example those recently approved by the Washington State Hospital Association and the Washington State Medical Association, employ the modifier "serious," penalizing hospitals only for "serious disability associated with a fall" or "serious disability from medication error," without, not surprisingly, offering criteria for defining the term "serious."¹⁰ This may then be left for the legal system to define.

It is not clear how far out in time from the never event the ban on hospital charges extends. On the one hand, if a patient sustains a

hip fracture from an in-hospital fall, it is clear that the hospital may not bill for the fracture repair. If, on the other hand, three months post-discharge, the patient develops what appears to be a non-hospital acquired infection at the hip repair wound site and the patient is readmitted, who pays the bill? What if a patient develops a deep pressure ulcer in the hospital (clearly, not reimbursable) and is discharged when the ulcer appears to be healed, but is readmitted after two weeks at home with an ulcer at precisely the same site. Who pays? It is possible to develop many confusing and confounding scenarios that may evolve from the new CMS rule and its progeny, and the end effects are not in sight.

Conclusion

The full implementation of non-payment for never event complications will eventually require major policy decisions for hospitals. At this juncture, we cannot foresee all of the downstream effects of the federal government's never event policy decision. However, there can be little doubt that the impact will be profound not just for hospitals but for healthcare providers of every category, as well as for others associated with healthcare.

** The authors are principals of Healthcare Quality Support LLC, a consulting firm focusing on obstacles to healthcare quality improvement. Dr. Chabon recently retired as Medical Director of the Heartland Health Plan associated with the Heartland Medical Center, St. Joseph, MO. Dr. Goldenberg is a member of the faculty at Georgetown University's School of Nursing and Health Studies. Mr. Hansen is Of Counsel to the Washington, DC, law firm of Alderman Devorsetz & Hora PLLC where he provides legal assistance to nonprofit organizations, including healthcare providers. Dr. Heller has been the chief executive of Physician Hospital Organizations in Indianapolis, IN, Binghamton, NY, and Toledo, OH. Dr. McGinn heads his own consulting firm, Leadership Impact, and previously served as President & CEO of United Health Services, a 5,000-employee regional health system. The authors can be contacted collectively via email at ehansen@adhllawfirm.com.*

- 1 72 Fed. Reg. 47129 (Aug. 22, 2007)
- 2 Buerhaus, Peter (interviewer) "Is Hospital Patient Care Becoming Safer? A Conversation With Lucian Leape," *Health Affairs* vol. 26 no. 6 (2007) (web exclusive).
- 3 *Id.*
- 4 Carpenter, Dave "Never' Land," *Hospitals & Health Networks* (Nov. 11, 2007)
- 5 Wachter, Robert et al. "The 100,000 Lives Campaign: A Scientific and Policy Review," *Journal on Quality and Patient Safety* Vol. 32 No. 11 (Nov. 2006).
- 6 Obligations initially created by Section 501(b) of the Medicare Modernization Act of 2003 (Pub. L. No. 108-173) and modified by Section 5001(a) of the Deficit Reduction Act of 2005 (Pub. L. No. 109-171). These are codified as Social Security Act, § 1886(b)(3)(vii)-(viii) (initiative to which the CMS "never" events payment policy change was added).
- 7 Gawande, Atul (op-ed contributor) "A Lifesaving Checklist" *N.Y. Times* (Dec. 30, 2007).
- 8 *Id.*
- 9 Brown, Charles et al. "Litigation Impact of Never Events," *Health Lawyers News* Vol. 12 No. 2 (Feb. 2008) p.26.
- 10 These sets of never events, which can be found at www.wsha.org, are based on the National Quality Forum's publication, *Serious Reportable Events in Healthcare: A Consensus Report (2002)*, of which there is now a 2006 Update.