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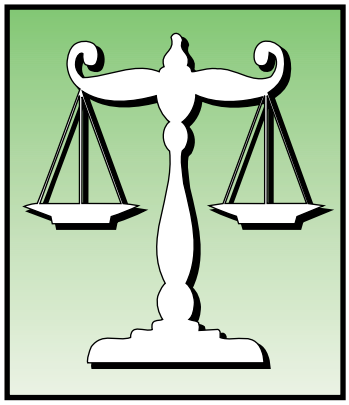

Healthcare Risk Management™

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Data bank: Risk managers say it is not as helpful or threatening as hoped

Reliable? Hardly, critics say

The National Practitioner Data Bank (NPDB) was hailed as a step forward in monitoring doctors' errors, but also feared as a central source for information that could be used against health care providers by plaintiffs and regulators.

Now it appears neither of those may come to pass.

The problem, some say, is that the data bank has little data that could be used either for good or bad. A new report from the government says 84% of managed care organizations have never reported an adverse action against a health care practitioner to the data bank.

In its critical report, the Health and Human Services' (HHS) Office of Inspector General (OIG) concludes that the low rate of reporting to the NPDB raises a broader concern about patient safety and underscores the importance of hospitals, physician groups, and state licensure boards in reporting doctors who pose a threat to patients. The OIG says many health plans rarely report to the data bank because they devote little attention to clinical oversight. That, in turn, is blamed in part on their heavy use of contracted panels of physicians, rather than salaried doctors, to perform those duties.

Health plans also depend on hospitals, physician group practices, and state licensure boards to monitor and report questionable physicians, a system the OIG says may be ineffective. The American Association of Health Plans responded to the OIG report with its own written report that insists health plans do identify quality problems and take action. However, the

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If you're MedMARx, Oklahoma is not OK

Oklahoma is the first state in the nation to specifically bar information reported to MedMARx, a national medical errors database, from being introduced as evidence in a legal proceeding. The US Pharmacopeia in Rockville, MD, launched MedMARx in 1998 to enable hospitals to report and track medical errors anonymously. The action by the Oklahoma State Board of Health is seen as a possible step in the patient safety movement. 81

Medical gas mix-ups are set straight by the FDA

The Food and Drug Administration (FDA) has issued a special warning to alert hospitals, nursing homes, and other health care facilities to the hazards of medical gas mix-ups. The FDA has received reports during the past four years from hospitals and nursing homes involving seven deaths and 15 injuries to patients who were thought to be receiving medical-grade oxygen, but were receiving a different gas that had been mistakenly connected to the oxygen supply system. 81

HealthSouth says it will pay to settle allegations

HealthSouth, the nation's largest outpatient surgery and rehabilitation chain, has agreed to pay $7.9 million to settle allegations that the company overcharged federal health programs. The Justice Department says the health care provider had agreed to pay the penalty, plus 7% interest, from Oct. 1, 2000, without admitting liability 83

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association points out that many situations require further review by medical groups, hospitals, and medical boards, so the health plan does not report the physician.

The OIG report is the latest criticism of the NPDB, but certainly not the first. Physicians' groups have criticized the NPDB since its inception and now say the report illustrates a weakness of the system.

"The OIG report confirmed what we've been saying all along about the NPDB — that it's flawed, incomplete, and it's not reliable," says **Robert Mills**, a spokesman for the American Medical Association (AMA) in Chicago. He says the group has opposed the NPDB for years because it provides an incomplete picture of disciplinary action and other incidents. An earlier report from the General Accounting Office (GAO) reached a conclusion similar to that of the OIG, saying, "While the National Practitioner Data Bank is presently the nation's only central source of medical malpractice payment information, it is not clear that all such data are being properly reported."

The Nov. 17, 2000, report goes on to say that "while GAO sampled one month's submissions, its review suggests that NPDB information may not be as accurate, complete, or as timely as it should be. Inaccuracies in the way reported information was coded could confuse or mislead querying organizations about the severity of actions taken against practitioners. Additionally, duplicate reports overstate the amount of information the NPDB has on a particular practitioner."

Thomas R. Reardon, MD, AMA immediate past president, says the government reports confirm the AMA's view that the NPDB is "seriously flawed." He says the data bank is "riddled with duplicate entries, inaccurate data, and incomplete and inappropriate information. In addition, many of the medical malpractice citations name the patient as well as the practitioner — raising a serious red flag regarding patient privacy." He adds that the NPDB "is clearly struggling to fulfill its mandate."

Federal law requires hospitals and health plans to inform the government of any disciplinary action taken against a physician for incompetence or misconduct. The OIG report, however, reveals that over the past 10 years 84% of health plans and 60% of hospitals have never reported even a single adverse action. The OIG notes that this finding is particularly surprising in the wake of the recent furor over medical errors, in which research suggested that tens of thousands of people die each

year from errors and at least some are attributable to doctors' mistakes.

The OIG report is the result of an 18-month study. Between 1990 and 1999, health plans reported only 715 adverse actions, even though the plans became the dominant form of health care during that period, covering 100 million people. Physician groups reported 60 adverse events. **(See story, below right, for a summary of what information now is in the data bank.)**

The NPDB may be less useful than risk managers had originally hoped, but it also appears to be less threatening than they feared, says **John Metcalfe**, JD, BA, FASHRM, director of risk management services at Memorial Health Services in Long Beach, CA.

"There were a lot of fears surrounding the data bank when it first started out, with people wondering how all that information would be used and how plaintiffs' attorneys might get hold of it. People were afraid it would turn into a witch hunt," he says. "None of those things that we all feared seems to have come to pass. It appears that in terms of the information being used against us in court, that's not really happening."

However, Metcalfe is familiar with several cases in which physicians have sued the individuals or institutions who reported them to the data bank. He has been asked to serve as an expert witness in those cases but declined.

"The data bank does give the physician an opportunity to challenge the information, but if it is not modified then the physician can pursue litigation against those reporting," he says. "I don't know if that discourages institutions from reporting, but I suppose it could."

Even with that risk, Metcalfe says he thinks of the data bank as largely benign for risk managers.

