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Special Report: Medical Errors

IOM report puts focus on medical errors, pressure on risk managers

Public, government demand action on old problem

The recent report from the Institute of Medicine on medical errors did not initially raise nearly as much interest among health care risk managers as it did among the public, government leaders, and the general media because risk managers already knew about this serious problem and were working hard to reduce the errors.

Nearly everyone else, on the other hand, responded to the IOM report with shock and outrage. There was immediate support for the formation of an entirely new government agency to monitor and reduce medical errors, even though many risk managers express doubt that such an agency would accomplish anything positive. The result, say some risk managers, is that the profession is now being pressured to do something — preferably something big — about a problem they have spent their careers working on.

On the whole, the IOM report is a good development for risk managers, says **Fay Rozovsky**, JD, MPH, DFASHRM, a risk management consultant in Richmond, VA. Rozovsky, president of the American Society for Healthcare Risk Management in Chicago, has been chair of the ASHRM Sentinel Event Task Force and the ASHRM representative on the Joint Commission-American Hospital Association National Legal Task Force that has been addressing risk managers' concerns about the sentinel event

COMING IN FUTURE ISSUES

- Credentialing opportunities for risk managers
- ASHRM teams with feds on siderail safety
- Injury rates down at health care facilities
- New agency on medical errors: Early word on what it will be
- Selecting an attorney: Tips from the trenches

policy. She has significant concerns about how government and health care leaders will react to some parts of the report, but in an overall sense, Rozovsky says, it probably is good for the public to be informed about a problem that risk managers spend every day trying to correct. She would like the public to understand what measures already are being taken to address medical errors, but she fears the report will denigrate hospitals unnecessarily.

"I don't know if it's good to draw all the attention to this, but it has raised the awareness of an important part of health care," she says. "How the report will be used is another question. It can be used to frighten people unnecessarily, or it can be used to make positive changes. I think it's good to get it on the table and discuss it."

Unanswered questions for risk managers

Rozovsky says she was impressed by the depth of the IOM report and its apparent accuracy. Although the report addresses risk management concerns, she says she is not surprised that health care risk managers haven't responded immediately with a sense of alarm.

"There is a lot there in the report that affirms what risk managers have believed and espoused for a long time," she says. "I think something definitely is going to come out of this report and all of this concern. We should sit down and review what's going on and how we can make something positive from this report. We should consider the synergies that are in place with this, the support of the president and other stakeholders, and see how we can set differences aside and create some positive changes."

Risk managers may see the report as a vindication of all their past work, suggests **Leilani Kicklighter**, RN, ARM, MBA, DASHRM, assistant administrator for safety and risk management with the North Broward (FL) Hospital District. Kicklighter, a past president of ASHRM, says the report has "raised the level of visibility of a very important issue to the forefront. I think that down the road some good things for patient care will come out of this just because of the high visibility the report has given the issue."

One immediate concern is the report's proposal for a new government agency to monitor and reduce medical errors. That sounds to some risk managers like a knee-jerk reaction to the sudden discovery of a long-term problem. Rozovsky expresses particular concern about how such an

agency would be set up and what it would do. After all, what risk manager really wants to deal with yet another government agency?

"I really wonder about that. I have some major worries about that, but I'm trying to stay open-minded," she says. "What benefit would such an agency do for health care and particularly for the consumer? How would it relate to the agencies already present, and would it duplicate their efforts, or would it be able to streamline things?"

There are so many unanswered questions about the proposed agency that it is difficult to do more than wonder about the possibilities, both good and bad, Rozovsky says. Other questions concern what information will be collected, how it will be collected, how it will be used, and who will pay the expense of all this proposed data collection, she says. The basic purpose of the agency must be refined beyond just trying to reduce medication errors, she says. "We don't want to embark on something that will be punitive in nature. We want a positive, quality-driven approach. How we get there, whether it's through an agency or otherwise, remains to be seen."

Grena Porto, RN, ARM, DFASHRM, director of clinical risk management and loss prevention services at VHA Inc. in Berwyn, PA, and past president of ASHRM, says the IOM report can be a tremendous step forward for patient safety efforts as long as it is not used punitively.

"Our challenge is to define and demonstrate accountability without punishing individuals for their human failings," says Porto, who also is on the board of directors for the National Patient Safety Foundation. "This means working on solutions and being committed to prevention. Medical errors cannot simply be legislated away; it is not a legal problem. It is a human condition that we have to learn more about and deal with in a constructive and collaborative way."

Kicklighter says the enormous political response to the IOM report leaves her a bit uneasy. It could represent an opportunity to focus political power on a longstanding risk management problem, she says, or it could portend a messy government intervention that accomplishes little.

"Back with the sentinel event issue, I said that if reporting of untoward outcomes makes for better health care, then Florida should have perfect health care because it has required reporting since the mid-80s," she says. "So reporting in and of itself does not improve health care. It's what you do with what's reported."

Sources

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- **Leilani Kicklighter**, Safety and Risk Management, North Broward Hospital District, 303 S.E. 17th St., Ft. Lauderdale, FL 33316. Telephone: (954) 355-4993. E-mail: Lkicklighter@NBHD.org.
- **Grena Porto**, VHA, 200 Berwyn Park, Suite 202, Berwyn, PA. Telephone: (610) 296-2558.

Rozovsky notes, however, that a new agency requiring health care providers to report medical errors may not be as troublesome as it first seems. She compares the possible reporting requirement to the introduction of the Joint Commission's sentinel event policy but says risk managers should not assume it would be as difficult. The sentinel event reporting requirement was a major headache for risk managers until the Joint Commission clarified the rules to make it only a moderate headache, and Rozovsky says that experience will be useful for any new agency.

