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IN THIS ISSUE:

* RISK MANAGEMENT: PHYSICIANS' RESPONSE TO PATIENT SAFETY AND QUALITY INITIATIVES-COORDINATED EFFORTS RECOMMENDED

* ASK THE EXPERT: DENISE L. SANDER, ESQ.

* A.M. BEST UPGRADES MEDICAL PROTECTIVE TO "A++"

* ACOG SURVEY REPORTS OB/GYNS CHANGING HOW THEY PRACTICE

*NEW PHYSICIANS PRACTICE ONLINE SAFETY TOOL

AND MORE.....

RISK MANAGEMENT: PHYSICIANS' RESPONSE TO PATIENT SAFETY AND QUALITY INITIATIVES-COORDINATED EFFORTS RECOMMENDED

By: James B. Couch, MD JD, FACPE

First: The Good News for Physicians!
Literally in the eleventh (if not twelfth) hour at around 4 a.m. on Saturday, December 9th, in its final gaps, the 109th Congress voted to forego the previously HHS ordered 5.1 percent decrease in Medicare reimbursement for physicians in 2007. Instead, reimbursement will be frozen this year. That may not be cause to pop the champagne corks, but as W.C. Fields would respond to a questions about this life: "Not bad, considering the alternative."

A Hidden Bonus: Pay for Performance?
Tucked into the legislation freezing 2007 Medicare physician reimbursement rates was a provision that beginning in July, 2007, those who submitted quality information in 16 (as yet to be finally determined) areas on some (also as yet to be percentage of their Medicare patients) would qualify for a 1.5% "bonus" in their Medicare reimbursement. At least initially, all that physicians will need to do is to submit the quality information. Their 1.5% bonus will not be conditioned on their results. Also, those physicians not submitting the required quality information will not be penalized. They just won't get the 1.5% bonus.

This represents yet another move by the federal government into what has now come to be known as the "Pay for Performance' arena. There are over 100 such initiatives in various states of evolution in the private sector. Also, last August, President Bush signed an Executive Order requiring all those delivering health care services to federal beneficiaries in the Medicare and Medicaid programs, the Veterans and Military Health Systems and civilian federal employees (covered by the Office of Personnel Management) to make the quality and cost (price) of their services know.

This is all part of the Bush Administration's Transparency Initiative intended to provide this type of information to patients, their families and others in the federal sector involved in both the receipt and purchasing of heath care services. HHS Secretary Michael Leavitt is pushing hare for Pay for Performance (also know as Health Care Value Purchasing) to become a significant force in the purchasing and deliver of care to government subsidized beneficiaries before the end of this tenure in 2009.

(continued on page 2)
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(continued from page 1)

Is All This Going To Be Worth It? Recent Research And Other Initiatives

For now, the reward for submitting the required quality information is not that great – only a 1.5% increase in reimbursement. For physicians who would either have to expand a significant amount of their or their staffs' time to collect and report this information and/or to install electronic systems capable of doing this, the return on investment (strictly from a financial perspective at least) may not justify it. Based on the relatively limited number of studies completed on the impact of Pay for Performance, the consensus is that incentives approaching 10% of base reimbursement will probably be required for most physicians to make the necessary investments not only to report on quality, but, more importantly, to improve results sufficiently to qualify for that extra money.