"I look at the data bank as more of a resource for the medical staff office," he says. "It can be helpful in their process of evaluating new medical staff members and re-evaluating medical staff members for reappointment and so forth. But in terms of assisting the risk manager in our everyday activities, it doesn't provide a very valuable service."

The data bank may be of more use to risk managers whose work includes quality issues more than some of the financial and legal issues. Metcalfe cautions that risk managers who use the data bank should think carefully about what the data really mean.

"One problem with the data bank, in my experience, is that some of the best physicians who treat high acuity with the most frequency are at high risk for fallout," he says. "When they have an aberrational outcome, those are the ones that turn into a lawsuit. One of the problems with the data bank is that it doesn't indicate the best of the physicians. It indicates the worst, but the best might be blemished by the frequency of claims."

Data bank managers unhappy with trends

The NPDB is managed by the Health Resources and Services Administration (HRSA), an HHS agency based in Chantilly, VA. HRSA has made it clear that health care providers are not reporting information as they should.

"HRSA continues to be concerned about the low level of clinical privileges actions reported by hospitals and other clinical privileges reporters such as health maintenance organizations," the agency said recently in a public statement. The level of reporting is "unreasonably low. Nationally, over the history of the NPDB, there are 3.9 times more licensure reports than clinical privileges reports. Moreover, 52.5% of the hospitals currently in 'active' registered status with the NPDB have *never* submitted a clinical privileges report. Clinical privileges reporting seems to be concentrated in a few facilities even in states which have comparatively high overall clinical privileging reporting levels."

Kay Garvey, a spokeswoman for the HHS, tells *Healthcare Risk Management* that the OIG report could lead to changes in how the database is managed. HHS is preparing a formal response to the OIG conclusions, but Garvey says it is clear that information is not being reported to the data bank in the way the HHS intends.

"I think the folks who have been using it so far have found it reliable, but we will be looking at ways to improve the information in the data bank and how that information is obtained," Garvey says. "The data bank is only as good as the information in it, so we are interested in improving the data collection if that's possible." ■

Are the data bank's big numbers useful?

The raw numbers reported from the National Practitioner Data Bank (NPDB) can seem impressive, but risk managers still question just how useful the data bank is as a resource for improving patient safety and reducing liability.

In its most recent report, the NPDB reported that the data bank contained reports on 264,065 reportable actions, malpractice payments, and Medicare / Medicaid exclusions involving 164,320 practitioners. Those figures were current as of Dec. 31, 2000, the end of its 124th month of operations.

Of the 164,320 practitioners reported to the NPDB, 69.7% were physicians (including MD and DO residents and interns); 14.1% were dentists (including dental residents); 6.2% were nurses and nursing-related practitioners; and 10% were other health care practitioners. About two-thirds of physicians with reports (65.4%) had only one report in the NPDB, 85% had two or fewer reports, 97.4% had five or fewer, and 99.6% had 10 or fewer. Notably, few physicians had both Medical Malpractice Payment Reports and Reportable Action Reports. Only 6.2% had at least one report of both types.

Approximately 53% of all reports received during 2000 concerned malpractice payments, although cumulatively malpractice payments comprised 72.7% of all reports. The lower percentage of Malpractice Payment Reports for 2000 reflects a large number of Medicare / Medicaid Exclusion Reports received during 2000. These reports also were placed in the NPDB. During 2000, physicians were responsible for 80.3% of all Malpractice Payment Reports. Dentists were responsible for 12.2%, and all other health care practitioners were responsible for the remaining 7.5%. These figures are similar to the percentages from previous years.

Cumulatively, the median malpractice payment for physicians was $99,500 ($105,708 adjusting for inflation to standardize payments made in prior years to year 2000 dollars), and the mean malpractice payment for physicians was $202,301 (approximately $225,600 adjusting for inflation). Both the mean and the median payments for 2000 were higher than the cumulative figures. During 2000, as in previous years, obstetrics-related cases, which represented approximately 8.3% of all physician Malpractice Payment Reports, had the highest median and mean payment amounts ($225,000 and $417,181, respectively).

The median obstetrics-related payment for physicians was $25,000 more than 1999, and the mean was $55,329 more than in 1999. Incidents relating to equipment / product failures (0.19% of all reports) had the lowest mean and second-lowest median payments during 2000 ($73,821 and $45,000, respectively). For all medical malpractice payments made during 2000, the mean delay between an incident that led to a payment and the payment itself was 4.48 years. This is about three and a half days longer than in 1999. The 2000 mean physician payment delay varied markedly between the states, as in previous years, and ranged from 2.99 years in Minnesota to 6.28 years in New York.

Reportable actions (licensure, clinical privileges, professional society membership, and DEA actions) represent 18.1% of all reports received from Sept. 1, 1990, through Dec. 31, 2000, and 15.5% (5,703 of 36,763) of all reports received by the NPDB during 2000. The 5,703 reportable action reports received during 2000 are 9.9% more than the number of reportable actions submitted to the NPDB during 1999, reversing a decline of 2.9% from 1998 to 1999. The number of licensure action reports received increased 12% and the professional society membership action reports increased 66.7%, from 18 in 1999 to 30 in 2000. During 2000, licensure actions comprised 80.5% of all reportable actions and clinical privileges reports comprised 18.9% of the total. ■

Compliance programs studied for effectiveness

PricewaterhouseCoopers legal and health care industry experts — along with faculty at the University of California-Los Angeles (UCLA) School of Public Health's department of health sciences — are making it possible for the first time to measure effectiveness of compliance programs in the nation's hospitals.

The accounting and consulting giant is conducting a two-year study to create the basis for initiating an industry standard for effective compliance in health care organizations, says PricewaterhouseCoopers partner **Lori Richardson-Pelliccioni**, JD, MPH, principal investigator. She will collaborate with UCLA's department of health services faculty.

She says this is the first empirical research to identify best practices in compliance programs and study their relationships to effective compliance as defined by billing accuracy and employee awareness of compliance regulations. While compliance programs have long been a mainstay in business and industry, the practice is relatively new to health care.

"Generally, compliance programs have been in hospitals for less than 10 years," she says.