"We now have a whole history behind us, and we know that some states have changed laws to accommodate sentinel event reporting, and we can learn from that rich history," she says. "If the same kind of reporting flows from this, I don't think it will be as traumatic as setting up the sentinel event system. We know how to make it work." ■

IOM calls for new agency, mandatory reporting

Political leaders are responding eagerly to the idea of mandatory reporting requirements as outlined in the recent report from the Institute of Medicine. The recent report lays out a comprehensive strategy for government, industry, consumers, and health providers to reduce medical errors, and it calls on Congress to create a national patient safety center to develop new tools and systems needed to address persistent problems.

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The report estimates that medical errors kill at least 44,000 people in U.S. hospitals each year, and possibly as many as 98,000. Even using the

Look for ways to make IOM report work for you

Hidden behind all the negative publicity about medical errors in hospitals, there could be a golden opportunity for health care risk managers.

Because the Institute of Medicine (IOM) report addresses problems risk managers have battled all along, the ruckus spurred by the report could work to your advantage, says **Leilani Kicklighter**, RN, ARM, MBA, DASHRM, assistant administrator for safety and risk management with the North Broward (FL) Hospital District and a past president of the American Society for Healthcare Risk Management. Rather than seeing the report as a bad thing, she suggests looking for ways to bolster your own efforts at reducing errors. "This is a major report from a respected institution that essentially backs up everything you've been telling your boss for years. This is someone from outside your institution, with no axe to grind, saying that these are very serious problems that need attention."

It's not over yet

A savvy risk manager could use the report, and all the surrounding publicity, to push for improvements that might have received a poor reception in the past, she says. Take advantage of the fact that other health care leaders are finally getting excited about medical errors, she suggests. "If a risk manager could turn this into a benefit for themselves to get risk management issues strengthened within the organization, you should take every opportunity to take advantage of it."

One way to do that is to keep your organizational leaders apprised of what will happen in the next months as a result of the report, she says. Study the report yourself and provide others in the organization with useful summaries, and then provide updates on what is going on with the proposal to create a federal agency and other possible outcomes from the study. Position yourself as the expert on this topic, Kicklighter says, and you will be able to exert more influence over how the organization responds; you also will be better received when you suggest in-house improvements.

"You need to review the IOM report and then watch the climate. Be sure your organization is kept abreast of what's going on and how things are progressing on a federal level," she says. "Sometimes, if something is happening on a federal level, the states will decide to do something, too. So you have to monitor your state activities and keep your internal stakeholders advised." ■

lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS, says **William Richardson**, chair of the committee that wrote the report and president and chief executive officer of the W.K. Kellogg Foundation in Battle Creek, MI. While errors may be detected more easily in hospitals, they afflict every health care setting: day-surgery and outpatient clinics, retail pharmacies, nursing homes, and home care. Deaths from medication errors that take place both in and out of hospitals — more than 7,000 annually — exceed deaths from workplace injuries, the report says.

"These stunningly high rates of medical errors — resulting in deaths, permanent disability, and unnecessary suffering — are simply unacceptable in a medical system that promises first to 'do no harm,'" Richardson says. "Our recommendations are intended to encourage the health care system to take the actions necessary to improve safety. We must have a health care system that makes it easy to do things right and hard to do them wrong."

He says the technology and know-how exist to prevent many mistakes, so the committee sets as a minimum goal a 50% reduction in errors over the next five years. "We believe that with adequate leadership, attention, and resources, improvements can be made. As we say in the report, 'It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives, and meet the challenges ahead.'"

A work in four parts

To achieve a better safety record, the committee recommends a four-part plan designed to create both financial and regulatory incentives that will lead to a safer health care system. Taken together, these recommendations and findings represent a systematic way to design safety into the process of care, Richardson says. They should be evaluated after five years to assess progress in making the health system safer.

Citing examples from other industries, such as the airline industry, the committee says the health care industry needs a federal agency to ensure safety. The report says Congress should create a center for patient safety within the U.S. Department of Health and Human Services (HHS). The center would set national safety goals, track progress in meeting them, and invest in research to learn more about preventing mistakes.

The center also would act as a clearinghouse, an objective source of the latest information on patient safety for the nation. For example, if a health care organization improves safety, its practices should be shared with a broad audience; the center, working with others, would help provide the needed channel.

Administratively, the center should be based in the HHS Agency for Healthcare Research and Quality, formerly the Agency for Health Care Policy and Research. Congress would need to spend $30 million to $35 million to set it up, the committee says, depending upon the kind of work the center would perform and on investments in issues of similar magnitude, as well as safety research by the public and private sectors. Funding would need to grow to at least $100 million annually, a little more than 1% of the estimated $8.8 billion spent each year as a result of medical errors that cause serious harm.

Businesses leap in

The committee defines "error" as the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim, and it notes that not all errors result in harm. To learn about medical treatments that lead to serious injury or death and to prevent future occurrences, the committee recommends establishing a nationwide, mandatory public reporting system. Hospitals first, and eventually other places where patients get care, would be responsible for reporting such events to state governments. Currently, about a third of the states have mandatory reporting requirements.

The IOM report produced a quick response from leaders in business, not just health care, and from President Bill Clinton. Soon after the report was released, eight executives of some of the country's biggest companies announced that they had formed an organization called the Leapfrog Group that will work to reduce medical errors, partly by putting pressure on health care providers and shunning those with high error rates. The health insurance provided by those employers is a strong economic incentive for the health care industry, they say, because employers will steer workers to those hospitals with the lowest error rates.