In addition, most researchers would have to admit that the proverbial jury is still out on whether improved adherence to best medical, safety and preventive practices results in significant improvements in the outcomes of medical care. A recent study by researchers at the University of Pennsylvania published in the December 13th edition of the "Journal of the American Medical Association" (JAMA) demonstrated that there was not that significant a difference in the mortality rates of patients whose physicians were in the 75th vs. 25th percentile in adhering to 10 of the so-called Hospital Quality Measure Set standards of care promulgated by the federal government for the treatment of myocardial infarction, congestive heart failure and pneumonia. (*Werner, Bradlow, Relationship between Medicare's Hospital Compare Performance Measures and Mortality; JAMA; 2006: 296:2694-2702*). However, the Penn researchers were comparing mortality, as opposed to a potential myriad of other outcome indicators. The same day that this study was reported, the Institute for Healthcare Improvement (IHI) announced its upgrade of its previously successful 100,000 Lives Campaign to prevent unnecessary deaths through six safety interventions. IHI's new 5 *Million* Lives Campaign aims to eliminate not just deaths, but *any* kind of injury, due to preventable medical errors through the implementation of both the original six, plus six additional safety and quality improvement interventions (*IHI Launches National Campaign to Reduce Medical Harm in U.S. Hospital's Building on it's Landmark 100,000 Lives Campaign; Institute for Healthcare Improvement Press Release; Orlando Fl; December 12, 2006*).

It could well be the case that the real pay off from improving adherence to best evidence based medical, safety and preventive practices is in eliminating or minimizing *any* king of patient injury, not just deaths. Since the vast majority of litigation derives from allegedly preventable errors resulting in medical harm, short of death, the extent to which safety and quality improvement interventions may minimize these should produce medical legal risk management benefits. Also, the measurement of performance for value based purchasing rewards is much more likely to be based on producing superior value clinical outcomes (as opposed to avoiding deaths).

The Value of Patient Safety and Quality Improvement Initiatives for Physicians and their Patients

In announcing the 5 Million Lives Campaign at IHI's Annual Meeting in Orlando on December 12, Dr. Donald Berwick, President and CEO of the Institute for Healthcare Improvement (IHI) defined medical harm as "…. The unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment or hospitalization, or results in death…" IHI provides a more detailed description of this medical harm at its website: http://www.ihi.org

It is important here to recognize the much more sweeping approach that IHI is taking here in its newest campaign-this one lasing two

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years. As dramatic as the success of its first campaign was resulting in the saving of an estimated 122,300 lives at 3,100 participating hospitals based on their implementing between three and six of the original set of safety and quality improvement interventions, this new campaign goes much further. By seeking the involvement of 4,000 hospitals and their staff physicians to implement up to 12 safety and quality improvement interventions, this time, the goal is to eliminate around one-third (5 million) of the estimated 15 million instances of medical harm which occur to patients annually as a result of preventable medical errors and suboptimal practice.

The most obvious benefit of implementing the 12 interventions (explained in their entirety at http://www.ihi.org) is to avoid the preventable harm (as Dr. Berwick defined this, above) to millions of patients. As Dr. Berwick said, "We can and we will, equip all willing health care providers with the tools they need to make the motto 'First, do not harm' a reality."

For the physicians of these millions of patients whose medical harm may be averted, however the value is equally great, viz. to improve physician patient relations and minimize the risk of litigation that might otherwise follow from suboptimal care. This constitutes a potentially huge benefit to physicians. Fear of potential medical liability is one of the most important reasons for the significant drop in physician morale across the country (The American College of Physicians Executives Poll on Physician Morale; Physician Executive; December, 2006). Although never being able to eliminate the possibility of litigation altogether, being involved in these twelve improvement interventions should both protect physicians from being sued and from weak defense in the event of litigation.

The concluding section of this article will discuss how physicians may join with themselves, their hospitals and liability carriers in this and other safety and quality improvement initiatives to acquire these protections.

Physicians, Hospitals and their Liability Carriers: Their Mutual Stakes

Plaintiffs' attorneys can testify that their favorite cases are those where defendant hospitals and physicians are not united in their defense. That makes it really easy for judges and juries to find liability against one or the other (and usually both) defendants. Not being on the same page can prove very costly in so many ways for defendant hospitals, their staff physicians and liability carriers.

The success of any quality and safety improvement initiative depends on the alignment of interests and ongoing cooperation of participating hospitals and their staff physicians. Since physicians still control approximately 75% of the more that $2 trillion spent on health care annually in this country, that fact goes without saying.