"Consequently, few substantive benchmarks to measure effectiveness have been established."

As federal and state governments, as well as accrediting organizations, step up their surveillance of the health care industry, hospital administrators and board members alike are focusing on the risk management role that measuring compliance effectiveness plays. **Stuart O. Schweitzer**, professor of health services at UCLA and former researcher for the National Institutes of Health and the Health Care Financing Administration, says the PricewaterhouseCoopers project should yield an effective way to determine when a compliance program is working and when it's not.

"Until now the instruments for detecting fraud in health care have been very crude and not very effective," he says. "The U.S. General Accounting Office [GAO] estimates that about 10% of all health care expenditures in the U.S. are lost to fraud. So if the GAO is close to being correct, the loss is in the neighborhood of $85 billion per year."

Vague and untested

Schweitzer says the model compliance program developed by the U.S. Department of Justice is vague and untested. There is no evidence that health care organizations that have a compliance program consistent with Justice Department guidelines are any less likely to have fraudulent billings than an organization that has no such compliance program in place, he says.

"If this study is successful in identifying characteristics of effective compliance then, without a doubt, this PricewaterhouseCoopers / UCLA model will become a useful tool both for institutions that endeavor to reduce fraud and for the Justice Department to better determine criteria for prosecuting and sentencing," he says.

The Federal Sentencing Guidelines, used to construct the model compliance program, identify these seven areas that should be included in a comprehensive compliance program:

- compliance standards and procedures;
- oversight responsibilities;
- delegation of authority;
- training and education;
- monitoring and auditing;
- enforcement and discipline;
- response and prevention.

The study began with a literature review of 18,381 current articles relating to compliance programs, corporate compliance effectiveness, corporate integrity agreements, and federal sentencing guidelines. This literature review included such industries as health care, banking, defense, insurance, and environmental services. The review yielded 593 compliance principles that two expert panels then developed into 137 indicators of effectiveness.

Next, four data collection instruments were created: the Indicator Questionnaire, the Employee Awareness Questionnaire, the Physician Awareness Questionnaire, and the Billing Accuracy Review database, which looked at both coding and billing accuracy.

The Indicator Questionnaire assessed the existence of defined attributes of compliance and processes regarding the seven elements. It was administered via face-to-face interviews with up to seven senior management representatives at each of the randomly selected subject hospitals. These interviewees included the CEO, general counsel, member of the board of directors, compliance officer, director of human resources, audit manager, and department head.

The self-administered Employee and Physician Awareness Questionnaires assessed the level of employee and physician knowledge about their health care organization's compliance program and the level of their substantive knowledge about compliance. The 50-member pool of respondents included 25 from clinical and administrative departments and 25 physicians.

Using the Billing Accuracy Review database, coders conducted a retrospective billing review of 100 inpatient and 100 outpatient claims for selected Medicare and Medicaid services rendered between March 1999 and February 2000. Inpatient billing included a random sample of admissions. The outpatient billing review addressed encounters in one of the following areas: covered ambulatory surgery, emergency, outpatient ancillary, observation, and clinic visits. Both types of visits were evaluated for coding appropriateness and claims accuracy.

The 30-subject sample was stratified according to small hospitals of 50-99 beds, medium hospitals with 100-249 beds, and large hospitals with 250 or more beds. Medium-sized hospitals made up 43.5% of the study, followed by 28.6% in the large range and 27.9% in the small category.

With the first empirical study of compliance effectiveness in hospitals being finalized, the next step is to seek industry adoption of Compliance Effectiveness Standards, as well as endorsement by at least two federal governing bodies. Both the Department of Health and Human Services and the U.S. Sentencing Commission will be invited to

participate in discussions that seek to establish a minimum standard for effective compliance in health care organizations. Health care industry input in this process will be achieved through the Health Care Compliance Association, an organization begun in 1997 to champion ethical practices and compliance standards in the health care community and to provide resources for compliance officers and others who share its principles. ■

Confession can be good for your job

If you've been bad, go ahead and admit it. It probably will make your punishment a little easier.

That's the message in a little-publicized document obtained by *Healthcare Risk Management* from the federal government. The feds recently assessed the way the government has been dealing with health care organizations that have strayed from the straight and narrow. As part of an ongoing self-assessment of health care compliance initiatives, the Office of Inspector General (OIG) conducted an informal survey of the results of corporate integrity agreement (CIA) negotiations since the issuance of the "Open Letter to Health Care Providers" in March 2000. The purpose of the review was to determine the extent to which health care providers' existing compliance efforts and self-disclosure of misconduct influenced the decision to require a corporate integrity agreement or modify specific terms.

"An informal review of the results of recent CIA negotiations confirms that significant and appropriate modifications are being made to CIAs with health care providers that have established compliance programs and make disclosures of misconduct to the government," the OIG says. "When negotiating a resolution to its administrative liability, a provider is often able to limit the scope and reduce the cost of a CIA or, in some instances, as a result of its self-disclosure and pre-existing compliance efforts, avoid the imposition of a CIA."

The OIG and the Department of Justice use the False Claims Act and other tools to sanction health care providers that have knowingly submitted false claims to Medicare. In addition to monetary penalties, the OIG can exclude providers from participation in Medicare and other federal health care programs. A criminal conviction triggers mandatory exclusion, but in other cases, the OIG usually requires that the provider adopt specific measures to better ensure its integrity. Those measures are set forth in what is known as a CIA.

Consistent with the United States Sentencing Commission's *Federal Sentencing Guidelines Manual*, the CIA contains the seven core elements of an effective compliance program. In addition, the OIG generally requires the submission of periodic reports concerning the provider's compliance efforts and reserves the right to impose sanctions for a material breach of the CIA. While CIAs almost always include these basic elements, the specific terms of a provider's CIA are subject to extensive negotiations. Among the relevant factors considered in crafting a specific CIA are the severity and extent of the underlying misconduct, the provider's existing compliance infrastructure and the resources available for such efforts.

Potential for misconduct

Perhaps the best measure of a provider's existing compliance efforts is the ability to identify and respond to potential misconduct. Inspector General June Gibbs Brown observed in her March 9, 2000, "Open Letter to Health Care Providers" that "the best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities."