President Clinton has ordered federal health agencies to reduce the number of medical errors by 50% in five years. Three U.S. senators have announced they will begin hearings into medical errors early in 2000. ■

Veterans Affairs report outlines high error rate

On the heels of the report from the Institute of Medicine (IOM), a report from the Department of Veterans Affairs detailing a high error rate at VA hospitals has gained more attention than it might have otherwise. Some observers have suggested the VA report is typical of what might be required of all hospitals under the reporting requirements proposed in the IOM report.

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Although the report was published July 15, 1999, it received no attention outside the VA until the IOM report was released at the end of 1999. The report documents nearly 2,927 medical mistakes in less than two years at VA hospitals around the country, including those leading to 710 patient deaths. The mistakes and deaths were recorded from June 1997 to December 1998 in the first 19 months of a new policy requiring VA employees to report medical errors and adverse events. The policy has resulted in about 200 reports per month, the report says.

The VA report concludes that the mandatory reporting policy is "a valuable and useful tool. It provides VHA additional data upon which to improve patient safety system-wide." The VA noted a number of ways to improve the data collection system, and the report calls for improved education of employees in how and what to report.

The VA medical system is the largest in the country, with 172 hospitals, 132 nursing homes, and more than 650 outpatient clinics. ■

IOM, VA reports available

- ❑ Copies of the Institute of Medicine's report *To Err Is Human: Building a Safer Health System* are available from the National Academy Press by calling (202) 334-3313 or (800) 624-6242. The report costs $45 (prepaid) plus shipping charges of $4.50 for the first copy and $.95 for each additional copy.
- ❑ A summary of the VA report can be obtained by contacting The Office of the Medical Inspector, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. N.W., Washington, DC, 20420. Telephone: (202) 273-6000.

Groups join to cut errors, protect confidentiality

The nonprofit Institute for Safe Medication Practices (ISMP) is joining with the American Hospital Association (AHA) in announcing a new national initiative to help hospitals examine and further improve medication safety.

As part of this national initiative, ISMP will partner with the AHA to provide hospital leaders with an inventory of successful practices for reducing errors that can be adopted in every hospital. In addition to building upon the ongoing knowledge and work of the AHA and ISMP, the practices are formulated from the work of many experts and organizations that have been studying medication safety, including the Institute for Healthcare Improvement, the Massachusetts Coalition for the Prevention of Medical Errors, the National Coordinating Council on Medication Error Reporting and Prevention, the National Patient Safety Partnership, and many others.

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The campaign aims to share the successful practices list with every hospital and health system, develop for hospitals a "medication safety awareness test" that surveys hospitals' current status and future progress on medication error prevention, track implementation of the practices for reducing and preventing errors within the hospital and health system field, work with national experts to develop a nonpunitive model medication error reporting process, and serve as a clearinghouse of information and resources for the hospital field on medication errors.

The campaign was endorsed publicly by President Bill Clinton, which AHA president **Dick Davidson**, MD, says bodes well for its success. "We are pleased that President Clinton is showing significant leadership in this area by taking an in-depth look at the Institute of Medicine's findings. It is going to take all of us working together to continue to improve the safety of our medical system."

The cooperative effort means the AHA and ISMP can partner more effectively with health care and public policy leaders to make a difference in patient safety, says ISMP president **Michael Cohen**. "Of course, we already have a good working model for reporting of errors nationally, and many health care professionals are taking advantage of it. But because better understanding of medication errors is at the heart of any prevention effort, more must always be done to improve and increase reporting. This initiative is an ideal way to do just that."

In a related move, the U.S. Pharmacopeia (USP) is leading the development of legislation that supports confidentiality of information submitted to national medication error reporting systems. As the nation's drug standards-setting organization, USP is calling for protection of the information, noting that the assurance of confidentiality encourages health care providers and facilities to report medication errors, says **Diane Cousins**, RPh, vice president of the USP's practitioner and product experience division. USP is developing draft legislation and will seek to build health care coalition and bipartisan Congressional support for legislation that will:

- encourage active participation in voluntary medication error reporting programs;
- facilitate development and dissemination of information on trends in medication errors — including dissemination to governmental and nongovernmental agencies concerned with medication error prevention — to stimulate development of systems to prevent medication errors;
- ensure that information developed in connection with such programs is privileged and confidential to maximize participation by health care providers and facilities;
- authorize government agencies to obtain information from voluntary medication error reporting programs on a privileged and confidential basis.

USP has been tracking medication errors since 1991 and last year introduced MedMARx, a national data repository that allows hospitals to voluntarily report medication errors to an anonymous, secure database program. The system is used by more than 100 hospitals.

"Confidentiality is a key factor in the success of our program," Cousins says. "Hospitals can compare the frequency and severity of medication errors with other hospitals while protecting the identity of each institution. The anonymity breaks down significant barriers to reporting those errors." ■

Source

❑ **Tom Norton**, U.S. Pharmacopeia. Telephone: (202) 955-6222. Web site: http://www.usp.org.

JCAHO suggests ways to prevent med errors

The Joint Commission on Accreditation of Healthcare Organizations reports that, since it began tracking sentinel events in 1995, it has reviewed 89 cases related to medication errors. That makes medication errors one of the most common causes of avoidable harm to patients in health care organizations.

A study by the Institute for Safe Medication Practices (ISMP) showed that a majority of medication errors resulting in death or serious injury were caused by a short list of medications. ISMP studied the problem during 1995 and 1996 to determine the drugs and situations most likely to cause harm to patients, with approximately 161 health care organizations submitting data on serious errors that had taken place during that period.[1]

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Medications with the highest risk of causing injury when misused are known as "high-alert." The top five high-alert medications identified by the ISMP are insulin, opiates and narcotics, injectable potassium chloride (or phosphate) concentrate, intravenous anticoagulants (heparin), and sodium chloride solutions above 0.9%.