The precarious intra-organizational relationship of hospitals with their autonomous medical staffs, lends itself to conflict. However, the area of improving the safety and quality of care is one in which all hospitals and their staff physicians can (indeed must) be aligned. It strikes at the very heart of their individual and mutual reasons for being. Achieving ongoing collaboration and success in pursuing the noble goals of the 5 million Lives Campaign (and those of other safety and quality improvement initiatives such as Princeton Insurance discussed in December, 15, 2006 Risk Review Online) can and should result in significantly improved hospital physician relations. This should also produce a much more aligned mutual defense posture in the event that litigation involving both parties still occurs. *(continued on page 4)*

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The Way Forward

Although this piece is not intended to kick-off a formal series of articles, it is intended to introduce what will be a common theme throughout 2007, viz. the necessity for hospitals and physicians to cooperate and coordinate their safety and quality improvement initiatives. Subsequent articles in Risk Review Online will focus on more specific ways for hospitals and physicians to cooperate in improving the safety and quality of care, especially in those areas most likely to result in potentially compensable medical harm to patients.

Ask the Expert

Expert: Denise L. Sander, Esq.

What do I need to know about releasing copies of medial records of deceased patients in my practice? Answer: Unless involved in performing autopsies, most physicians generally do not consider the liability that exists from the way patients are treated after they die. However, at a time when many different areas of law can apply to the same issue, it is important to understand how to deal with a patient's medical records, once he passes away.

The main body of law that governs patient records is the Health Insurance Portability and Accountability Act's (HIPPA) Privacy Rule, which requires a covered entity (which includes a physician and/or medical practice) to protect the medical records, or "Protected Health Information" ("PHI"), of a patient. This obligation continues even post-mortem, and is quite similar to the obligation that exists when a patient is sill alive. The primary, and obvious, distinction is that authority over records can no longer belong to a deceased patient. Upon death, this authority gets transferred to the patient's "personal representative."

Under 45 CFR 164.502 (g) (4), a covered entity must treat a person as a personal representative, "If under applicable law an executor, administrator or other person has authority to act on behalf of a deceased individual or of the individual's estate."

A personal representative is generally appointed in a will, where an individual selects the person to carry out her wishes at death. This person is then granted either a letter testamentary or a letter of administration. If a personal representative has been appointed, it is important to note that authorization to release records then lies only with that person, who may be someone other than a former spouse or another family member. In fact, even if a decedent had provided a surviving party with a separate form granting authorization to obtain or grant disclosure of medical records, there is risk in relying on that as continuing authority. Even though the actual person obtains or releases the deceased's records, technically that person loses authority to the appointed representative immediately upon death. To avoid this conflict, a separate authorization should be included from the deceased's representative for any further disclosure of the patient's PHI. Any use or disclosure that has already been made in reliance on the now deceased patient's authorization is valid, however.

If an individual dies without appointing a personal representative in a will, then state intestate laws govern. In New Jersey, this authority would automatically first pass either to a surviving spouse or a surviving domestic partner, who receives the same treatment for these purposes under New Jersey law. To officially become appointed through intestate law, a party must first consent to the responsibility (see N..J.S.A 10:3B-2). *(continued on page 5)*

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Exceptions

Since privacy laws were created to protect patients from having their personal histories made public in ways against their wills, exceptions were created to avoid preventing professionals from carrying out their jobs in good faith. For example, healthcare provides can exchange the PHI of a deceased patient among one another f the purpose is to treat another patient, mainly in the case of a relative with a potentially similar genetic makeup. Also, in the event that covered entities want to notify family members or representatives of a death, or need to identify deceased persons to establish the cause of death, authorization is likewise not required. Some additional exceptions for professionals permit funeral directors, organ procurement organizations, and law enforcement personnel to obtain information consistent with carrying out their jobs.

Beyond these carefully carved out exceptions, PHI can also be transferred under the umbrella research, but only if the researchers provides a covered entity with assurance that the information will strictly be sued for, and is necessary for, research on the PHI of decedents, and provides supporting documentation to confirm the death of the individual.