The Open Letter went on to explain that the OIG would give more deference to the self-disclosing provider when negotiating a CIA and, under certain circumstances, might not even require a CIA as part of the resolution of the matter. The recent analysis by the OIG shows that the feds are coming through on that promise.

The OIG analysis found that when the provider admitted its wrongdoing and produced evidence of a comprehensive compliance program, the OIG usually made two changes to the CIA. The OIG reduced the term of the CIA from the usual five-year time period to three years, and reduced the role of the independent review organization (IRO) in those cases where the provider was able to demonstrate that it had an established system of internal audits.

"These two modifications alone represent a

significant benefit to the provider," the OIG analysis says. "Other modifications generally focused on conforming the requirements of the CIA to the provider's existing compliance infrastructure. These modifications to the CIA were intended to promote continuity in the provider's ongoing compliance program, as well as reduce the overall costs of such efforts."

Negotiating a CIA

The OIG provides these examples of how a hospital's self-disclosure could be considered in negotiating the terms of a CIA:

• A rural hospital in the Southeast self-reported that, while under former ownership and management, it had submitted claims with information that was falsified to support reimbursement. The hospital uncovered the false claims during the course of an internal audit performed as part of its voluntary compliance program. In the fall of 2000, the hospital agreed to resolve its financial and exclusion liability. The OIG did not impose a CIA because the misconduct was committed by the former management and the new management disclosed its findings to the government as part of a comprehensive pre-existing compliance program.

• A Northeastern hospital system identified that one of its teaching hospitals had submitted improper claims, i.e., it did not have the proper documentation or were upcoded, to the federal health care programs. The hospital system uncovered the false claims during the course of an internal audit performed as part of its voluntary compliance program. In the summer of 2000, the hospital system agreed to resolve its False Claims Act liability. The OIG did not impose a CIA because the hospital system disclosed the misconduct to the government and the hospital system had a comprehensive pre-existing compliance program.

• An acute care hospital in the Southwest — one of several nonprofit affiliates of a larger health system — identified that it had improperly coded claims to the federal health care programs for mammography services. The hospital uncovered the false claims during the course of an internal audit performed as part of its voluntary compliance program. In the summer of 2000, the hospital agreed to resolve its False Claims Act liability. Because 1) the misconduct was isolated and distinct; 2) the hospital disclosed its findings to the government; 3) the damages to the federal health care programs were relatively small; and 4) the hospital had a comprehensive pre-existing compliance program, the OIG did not impose a CIA.

• A rural hospital in the Northeast self-disclosed that it had been submitting claims that were not in compliance with rules governing coding, documentation, and reimbursement for anesthesia services. The hospital uncovered the false claims during the course of an internal audit performed as part of its voluntary compliance program. In the fall of 2000, the hospital agreed to resolve its False Claims Act liability. Since the hospital disclosed its findings to the Government and had a comprehensive pre-existing compliance program, the OIG imposed limited integrity measures for a term of four years instead of five years, and permitted three years of internal audits instead of external reviews by the IRO.

• A network of physician clinics in the Northeast agreed in the spring of 2000 to resolve its False Claims Act liability arising out of its submission of claims to the federal health care programs that violated Medicare's billing rules. The OIG imposed a CIA on the network for a term of five years. However, the integrity obligations were tailored to the providers' pre-existing compliance program. Furthermore, the physician clinics were allowed the opportunity to qualify for internal annual reviews instead of reviews conducted by an IRO.

• A mental health facility in the Midwest agreed in the spring of 2000 to resolve its False Claims Act liability arising out of its submission of claims to Medicaid for nonreimbursable services. The facility uncovered the false claims during the course of an internal audit performed as part of its compliance program. Because the facility had disclosed the false claims to the government, cooperated with the government to perform an internal audit, and had already implemented a comprehensive pre-existing compliance program, the OIG made certain modifications to the CIA. The OIG imposed corporate integrity obligations for a term of three years instead of five years. Furthermore, the integrity measures were tailored to the facility's pre-existing compliance program and the OIG allowed internal annual reviews instead of IRO reviews.

• A national health system, which operates multiple hospitals in 20 states, entered into a global settlement in the spring of 2000 to resolve its False Claims Act liability arising out of its upcoding of pneumonia claims at several of its hospitals. The health system 1) disclosed its problems with

pneumonia claims, as well as additional problems; 2) cooperated with the government to perform an internal audit with mutually agreed-upon parameters; and 3) had implemented a comprehensive compliance program. Based on these and other facts, the OIG made certain modifications to the CIA and imposed a CIA for a term of three years instead of five years. Furthermore, the corporate integrity measures conformed to the hospital system's comprehensive pre-existing compliance program and the IRO review was limited to the covered conduct.

A nursing home in the Midwest identified that it had been improperly waiving copayment amounts for Part B services rendered to Medicare beneficiaries for nursing and clinical laboratory services, occupational and physical therapy and physician services. In the summer of 2000, the nursing home agreed to resolve its False Claims Act liability. Because the hospital disclosed its findings to the government and was in the process of implementing a comprehensive compliance program, the OIG imposed a CIA for a term of three years instead of five years and tailored the integrity measures to the provider's pre-existing compliance program. ■

Adverse events data shared in Minnesota

A new law in Minnesota will allow hospitals, doctors, and health care professionals from across the state to share patient safety information in ways that previously were impossible.

The law changes the Minnesota Peer Review Statute, which previously inhibited the exchange of information from one hospital to the next for fear of litigation. In essence, Minnesota hospitals could learn from adverse events within their own organizations, but not others.

Senate File 560 was championed by the Minnesota Hospital and Healthcare Partnership (MHHP), an association representing Minnesota's 142 hospitals and 20 health systems. Signed into law recently by Gov. Jesse Ventura, the new measure allows hospitals, doctors, and medical staff to anonymously report medical errors in a web-based registry that can be aggregated and accessed by other health care professionals and the public.

Individual patient and caregiver information is not provided, only the data needed to learn from the event, says **Bruce Rueben**, president of MHHP.