The Joint Commission has provided a set of common risk factors and suggested strategies for increasing patient safety with respect to these high-alert medications. **(See chart, p. 20.)**

Reference

1. Cohen MR, Kilo CM. "High-Alert Medications: Safeguarding Against Errors." In: Cohen MR, ed. *Medication Errors.* Washington, DC: American Pharmaceutical Association, 1999. ■

Where to find the reports

- ❑ A copy of "High-Alert Medications and Patient Safety" can be found on the Web site for the Joint Commission on Accreditation of Healthcare Organizations: www.jcaho.org.
- ❑ Copies of the Institute for Safe Medication Practices' study (called the 1996 Benchmarking Project) are available free of charge from the ISMP, 1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006. Telephone: (215) 947-7797.

Report could spur animosity from patients

One result of the Institute of Medicine report on medical errors could be a heightened awareness of the ability to sue for adverse outcomes, although public awareness might be so high already that it won't change much.

Much of the effect from the report cannot be determined now, but a change in public perception could come much sooner than any other effects, says **Fay Rozovsky**, JD, MPH, DFASHRM, a risk management consultant in Richmond, VA, and president of the American Society for Healthcare Risk Management in Chicago.

Encourage questions

The IOM report received so much publicity in the general media that patients may be more assertive about their rights and have a higher awareness of medical errors. That could lead to a higher likelihood that patients will sue after an adverse outcome, she says.

"This report is coming at a time when the public already has a lot of concerns about health care, and it reinforces and exacerbates those concerns," Rozovsky says. "That means health care providers should anticipate more questioning — more assertiveness from the patient and the family. They might be more likely to ask why today's pill is green when yesterday's was pink, and that's a good thing. You just have to hope they're not also more attuned to the liability aspect if they learn of a medical error."

Leilani Kicklighter, RN, ARM, MBA, DASHRM, assistant administrator for safety and risk management with the North Broward (FL) Hospital District and a past president of ASHRM, agrees to some extent, but she says the effect on the litigation risk may be less pronounced in some areas of the country. The IOM report is not the first to put the spotlight on medical errors, she says, so patients already have been alerted.

"The media have more involvement in medical issues in some parts of the country, like South Florida," she says. "We get a lot of articles about medical errors and other problems already. We have so much in the media already, and that doesn't seem to have influenced an increase in litigation. If people think they have a basis for suing, they will pursue that regardless of what they hear in the media." ■

High-Alert Medications and Patient Safety

DRUG	COMMON RISK FACTORS	SUGGESTED STRATEGIES
Insulin	• Lack of dose check systems	• Establish a check system whereby one nurse prepares the dose and another nurse reviews it
	• Insulin and heparin vials kept in close proximity to each other on a nursing unit, leading to mix-ups	• Do not store insulin and heparin near each other
	• Use of "U" as an abbreviation for units (which can be confused with "O," resulting in a tenfold overdose)	• Spell out the word "units" instead of writing "U"
	• Incorrect rates being programmed into an infusion pump	• Build in an independent check system for infusion pump rates and concentration settings
Opiates and narcotics	• Parenteral narcotics stored in nursing areas as floor stock	• Limit the opiates and narcotics available in floor stock
	• Confusion between hydromorphone and morphine	• Educate staff about hydromorphone and morphine mix-ups
	• Patient-controlled analgesia (PCA) errors regarding concentration and rate	• Implement PCA protocols that include double-checks of the drug, pump setting, and dosage
Injectable potassium chloride or phosphate concentrate	• Storing concentrated potassium chloride/phosphate outside of the pharmacy	• Remove potassium chloride/phosphate from floor stock
	• Mixing potassium chloride/phosphate extemporaneously	• Move drug preparation off units and use commercially available premixed IV solutions
	• Requests for unusual concentrations	• Standardize and limit drug concentrations
Intravenous anticoagulants (heparin)	• Unclear labeling regarding concentration and total volume	• Standardize concentrations and use premixed solutions
	• Multi-dose containers	• Use only single-dose containers
	• Confusion between heparin and insulin due to similar measurement units and proximity	• Separate heparin and insulin and remove heparin from the top of medication carts
Sodium chloride solutions above 0.9%	• Storing sodium chloride solutions (above 0.9%) on nursing units	• Limit access of sodium chloride solutions (above 0.9%) and remove from nursing units
	• Large number of concentrations/formulations available	• Standardize and limit drug concentrations
	• No double-check system in place	• Double-check pump rate, drug, concentration, and line attachments

Source: Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL.

Supreme Court to review False Claim Act lawsuits

The U.S. Supreme Court may give health care providers a huge gift in the near future by ending the qui tam False Claims Act lawsuits that have proven so damaging to providers and so lucrative to whistle-blowers.

The court announced recently that it will determine in the coming months whether a private individual who files a qui tam lawsuit actually has standing to bring such a case. If the court determines that whistle-blowers have no standing in the suit, the ruling could essentially put an end to a method that prosecutors have found effective in rooting out health care fraud.

"We're going full steam ahead with our arguments," says **Bill Boyce**, JD, an attorney with Fulbright & Jaworksi who represented St. Luke's Episcopal Hospital in Houston in a qui tam lawsuit. The Fifth Circuit panel recently ruled the qui tam statute unconstitutional, saying it infringes on the executive branch's power to protect government interests.

Although the circuit court immediately vacated the ruling and scheduled another hearing to determine the constitutionality of the law, Boyce says the challenge to the statute shouldn't be taken lightly.

"We'll just have to see whether the Supreme Court or the Fifth Circuit comes out with a decision first," Boyce says. "The court has indicated to us that everything is still on the table in terms of constitutional challenges. There's a lot up in the air right now, but we feel like the circuit court's initial ruling gives us reason to be optimistic about seeing the whole thing thrown out as unconstitutional."