Perhaps the most unnerving requests for medical records are those associated with any pending or future litigation. PHI requested for purposes of litigation are subject to an entirely different set of very specific rules, the precise details of which are beyond the scope of this article, but physicians should always first ensure that the PHI requested for legal proceedings can legally be disclosed. If a physician is a party to the litigation (e.g. a defendant in a medical malpractice suite for plaintiff in a suit for reimbursement), PHI can be used or disclosed as part of the physician's "health care operations" (See 45 CFR 164.501), including for the purpose of justifying a particular course of treatment. However, physicians can only offer this information for the narrowly defined purpose.

When a physician is not a party to the litigation, and consent cannot be obtained to release PHI, physicians are again charged with the burden of making reasonable efforts to ensure that the PHI is being used only for the narrow purpose that it was intended for. The specific intentions can be found by reading the original requesting document, which may appear in various forms including a subpoena or court order. Moreover, when responding to a subpoena, covered entities must confirm that efforts have been made to inform that patient that a request has been made for disclosure of her medical records and the patient given a sufficient time to respond or object. In the event that the party for whom the records apply is deceased, efforts to locate and notify the representative should then be undertaken instead.

Even after patients die, physicians and covered entities can still face liability for them.

This article is intended to make healthcare professionals aware of these risks and to serve as a general guideline for dealing with requests for the PHI of a deceased patient. This article does not offer any legal advice and should not be relied on for such. Prior to sending any records or taking any action that could be governed under HIPPA, it is suggested that physicians consult their personal attorney.

Tort Reform Legislation

As found in the Medical Liability Monitor

On January 10, 2007 Senators John Ensign and Judd Gregg introduced two vital pieces of legislation to end medial lawsuit abuse and improve patient access to care nationwide. S.243, "Medical Care Access Protection Act of 2007," and S.244, "Healthy Mothers and Healthy Babies Access to Care Act of 2007," are each modeled after successful legislation passed in Texas and included reasonable limits on non-economic damages that have proven to be effective at the state level. These bills were also introduced in the 109th Congress.

ACOG Survey Reports Ob/Gyns Changing How They Practice, Many Women Lack Care

As found in the Medical Liability Monitor

Increasing medical liability insurance premiums and the fear of lawsuits continue to force Ob/Gyns to change how they practice medicine, according to the latest medical liability survey conducted by the American College of Obstetricians and Gynecologists (ACOG).

As a result, many women across the country are going without basic health care and treatment of serious health conditions, as more Ob/Gyns are providing fewer services, retiring from practice completely or relocating to areas where there are less liability concerns.

According to the ACOG survey, 70 percent Ob/Gyns have made changes to their practice because of the lack of available or affordable medical liability insurance, and 65 percent have made changes because of the risk or fear of liability claims or litigation. Between 7 and 8 percent have stopped practicing obstetrics altogether because of either insurance affordability or availability issues or the risk or fear of being sued.

"The results of this survey provide a bleak outlook for the future of women's health," said ACOG president Douglas W. Laube, MD, MEd. "Medical lawsuit abuse continues to wreak havoc on physicians across America, and today fewer and fewer Ob/Gyns are available to provide prenatal and delivery care, routine gynecological care or major gynecologic surgery."

The average age at which physicians stopped practicing obstetrics was 48 – an age once considered near the midpoint of an ob/gyn's professional career. ***(continued on page 7)***

A.M. Best Upgrades Medical Protective to "A++"

As found in the Medical Liability Monitor

A.M. Best Co. upgraded Medical Protective's financial strength rating to "A++," its highest rating, citing the company's "leading market presence in the primary medical professional liability market, distribution capabilities, aggressive claims philosophy and comparatively strong operating performance" along with "support provided by [its] ultimate parent Berkshire Hathaway."