"This law will improve patient safety," Rueben says. "Minnesota hospitals fought hard to create this web-based registry. By capturing and sharing information on medical accidents regardless of whether or not a patient is harmed, hospitals can provide safer care and prevent mistakes before they happen."

Scott Anderson, vice president of information services with MHHP, says a key aspect of the system is that it is voluntary.

"Hospitals understand the importance of learning from each other," Anderson says. "This system will help facilitate that process because it is designed to capture both adverse events and near misses."

MHHP launched a pilot program with a few hospitals in June, with plans for a statewide rollout later in 2001. The new law will take effect Aug. 1, 2001. ■

Tenet settles, agrees to access for disabled

Tenet Healthcare Corp. in Miami recently announced it has reached agreement on a nationwide plan to improve access for the disabled at all Tenet acute-care hospitals and related facilities across the country.

The court-approved agreement concludes a class-action lawsuit filed by Access Now, an activist group for the disabled, against Tenet in November 1997 that sought to assure Tenet's compliance with the Americans with Disabilities Act. In collaboration with Access Now, Tenet will develop individual compliance plans for 15-20 of its facilities each year. Each plan will be submitted for approval to U.S. District Court Judge Alan S. Gold in Miami.

All improvements will be designed to help provide equal access to Tenet facilities for those with hearing, vision, and mobility impairments. Work at all facilities is scheduled to be completed in seven to 10 years. Both parties called the settlement a positive, forward-looking outcome.

In a prepared statement, **Thomas B. Mackey**, COO in Tenet's office of the president, said, "Tenet voluntarily agreed to do this because improved access for the disabled is an essential

part of the commitment we have made to provide quality care and service to all patients and their families. We see this as part of our responsibility as a leader in bringing change and improvement to the health care delivery system."

Edward Resnick, president of Access Now, commended Tenet on its sensitivity to the medical needs of the disabled community. "Tenet has become a model on which others can base their own efforts to extend accessible care to millions of disabled Americans. Together, we are doing good for many people," Resnick says.

At a court hearing, Gold also praised the agreement. "I think you have achieved something here that is unique and precedential for those who are looking to deal with these types of issues in the future, and I have to assume that will occur fairly often," he said. ■

Oklahoma is first to bar MedMARx

Oklahoma is the first state in the nation to specifically bar information reported to MedMARx, a national medical errors database, from being introduced as evidence in a legal proceeding.

The US Pharmacopeia (USP) in Rockville, MD, launched MedMARx in 1998 to enable hospitals to report and track medical errors anonymously. The action by the Oklahoma State Board of Health is seen as a possible step in the patient safety movement, says **Jay A. Gregory**, MD, president of the Oklahoma Board of Health.

"It is our hope that this recognition will encourage Oklahoma health care facilities and practitioners to report medication errors in a consistent and nonpunitive manner, and therefore increase the chances of identifying trends and implementing systemwide improvements and safety measures to help prevent medication errors," Gregory says.

Explicit legal protection

MedMARx has more than 400 users across the country. USP asked Oklahoma to recognize reports to USP's medication error reporting programs as a privileged communications after learning that the state's privacy statute extends protection to national organizations approved by the Board of Health. No other state has granted explicit legal protection to USP.

On the federal level, Sen. James Jeffords (I-VT), chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee, and Sen. Edward Kennedy (D-MA), ranking Democrat on the HELP committee, hope to introduce bipartisan legislation to reduce the rate of medical errors, but it remains unclear how they will treat the liability issue. ■

FDA warns of risks from medical gas

The Food and Drug Administration (FDA) has issued a special warning to alert hospitals, nursing homes, and other health care facilities to the hazards of medical gas mix-ups. The FDA received reports during the past four years from hospitals and nursing homes involving seven deaths and 15 injuries to patients who were thought to be receiving medical-grade oxygen, but were receiving a different gas that had been mistakenly connected to the oxygen supply system.

The FDA's guidance paper makes recommendations that will help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups. Here are the incidents that prompted the FDA's warning:

• On Dec. 7, 2000, a nursing home in Bellbrook, OH, reported two patient deaths and eight patients injured following a mix-up in their oxygen supply system. The nursing home had supposedly received a shipment of four cryogenic vessels, two containing medical-grade oxygen. Included in the delivery, however, was a cryogenic vessel of industrial-grade nitrogen. The nursing home was running low on oxygen and sent a maintenance employee to connect a new oxygen vessel to the oxygen supply system. The employee selected the nitrogen vessel and discovered, correctly, that he was unable to connect the vessel to the oxygen system — as a safeguard, the connectors for oxygen vessels are specially fitted so they are compatible only with oxygen delivery systems. Trying to be helpful, the employee removed a fitting from an empty oxygen vessel and installed it on the nitrogen vessel.

The employee then connected the deadly product to the oxygen system. Several days later, two of the injured patients died from

exposure to industrial nitrogen, bringing the death total from this one incident to four.

• On April 22, 1998, a hospital in Idaho discovered that a large cryogenic vessel of industrial nitrogen had been connected to the oxygen system supplying the operating rooms, labor and delivery rooms, and emergency department. The hospital discovered that the medical gas delivery person initially had been unable to connect the incompatible nitrogen vessel outlet fitting to the oxygen system, but had used a wrench to disconnect the nitrogen fitting and replace it with an oxygen fitting. Two patients died as a result of this medical gas mix-up.

• In October 1997, a hospital in Nebraska received a shipment of medical-grade oxygen in large cryogenic vessels. The shipment included one cryogenic vessel of industrial-grade argon that was properly labeled. The hospital was running low on oxygen and sent a maintenance employee to connect an oxygen vessel to the oxygen supply system. Without examining the label, the employee selected the argon vessel, and, discovering he was unable to connect the vessel to the oxygen supply system, he removed a fitting from an empty oxygen vessel, installed it on the argon vessel, and connected the deadly product to the oxygen system. Argon was administered to a patient undergoing minor surgery. The patient died.