The game's afoot

The debate over the constitutionality of qui tam lawsuits is not a new development. Since a 1986 amendment to the False Claims Act greatly expanded the rights and powers of whistle-blowers, critics have argued the lawsuits are unconstitutional. The Fifth Circuit ruling in November breaks with five different circuit courts over the last 13 years which have held that the qui tam statute is constitutional. That conflict among federal circuit courts suggests there might be change afoot.

But it is far from certain that the Supreme Court will make any change in the way qui tam lawsuits currently are used against fraud.

One attorney whose practice depends almost entirely on qui tam suits tells *Healthcare Risk Management* he is not worried. It is merely curious that the Supreme Court has agreed to consider the case, says **John Phillips**, JD, an attorney with the law firm of Phillips & Cohen in Washington, DC. Phillips & Cohen specializes in representing whistle-blowers in False Claims Act cases. The firm's cases are responsible for about two-thirds of the $1.3 billion the government has collected through whistle-blower lawsuits in the last five years.

"I don't think any serious analyst of the law thinks there is any serious risk that this law will be struck down as unconstitutional," he says. "It's been around since the Civil War, and the idea that it would all of a sudden be ruled unconstitutional in 2000 is just not credible."

Phillips says it would be "a big deal if they threw it out, but I don't think that will happen. It would destroy my entire practice if they did, and I'm not worried about it."

Intent not necessary

The standing of the whistle-blower is an all-important point because a lack of standing could rob the False Claims Act of its power. The lawsuits depend on whistle-blowers coming forward, and the motivation for whistle-blowers can be strong because they are awarded 15% to 25% of money recovered if the government joins the case, and up to 30% if the government declines to intervene. The reward provision, which Congress strengthened in the 1986 amendment, and the job protection provisions of the law are the primary reasons for the growing success and use of the False Claims Act.

In the health care field, there have been False Claims Act lawsuits and investigations for practices such as upcoding and unbundling, billing for services not provided, billing for services that aren't medically necessary, substandard services, improper cost reporting, and grant or program fraud.

Lawsuits also have been filed for kickbacks, but the courts are divided on whether this is a False Claims Act violation or whether it is only a violation of the federal anti-kickback statute.

The False Claims Act is especially troubling to health care providers because it has a tremendous reach. The law has a 10-year statute of limitations,

Sources

- ❑ **John Phillips**, 2000 Massachusetts Ave. N.W., First Floor, Washington, DC, 20036. Telephone: (202) 833-4567.
- ❑ **Bill Boyce**, 1301 McKinney, Suite 5100, Houston, TX 77010-3095. Telephone: (713) 651-5151.

and here is an important point that may keep risk managers awake at night: Government and private attorneys do not have to prove the fraud was intentional. They only have to prove that improper claims were submitted "with reckless disregard of the truth." ■

OIG: Watch for individuals excluded from Medicare

Everyone knows that the really big penalty for Medicare and Medicaid fraud is the hospital's exclusion from participation in those and other federal programs, but the government is reminding risk managers that individuals can be excluded also. And if they are, they should not be welcome at your facility, according to a federal advisory.

The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) recently issued an advisory to health care providers suggesting they should determine whether potential and current employees and contractors have been excluded from participation in federal health care programs, including Medicare and Medicaid.

The advisory explains that an effect of an OIG exclusion from federal health care programs is that no federal health care program payments may be made for any items or services furnished, directly or indirectly, by an excluded individual or entity. Almost 17,000 individuals and entities have been excluded from participating in federal health care programs for misconduct including fraud convictions, patient abuse, and defaulting on health education loans. In fiscal year 1999, the OIG expects to exclude about 3,000 individuals and entities.

"Exclusion is one of the most important tools we have to protect beneficiaries and stem fraud and abuse in federal health care programs," Inspector General June Gibbs Brown said in the advisory. "To ensure that Medicare, Medicaid and other federal health care programs are protected, we need the cooperation of the entire health care community to help make sure excluded individuals are not involved in any way in the care of federal program beneficiaries."

Virtually all federal programs affected

Both the Health Insurance Portability and Accountability Act of 1996 and the Balanced Budget Act of 1997 expanded and strengthened the OIG's exclusion authorities. One of the most significant changes has been the expansion of the OIG's exclusion authority beyond HHS programs, such as Medicare and Medicaid, to all federal health care programs, including those administered by the Department of Veterans Affairs and the Department of Defense. The only federal health care program not covered by the OIG's exclusion authority is the Federal Employees Health Benefits Program.

The OIG also has the authority to impose civil monetary penalties against excluded individuals and entities that seek reimbursement from federal health care programs, as well as health care providers that employ or enter into contracts with excluded individuals to provide items or services to federal program beneficiaries. In both cases, civil monetary penalties of $10,000 for each item or service furnished by the excluded individual may be imposed, and the responsible party may have to pay three times the amount claimed for each item or service.

"In short, no federal program payment may be made to cover an excluded individual's salary, expenses, or fringe benefits . . . ."
— OIG advisory

"The prohibition against federal program payment for items or services furnished by excluded individuals and entities extends to payment for administrative and management services not directly related to patient care," the advisory says. "In short, no federal program payment may be made to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care. The payment prohibition applies whether federal payment results from itemized claims, cost reports, fee schedules or a prospective-payment system."

Health care providers that receive federal health care funding may employ an excluded individual only in limited situations where the provider is able to pay the individual exclusively with nonfederal funding and the items and services furnished by the excluded individual relate solely to nonfederal program patients.