"We are proud to offer healthcare providers the best financial strength and stability available in the country," said Timothy Kenesey, president and CEO of Medical Protective. "For over a century – wile so many other carriers have come and gone – Medical Protective has been protecting the reputations and assets of healthcare providers with the nation's best defense and solutions. We appreciate A.M. Best's recognition of our unmatched strength, and remain committed to giving healthcare providers across the country a rock-solid foundation in what continues to be a volatile medical malpractice segment."

Earlier in 2006, Standard & Poor's rating services {S&P} reaffirmed Medical Protective's AAA rating {it's highest} stating, "Medical Protective's ratings reflect it's leading market position, effective distribution,….. disciplined underwriting and pricing and prospectively strong earnings." ***(continued on page 7)***

(**ACOG Survey** - ***continued from page 6***)
"Women of all ages – including pregnant women – deserve the best possible medical care from experienced physicians," Laube said, "Yet the current litigious environment seriously hampers our ability to deliver quality healthcare and threatens women's access to care."

An alarming 89 percent of Ob/Gyns reported having had at least one liability claim filed against them during their professional careers, for an average of 2.6 claims per ob-gyn. Of these, 37 percent had been sued for care provided during their residency.

"I can't underscore enough that the high number of liability claims does not indicate a high rate of medical wrong- doing," said Ralph W. Hale, MD ACOG executive vice president. In fact, of cases that do proceed to court, Ob/Gyns win about 7 out of 10 times. "Ob/Gyns are vulnerable because they practice in a high-risk field, and all too often, doctors are held liable for less than perfect outcomes."

Professional liability insurance premiums have seen a meteoric rise in the past 10 years. Across the country, in areas where liability crisis is most pronounced, there are now populated areas with no Ob/Gyns actively practicing the specialty. Because of the lack of available Ob/Gyns, pregnant women must travel long distances – 60 miles or more in some instances- to find a physicians willing to provide obstetric care. The same goes for women trying to find Ob/Gyns willing to perform complicated gynecologic surgery.

Hale noted that ACOG has received anecdotal reports of women who have suffered from ruptured tubal pregnancies and obstetric hemorrhage, resulting in severe disabilities and even death, because of physician shortages.

(**AM BEST** - ***continued from page 6)***
"As we look to the future, Medical Protective is committed to growing profitably its insurance segments and continuing to serve healthcare providers with the nation's (i) most secure financial strength, (ii) most winning and proactive defense and (iii) smartest risk management solutions and patient safety education, " Kenesey said. "Being part of Warren Buffett's Berkshire Hathaway has helped us expand our offerings to healthcare providers and facilities."

Research Entities Debut New Physicians Practice Online Safety Tool

As found in the Medical Liability Monitor

Three leading research entities released the Physician Practice Patient Safety Assessment (PPPSA), a web-based tool (www.physiciansafetytool.org) that lets medical practices evaluate daily processes that affect patient safety. Practices that complete the PPPSA will received a comprehensive workbook that can help identify problem areas and pathways to improvement. Data analysis and benchmark information will also be available for a nominal fee to practices that submit their data online.

The PPPSA tool was created by the Medical Group Management Association (MGMA), the Health Research and Education Trust (HRET) and the Institute for Safe Medical Practices (ISMP). The tool's development and a related study of patient safety in medical groups has been supported by a grant from The Commonwealth Fund.

The PPPSA lets practices evaluate their effectiveness and minimize risk across multiple locations in the following areas:

- Medications – appropriate medical history, prescribing, storage, labeling purchasing, dispensing of samples and administration of vaccines;
- Handoffs and transitions of patients between clinicians or locations – proper procedures for care coordination to track patients and their clinical information;
- Surgery and invasive procedures – patient safety issues relating to ambulatory surgery, especially sedation and anesthesia;
- Personnel qualifications and competency-appropriately assessing the qualifications of caregivers;
- Patient education and communications-actions that practices can take to help patients understand and carry out their responsibilities; and
- Practice management and culture-administrative procedures to create a culture of safety.

We appreciate working with you. Please contact us with any questions or comments about our newsletter using the information listed below. Thank you.