• On Dec. 2, 1996, a children's home located in New York reported adverse reactions experienced by nine patients due to the inhalation of carbon dioxide. An employee of the home, asked to attach a large cryogenic vessel of medical-grade oxygen, unknowingly selected a carbon dioxide vessel from the home's inventory. He noted that the fitting on the carbon dioxide vessel was not compatible with the connector on the oxygen system. Nonetheless, he removed an oxygen fitting from an empty vessel, installed it on the carbon dioxide vessel, and attached it to the oxygen supply system. Two patients were injured critically, and four patients experienced varying stages of respiratory distress.

The FDA notes that all four cases reveal striking similarities. In all cases, the person connecting the vessel to the oxygen system (the delivery person or the facility employee) was not properly trained and did not understand that connection incompatibility is a built in safeguard. And prior to installing the cryogenic vessel to the oxygen supply system, the person making the connection did not examine the drug label applied to the cryogenic vessel to ensure that the product was medical oxygen.

The agency has identified additional practices that may contribute to continuing medical gas mix-ups resulting in injury and death. Although recommended by the Compressed Gas Association, many of the large cryogenic vessels used to contain medical gases do not have permanently brazed, or welded, connections or fittings that cannot be removed. In addition, not all medical gas vessels are labeled using 360-degree wraparound labels.

FDA recommendations

The FDA says all of the incidents could have been avoided if a few simple safety procedures had been followed. In particular, the agency urges health care providers to widen their safety training in gas handling to include any employee who *might* handle the gas containers, rather than just those who handle them regularly. These are the FDA's recommendations:

1. If your facility receives medical gas deliveries, you should store medical-grade products separately from industrial-grade products. The storage area for medical grade products should be well-defined with one area for receiving full cryogenic vessels and another area for storing empty vessels.

2. All personnel who will be handling medical gases should be trained to recognize the various medical gas labels. Personnel should be trained to examine all labels carefully.

3. If your supplier uses 360-degree wraparound labels to designate *medical oxygen,* personnel should be specifically trained to make sure each vessel they connect to the oxygen system bears such a label.

4. Make sure all personnel in your facility who are responsible for changing or installing cryogenic vessels are trained to connect medical gas vessels properly. Personnel should understand how vessels are connected to the oxygen supply system and be alerted to the serious consequences of changing connections.

5. You should emphasize repeatedly that the fittings on these vessels should *not be changed* under any circumstances. If a cryogenic vessel fitting does not seem to connect to the oxygen supply system fitting, the supplier should be contacted immediately. The vessel should be returned to the supplier to determine the fitting or connection problem.

6. Once a cryogenic vessel is connected to the oxygen supply system, but *prior* to introducing the product into the system, a knowledgeable person should ensure that the correct vessel has been connected properly.

The FDA reminds providers that medical gases are prescription drugs. Therefore, all medical gas manufacturers who receive reports of death or serious injury associated with the use of medical gases are required under 21 CFR 310.305 and/or 314.80 to report those incidents to the FDA. ■

HealthSouth pays $7.9 million to settle

HealthSouth, the nation's largest outpatient surgery and rehabilitation chain, has agreed to pay $7.9 million to settle allegations that the company overcharged federal health programs.

The Justice Department announced the settlement recently, saying the health care provider had agreed to pay the penalty, plus 7% interest from Oct. 1, 2000, without admitting liability. HealthSouth is based in Birmingham, AL.

Acting Assistant Attorney General **Stuart E. Schiffer**, JD, said the government alleged that HealthSouth overcharged Medicare and the Defense Department's TRICARE program for equipment and supplies purchased from G.G. Enterprises, a corporation owned by the parents of HealthSouth chairman and CEO **Richard M. Scrushy**. The allegations involved costs related to three rehabilitation hospital leases, the purchase of certain computers and related goods and services, and the abandonment of computer assets owned by another company acquired by

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HealthSouth in 1994.

HealthSouth said the previous company's treatment of those costs in cost reports submitted for reimbursement was inconsistent with Medicare regulations, resulting in overpayments. In a statement released at the time of the settlement, HealthSouth officials said they decided to settle the matter to avoid the time, expense, and distraction of litigation. Scrushy said, "While we devote significant resources to complying with all reimbursement regulations, the volume and complexity of those regulations make it inevitable that differences in interpretation and even errors may occur."

The settlement stems in part from a lawsuit filed by whistle-blower Greg Madrid, a former HealthSouth billing clerk. As part of the settlement, Madrid will receive $1.48 million. ■

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

Fire in a patient's throat during surgery leads to death: $2.1 million settlement

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

News: An 83-year-old retired farmer went in for day surgery to remove a cancerous lesion from a vocal cord. His anesthesia team, combining a higher-than-required concentration of oxygen and a failure to properly operate a laser-resistant tube, started a fire in the patient's trachea. Complications led to his death and a $2.1 million settlement.

Background: The patient was diagnosed as having a cancerous lesion on a vocal cord, and his physician recommended laser surgery. During the procedure, which was performed on an outpatient basis, the surgical and anesthesia team used a Z-Xomed laser-resistant tube, but failed to follow the manufacturer's recommendation to place wet pledgets around the cuff. This error, combined with a higher-than-recommended concentration of oxygen, caused a fire in the patient's trachea. The fire was long and hot enough to melt the patient's endotracheal tube. Suffering from burn and inhalation injuries, he soon died.

In addition to claiming the medical team failed to properly operate the laser, the plaintiff maintained that the anesthesiology team used an improper oxygen preparation with nitrous oxide as the anesthetic agent. The plaintiff maintained that the combination of the misuse of the equipment and high concentration level of oxygen started the fire. The plaintiff also alleged that once the fire started, the physicians failed to act timely and properly by either turning off the oxygen or crimping the line to limit the supply of fire-fueling oxygen. In conclusion, the plaintiff claimed that the misuse of equipment and failure to appropriately manage the accident once it occurred caused severe inhalation injury resulting in the subsequent development of acute respiratory distress syndrome and multiorgan failure, which lead to the patient's death.

The defendants contended they acted properly and denied using inappropriate concentrations of anesthetic agents. Additionally, they claimed the decedent died from unrelated hemorrhagic pancreatitis, which occurred after his trachea had healed.

The physicians settled prior to trial for $2.1 million.