Here are some examples in the advisory bulletin of situations that can expose excluded parties and their employers to civil money penalties:

• services performed by excluded nurses, technicians, or other excluded individuals who work for a hospital, nursing home, home health agency, or physician practice, where such services are related to administrative duties, preparation of surgical trays, or treatment plan reviews if such services are reimbursed, directly or indirectly, by a federal health care program, even if the individuals do not furnish direct care to federal program beneficiaries;

• services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs reimbursed, directly or indirectly, by a federal health care program;

• administrative services, including the processing of claims for payment, performed by an excluded individual for a Medicare fiscal intermediary or carrier or a Medicaid fiscal agent;

• services performed for program beneficiaries by excluded individuals who sell, deliver, or refill orders for medical devices or equipment reimbursed, directly or indirectly, by a federal health care program;

• items or equipment sold by an excluded manufacturer or supplier used to care for or treat a federal program beneficiary and reimbursed, directly or indirectly, by a federal health care program.

Check the Web

The OIG maintains a list of excluded individuals and entities accessible on the World Wide Web at www.hhs.gov/oig/cumsan/index.htm and urges health care providers to check the list before hiring or contracting with individuals or entities. Additionally, the OIG recommends that health care providers periodically check the list to determine the exclusion status of current employees and contractors. The OIG also will provide advisory opinions on specific employment or contractual arrangements that may violate the law. ■

HCFA: Problem nursing homes to face sanctions

Nursing homes that fail to protect residents from harm will face immediate penalties, and consumers will have access to more information about the quality of nursing home care, under new rules imposed recently by the Health Care Financing Administration (HCFA) in Washington, DC.

HCFA administrator Nancy-Ann DeParle recently announced new steps that she says represent the latest in an ongoing effort to ensure that Americans receive quality care in nursing homes. HCFA instituted these new directives:

• States must impose immediate sanctions, such as fines, against nursing homes in more situations — including any time a nursing home is found to have caused harm to a resident on consecutive surveys.

• States now have more flexibility to encourage speedier action to stop payments for new

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admissions and to impose other sanctions when nursing homes violate federal health and safety requirements.

• Nursing Home Compare, HCFA's consumer Internet resource found at www.medicare.gov, has been beefed up to include information about the prevalence of bedsores, weight loss, and other health conditions among residents in individual nursing homes.

• HCFA updated its "Guide to Choosing a Nursing Home" to take families and friends step-by-step through the process of identifying an appropriate home for a loved one.

DeParle said the actions extend the Clinton administration's aggressive initiative to improve enforcement of federal and state standards and to promote quality care for 1.6 million elderly and disabled Americans in nearly 17,000 nursing homes. HCFA strengthened the inspection process to increase its focus on preventing bedsores, malnutrition, and abuse, and it now requires states to crack down on homes that repeatedly violate health and safety requirements.

For fiscal year 2000, Clinton secured more than $50 million in new resources to support the nursing home initiative, including $18.1 million more for states' Medicare survey efforts and another $15.6 million in Medicaid matching funds available to states. Other resources will support federal oversight activities and increased legal activity related to enforcement.

More power for the states

HCFA issued additional instructions to the state agencies that conduct nursing home inspections for Medicare and Medicaid. Nursing homes that do not fix problems identified in the inspections will lose their ability to receive Medicare and Medicaid payments.

To encourage sanctions to be imposed more quickly, states also received expanded authority to notify nursing homes when they would be denied payments for new admissions and other sanctions for failing to meet health and safety requirements. In addition, HCFA provided guidance for the use of a new enforcement tool that allows fines of up to $10,000 for each serious incident that threatens residents' health and safety. In the past, fines could only be based on the number of days a nursing home failed to meet federal requirements.

HCFA this year has conducted an extensive training campaign for nursing home inspectors to help states enforce federal requirements more effectively and consistently. Since this spring, HCFA has trained more than 600 federal and state survey managers, who have trained their staffs. Those actions follow other steps HCFA has taken this year to strengthen the state inspection and enforcement process. It instructed state inspectors to increase their focus on preventing bedsores, malnutrition, and abuse in nursing homes. HCFA also is piloting education campaigns to prevent abuse, neglect, and malnutrition in nursing homes and has established a new requirement for states to focus on complaints alleging harm to residents and conduct investigations within 10 days. In addition, states will continue to be required to investigate complaints alleging the most serious violations within two days and to investigate other complaints in a timely manner.

States now must conduct more frequent inspections of nursing homes that have repeated serious violations without decreasing inspections of other facilities. State inspectors now must make the timing of inspections unpredictable and must conduct some visits on weekends, early mornings, and nights to look for quality, safety, and staffing problems at those times. ■

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Patient's daughter alleges inadequate medical care: Florida nursing home agrees to $1.1 million settlement

By **Mark K. Delegal**, Esq., and **Jan Gorrie**, Esq.
Pennington, Moore, Wilkinson, Bell and Dunbar, P.A.
Tallahassee, FL

News: The daughter of a nursing home patient, acting as personal representative, reached a $1.1 million settlement with the nursing home where the patient developed infected skin ulcers and had contracted to a fetal position. The daughter alleged that nursing home personnel failed to adequately address the patient's medical conditions.

Background: At age 83, the Alzheimer's patient entered a skilled nursing facility on May 8, 1992. The patient remained there until her discharge 30 months later on Nov. 3, 1994. During the final month of her stay, she developed decubitus ulcers on her left hip and coccyx and subsequently was transferred to an acute care hospital. The daughter alleged that the patient suffered from stage IV pressure ulcers that were draining foul-smelling gray / green discharge, that the patient was dehydrated, and that she had lost a significant amount of weight in the last months of her stay.

Nursing home records indicate that the patient had eaten less than 25% of her meals in the last months and that her physician had not been notified of the potential nutritional problems. Further, at the time of discharge, she had contracted to a fetal position, the records show.

The plaintiff sued under a Florida law that allows nursing home patients to bring a civil action and recover attorney's fees, costs, and damages (including punitive damages) when the patient's right to receive adequate and appropriate health care has been violated (400.023, Florida Statutes). This action is allowed in lieu of a wrongful death suit.

In the complaint, the resident's daughter alleged that the nursing home failed to follow the physician's orders, carried out treatments that were given without the physician's orders, and failed to notify the physician of significant changes in physical and mental health. Nursing home records indicated nursing notations made for services rendered when the patient was on an extended leave of absence from the facility; there was other evidence of falsified patient records as well, the complaint alleges.

The nursing home contended that nursing care was provided and available to the patient and that the patient's decline was attributable to her Alzheimer's disease.

What this means to you: "Documentation was a significant issue in this case, which is a deviation from nursing practice standards, whether falsified, as alleged, or inadequate, which is also alleged," says **Leilani Kicklighter**, RN, ARM, MBA, DASHRM, assistant administrator for safety and risk management with the North Broward (FL) Hospital District, and a past president of the American Society for Healthcare Risk Management. "From a claims perspective, falsified documentation can be a fraud and abuse /

corporate compliance issue, can modify the statue of limitations, and can be the basis of punitive damages," she says. "In addition, those professionals who made false entries in the medical record have exposed their professional license to review by their respective professional boards for disciplinary action, and certified patient care assistants jeopardize their certification.

"Further, if the facts of the case should reach the Joint Commission on Accreditation of Healthcare Organizations — if the organization is an accredited organization — the state regulatory agency, or the Health Care Financing Administration, the organization could be subject to a survey and potential loss of Medicare funding and/or accreditation/licensure. All of these potential issues are risk exposures that are significant," says Kicklighter.

The risk manager of a long-term care facility must put in place concurrent quality control measures that periodically review orders, physician progress notes, and nursing notes against the actual status of the patient, Kicklighter says. "It is recognized that contractures and decubitus do not occur overnight; therefore, the risk manager should work with the nursing service to implement a system to identify and report to nursing and risk management skin breakdown and significant reduction in mobility of patients.

"It is recognized that in some instances, in spite of outstanding nursing care, skin breakdown cannot be totally prevented. In those cases, and in all others, too, all preventive efforts must be implemented and properly documented.

"Methods to identify breaches in skin integrity might be to develop a skin assessment team that evaluates all pressure points against standardized criteria on all patients on a daily basis, develop standardized criteria to evaluate risk factors, and devise standardized preventive measures," she says. "Furthermore, the risk manager should conduct regular inservice sessions to address documentation, nutrition, passive range of motion, and communication with the patient's physician and the facility's medical director. In addition, the risk manager should periodically re-emphasize the requirement to complete incident reports to report situations that are unexpected [or] out of the ordinary. . . ."

Reference

Wade v. Arbors Health Care Company, Leon County, FL, Circuit Court, Case No.95-1194CA. ■

Pitocin harms infant: $1 million settlement

News: Plaintiffs alleged that hospital nurses inappropriately administered Pitocin and caused insufficient blood flow and oxygenation to the placenta prior to delivery and that the obstetrician failed to recognize and respond to fetal distress. When the child was born, APGAR scores were low, and the child required extensive resuscitation.

Background: The mother sued the hospital and obstetrician. The plaintiffs alleged that the hospital's labor and delivery nurses negligently administered excessive amounts of Pitocin to the full-term mother during labor in violation of the hospital's policies and procedures. The plaintiffs claimed that the dosage and frequency were excessive in relationship to length and strength of the contractions.

Administration of the drug resulted in uterine hyperstimulation, causing utero/placental insufficiency and hypoxia, the plaintiffs charged. Further, they claimed that the obstetrician failed to detect signs of fetal distress as indicated by the fetal heart monitor and that a cesarean delivery should have been performed. The child, who was born with low APGAR scores, required extensive resuscitation after delivery.

The hospital maintained that the Pitocin was properly administered to augment labor and that nursing personnel did not act negligently. The hospital also asserted that if negligence *was* found against the hospital, the obstetrician should have noticed the change in the fetal heart rate monitor and delivered the child by cesarean. The obstetrician claimed that the heart rate monitor did not indicate the child was in distress because there was no late deceleration but instead variable decelerations with a late component. The obstetrician also asserted that it would have taken just as long to perform a cesarean, and the reduction in blood flow caused by uterine hyperstimulation from the Pitocin was unavoidable.

What this means to you: The first red flag in this case is the fact that it seems the Pitocin procedures and protocols either were not followed in this case or staff was not familiar with them, says **Bucky Jones**, RN, BSN, LHCRM, manager of the department of risk management at Tampa

General Healthcare. "In order for protocols and procedures to be of use, staff must be regularly advised and educated as to what to do. And, for all protocols involving drugs, they should be regularly reviewed and updated by pharmotherapists and should always include reversing agents, if available," she says.

Further, Jones notes that "the condition of the fetal monitor strips is unclear. Protocols should include the appropriate chain of command with regard to who is notified when questions arise on monitoring results. Protocols should clearly indicate the order of notification, whether it is additional nursing staff and supervisors and/or the attending physician, when questions arise with patient monitoring."

The second red flag in this incident is that the hospital implicated its codefendant, the obstetrician, she says. "As a general rule, you never point a finger at the other defendants, even in situations where the heat is on," she adds.

Reference

Anonymous v. Anonymous, Santa Anna County California Superior Count. ■

Gunshot victim dies in OR: $1.4 million verdict

News: The case involves the victim of a fatal gunshot wound to the chest. The bullet penetrated the patient's right lung and caused significant internal bleeding. The plaintiff alleged that the victim was awake at the scene and in the emergency room but died of uncontrolled bleeding resulting from injury to the lung. The defendant hospital contended that the patient lost significant amounts of blood before arriving and while at the hospital and that appropriate care was given to stabilize him before surgery.