What this means to you: Hospitals, surgery centers, nursing homes, and physician offices are full of things that can and do ignite. As this and the subsequent scenarios illustrate, health care professionals must handle flammable and caustic materials with extreme caution and care, otherwise they and their patients might be unintentionally burned.

Even though this particular incident occurred in a physician's outpatient surgery center, it could have just as easily taken place in a hospital. Regardless of the setting, this case demonstrates the need for the adequate training of staff and appropriate credentialing of professionals.

"Training in the use of new equipment is critical, regardless of whether it is being used on an inpatient or outpatient basis," says **Ellen L. Barton**, JD, CPCU, risk management consultant, of Phoenix, MD. "While manufacturers clearly have a responsibility to provide instructions and training, health care practitioners also have a responsibility to acquire the appropriate proficiency and experience to be able to operate any new equipment without causing harm. Even in an outpatient setting, all staff assisting in a procedure should be trained in the use the equipment as well as the management of a malfunction or operational error. And, as may have been the case in this scenario, staff training in the outpatient setting may be even more critical than the inpatient setting simply because of the lack of additional resources, such as a designated rescue team. Staff have a right to such training and a duty to refrain form assisting in such procedures or using new equipment if they are not equipped to handle any contingency.

"A related issue is the credentialing of the practitioners performing various specialty procedures and using the specialized requisite equipment. Just as every hospital traditionally uses established credentialing criteria — education, training, experience, and references — for basic clinical privileges, the same should hold true for stand-alone outpatient facilities. Regardless of location, it is equally important to continuously update the list of each practitioner's specific privileges particularly as new technology and equipment enter the market place. Credentialing should be specific as to what the physician is able to perform and the exact equipment to be used each of the procedures," adds Barton.

"Clearly, the training provided to staff was not sufficient in this instance since the fire seemingly burned out of control. Whether this was because of the manufacturer's specifications or the trainees is uncertain. Although claims are not known to have been brought against the equipment manufacturer, it is likely that the equipment manufacturer's instructions for using the laser were clear and available to the health care providers. To avoid such allegations in the future, a facility's credentials committee must develop and apply appropriate criteria to the awarding of privileges and make sure that their own staff are familiar with the equipment being used. In addition and perhaps fortunate for future patients, various payers also are starting to require such credentialing of professionasl prior to their reimbursing for services," concludes Barton.

Reference

• *Helen Durston, individually and o/b/o the Estate of Everett Durston, deceased, et al. v. Rio Grand Surgery Center Associates, L/O., d/b/a Rio Grande Surgery Center, Michael J. Gossett, CRNA, Jaime Gumucio Viancos, MD, and Keith A. Picou, MD,* Hidalgo County (TX) District Court, Case No. C-2957-98-C. ■

Physician's inexperience: $1 million verdict in Ohio

News: A woman went in for elective cosmetic surgery based on an advertised claim that the physician performing the surgery was proficient in the procedure as "seen on TV." The physician had not been trained to use the technique and equipment and burned the patient's face. The jury returned a $1 million dollar verdict in the patient's favor.

Background: A 52-year-old university professor was considering cosmetic surgery to remove fine lines, which had developed with age, on her upper lip. She was involved in freelance projects for local and national theater and television productions that she performed in, directed, and/or produced. After seeing laser resurfacing demonstrated on the television show *20/20* and reading a local doctor's advertisement in the Yellow Pages that claimed his laser-resurfacing experience used the "same innovative techniques as seen on *20/20*," the woman had a consultation with the physician. She specifically asked if he had success with laser resurfacing and was told yes, and she shared with the physician her vocation and desire to remain gainfully employed as such.

The plaintiff underwent laser surgery, the doctor using a CO_2 laser known as Sharplan Silk Laser and the Silk Touch Mode with a power setting of 16 watts. Immediately after the surgery, the woman's chin area was bruised, blackened, and swollen. It remained swollen in the weeks and months that followed and then scarring developed. The doctor's attempts to treat the scarring were unsuccessful, and she was referred to a dermatologist.

However she went to another plastic surgeon and was told she had suffered third-degree

full-thickness burns as well as permanent scarring. Five corrective surgeries were performed using a Candela laser. The second plastic surgeon then recommended scar revision and skin graft surgery, which could then be followed by two to four more laser surgeries.

She claimed her original physician neglected to apprise her of all the risks involved in the laser procedure and was negligent in his performance of the procedure. She also claimed that the only risk of surgery discussed was redness and that the possibility of scarring and hypopigmentation were not mentioned. She further claimed that the Sharplan Silk Laser should have been placed on a more sensitive setting. She presented evidence that the doctor had never read or consulted the user's manual for the Silk Laser and had received no documented training with the laser.

The doctor admitted that he did not tell the plaintiff about the nature and extent of his training on the laser or other options for treating her. The plaintiff's claim also included improper credentialing of the doctor to use the Sharplan Silk Laser at the one-day surgery center where the procedure was performed.

The doctor had not attended the training session held at the center after the Sharplan Silk Laser was purchased. The defendant maintained that his time spent at the exhibit booth of Sharplan, at meetings of the American Academy of Dermatology, consulting with the Sharplan sales representative, as well as his past experience with a similar laser, gave him sufficient training to properly operate the Sharplan Silk Laser. The surgeon maintained that the plaintiff was fully informed of all relevant risks and that the scarring that the plaintiff suffered was idiopathic in nature and not the result of negligence on his part.

The claim went to trail. The jury found the physician negligent and awarded the plaintiff $1 million.

What this means to you: "In particular, this case highlights the absolute necessity of credentialing professionals for new procedures," says **Ellen L. Barton**, JD, CPCU, risk management consultant, of Phoenix, MD. "Again, in establishing the credentialing criteria — education, training, experience, and references — it is critically important that the Credentialing Committee educate themselves on the latest innovations and then incorporate appropriate criteria into the standards prior to granting privileges. Thus, in addition to the basic criteria, it is necessary to develop new and adequate criteria relative to the newest technology. Of course, this becomes even more challenging if a solo practitioner is the only one governing his actions, which may be the case when such surgery is performed in the physician's office.