Background: The 24-year-old man was shot at approximately 8 p.m. on May 26, 1998, by his girlfriend. The bullet penetrated the patient's right lung and did massive damage. He arrived at the hospital at 8:08 p.m. The plaintiff alleged that the patient was conscious in the emergency room and that patient records were altered, allegations the hospital disputes. Emergency room personnel inserted a chest tube at 8:12 p.m. to evacuate the hemothorax, and 800 cc of blood were drained. At 8:30 p.m., a chest X-ray indicated a massive right hemothorax (with a bullet in the lung) and ongoing blood loss.

The hospital asserted that it acted appropriately by administering fluids to the patient in an effort to stabilize him before surgery and, further, that if the patient was taken to surgery before stabilization with fluids and blood, he would have died immediately as a result of the stress of surgery and/or general anesthesia. The hospital said that the patient was taken to the operating room at 9:12 p.m. to repair the bleeding and that timely intervention occurred.

The plaintiff claimed that the victim was not transferred to the operating room until 9:40 p.m. When the chest was opened, surgeons found no circulation, blood pressure, or spontaneous cardiac activity. According to the defense, the surgeon massaged the heart for nearly two hours. The bleeding was finally controlled, but the patient could not be resuscitated and was pronounced dead at 12:30 a.m. on May 27, 1988.

The plaintiff claimed that the doctor should have performed chest surgery when 800 cc of blood were drained and certainly after the chest X-ray showed massive internal injuries to the lung. In short, the plaintiff contended that had the surgery taken place immediately after the blood drainage at 8:12 p.m. or chest X-ray at 8:30 p.m., the patient could have survived.

The plaintiff contended that the Advance Trauma and Life Support Guidelines adopted in New York clearly indicate that, when an X-ray demonstrates massive hemothorax, the appropriate course of action is to immediately open the patient and stop the bleeding.

"In this case, the patient bled out and was not taken to the OR until after he crashed," says the plaintiff's attorney, **Rhona Silverman** of Bruce G. Clark and Associates in New York City. "Hospitals not only need to have protocols, but staff must follow up on them or people will die," she says. Notably, the defendant hospital was not a level I trauma center and hence not subject to the state's Advance Trauma and Life Support Guidelines.

The trial court reduced the jury's verdict to less than $700,000, and the hospital has appealed based on liability and damages.

What this means to you: This case serves to highlight three issues for consideration by health

care risk managers, says **Robert E. White Jr.**, a medical malpractice consultant in Miami and former senior vice president of ProNational Insurance Company in Coral Gables, FL.

First, though the guidelines were not admissible, the danger that guidelines present is illustrated in this case. "Where guidelines exist and the health care provider goes against the guidelines, he or she should be very careful to document [his or her] awareness of the guidelines and the reasons why the guidelines were not followed," he says.

Avoiding 'cookbook medicine'

"This case makes the point that guidelines can create cookbook medicine. This is not something we want to see as a society because it is the experience and judgment of physicians that we rely on for the best of care. Good instincts are what we want to see in a doctor, and these instincts are invaluable to a patient," White says.

Second, from a clinical perspective, internal bleeding requires immediate action, he says. "In a case where there is significant blood loss, you have to find the source of the bleeding and stop it immediately," he advises. "Regardless of guidelines, the standard of care is to explore the wound, to find the source of bleeding, and to be sure the patient does not continue to bleed. Here, it appears, based on the defense's theory, that they attempted to stabilize the patient and performed emergency surgery to identify the source of the bleeding and stop it. This patient could have been taken to surgery at 8:12 or 8:30 and still expired because of the bullet wound. In the case of a bad outcome, the guideline is the sword and never the shield. The shield is documenting why the guideline was not followed," he notes.

Third, the allegation of alteration of the medical record illustrates the danger such an allegation can have in a jury trial, he says. "Whenever there is a suggestion that the records have been altered, it becomes problematic where credibility is at stake or where the jury must rely on the observations of the health care providers involved. If the jury starts to believe that the records are misrepresentations, then all of the themes of the defense become questionable to the jury. In this case, if the plaintiff gets the jury to believe that the records were altered, then why would the jury believe anything the defense has to say?"

While the allegations of records alteration is a major concern at trial, White says he feels that well-qualified handwriting experts for the defense should be able to support the validity of the chart and the credibility of the health care delivery team, and he observes that the tactic of alleging a record alteration is commonly utilized but seldom proven to a jury's satisfaction. The defense never takes a case to trial when it knows or suspects that the record has been altered, he says.

White says he believes that if the records were adequately documented regarding the patient's clinical condition, and the defense had experts to support the authenticity of the records, then defending the physician's clinical judgment by taking the case to trial was the correct course of action.

In conclusion, White says that everyone involved in the defense of health care providers must act to support the shrinking envelope of clinical judgment that physicians have left to them when resolving claims against them.

Reference

Darlington V. St. Barnabus Hospital, Bronx County, New York Supreme Court, Index 13767/90. ■

New contributors join *HRM*

With this issue, the firm of Pennington, Moore, Wilkinson, Bell and Dunbar, P.A. joins the contributors to *Healthcare Risk Management*.

The Pennington law firm has a substantial health care and medical negligence law practice in Florida. The firm serves as general counsel to one of the largest hospitals in the state and represents seven of the top 10 largest hospitals in the state before regulatory and legislative policy-makers. The firm represents hundreds of physicians and health care providers in various legal matters, including disciplinary and medical negligence actions.

Firm principals each month will review current health care risk management case law and help explain its relevance to health care operations. Mark Delegal and Jan Gorrie can be reached at (850) 222-3533. ■