"The issue of informed consent is also highlighted in this case. Since the patient was an individual that in her profession had a great need for 'facial' integrity, informed consent of the risks involved should have been paramount to the discussion regarding the procedure. Any risk, however insignificant it might be to someone else, that would have the potential to adversely effect the patient's looks was significant in this instance and should have been part of the informed-consent discussion. In failing to take this particular patient's profile into consideration, not fully informing the patient of his lack of experience with the new equipment, and seemingly not being frank with the patient regarding her poor outcome; the physician failed to meet the standard of care, and thus was appropriately found negligent. For institutional providers, credentialing and proper informed consent are critical elements in a preventive risk management program," concludes Barton.

Reference

• *Susan D. Speers v. Tri-County Dermatology Inc., et al.,* Stark County (OH) Court of Common Pleas, Case No. 1999-CV-02765. ■

Chemical disfigurement: $93,000 verdict in Texas

News: A woman went to an emergency department (ED) with severe muscle contractions and was given calcium chloride intravenously. The caustic material was inappropriately administered and her hand was so disfigured that reconstructive surgery was required. The jury returned a $93,000 verdict in the patient's favor.

Background: The 40-year-old patient had undergone surgery to remove her parathyroid gland because of cancer. Without the gland, she was required to take a daily calcium supplement. When she inadvertently ran out of calcium, she

experienced severe muscle contractions, which prompted her to go to the ED. When she arrived, the contractions were causing her to be short of breath. The ED physician ordered calcium chloride, provided intravenously. During one of the injections into the top of her hand, the calcium chloride extravasated under the skin, causing a chemical burn. Plastic surgery was required to repair the damaged tissue.

The plaintiff reported she has discoloration in cold weather and scarring involving this hand. She alleged that the doctor should have used calcium gluconate instead of calcium chloride because it is less caustic. Further, the plaintiff claimed that the IV was given in the wrong area, that it should have been administered into her arm rather than her hand. The plaintiff claimed the hospital was negligent, that the nurses improperly placed the IV, and that too much calcium chloride was administered too quickly.

The defendants contended that calcium chloride was appropriate and within the standard of care. The defendants maintained that since the patient's muscle contractions were extremely acute, the calcium chloride dosage was correct. Further, the defendants maintained that the site for the injection was appropriate and that the risk of IV infiltration is one that could not be completely eliminated.

What this means to you: "In addition to other risks, emergency medicine has an attendant risk of not knowing its patients. In this case, the use of the most appropriate substance and locating the most appropriate place to inject the substance was compounded by the risk of treating a patient in extreme, emergent discomfort," says **Ellen L. Barton**, JD, CPCU, risk management consultant, of Phoenix, MD. "However, emergency department health care practitioners take their patients as they find them and, in this case, had the injection been properly placed in a vein no extravasation would have occurred. Therefore in the emergency room setting, it is clearly important to have protocols that will provide the greatest protection to all patients, which means providing for the appropriate substance injected in the appropriate place.

"The training and education of staff become critically important in assuring that protocols are actually followed, particularly in emergency departments. Although it can be argued that infiltration is a known risk of injection [emergency or not] that cannot be completely eliminated, it is well-known that proper placement of a needle in a vein can be verified by checking blood flow. Thus, this risk argument can be easily countered by appropriate education and training to avoid or at least mitigate such mishaps," adds Barton.

"Undoubtedly, where there is fire, someone can get burned. And, as these cases illustrate, when the patient is burned, damages against the providers may be anticipated. Credentialing, education, and training are critical elements to employ so that providers don't burn their patients and in turn themselves. When equipment and materials are potentially flammable and caustic, there is not enough that can be said about the need for sufficient training and education for staff and professionals regarding their use. And, this training and education must also extend to handling the 'what if something goes wrong' untoward incidents," concludes Barton.

Reference

• *Karen Ippolito v. Tomball Regional Hospital and Dr. An Duc Tran*, Harris County (TX) District Court, Case No. 1999-13588. ■

American Health Consultants
Education and Training Fax-back Survey

We would like to learn more about training and education needs for you and your staff. Please circle the number corresponding to your level of interest in the following topics:

	No Interest		Some Interest		Much Interest
HIPAA privacy rules	1	2	3	4	5
Stark II	1	2	3	4	5
EMTALA	1	2	3	4	5
Aftermath of ergonomics	1	2	3	4	5
OSHA compliance	1	2	3	4	5
Post-exposure prophylaxis	1	2	3	4	5
Influenza update	1	2	3	4	5
Antibiotic resistance	1	2	3	4	5
Adverse drug reactions	1	2	3	4	5
Drug interactions	1	2	3	4	5
Medication errors	1	2	3	4	5
Herb-drug interactions	1	2	3	4	5
Nosocomial infections	1	2	3	4	5
Patient falls	1	2	3	4	5
Basic information for frontline workers	1	2	3	4	5
Needlesticks	1	2	3	4	5
Latex sensitivity	1	2	3	4	5
TB compliance	1	2	3	4	5
Restraints and the violent patient	1	2	3	4	5
Pain management	1	2	3	4	5

	No Interest		Some Interest		Much Interest
Palliative care	1	2	3	4	5
End-of-life care	1	2	3	4	5
Assisted suicide	1	2	3	4	5
Genetic testing	1	2	3	4	5
Organizational ethics	1	2	3	4	5
Human research protection	1	2	3	4	5
Informed consent documentation	1	2	3	4	5
New accreditation standards	1	2	3	4	5
Observation units (23-hour care or recovery beds)	1	2	3	4	5
ED diversion	1	2	3	4	5
Avoiding lawsuits: What to say when something goes wrong	1	2	3	4	5
Improving documentation for nurses and physicians	1	2	3	4	5
Nursing shortage	1	2	3	4	5
Bioterrorism	1	2	3	4	5
Disaster planning and mass casualties	1	2	3	4	5
Safety and security	1	2	3	4	5

What training format is preferred for you and your staff? Rate the following methods using the scale below:

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On-site speakers	1	2	3	4	5
Travel off-site to live conferences	1	2	3	4	5
Subscription-based newsletters/journals	1	2	3	4	5
Outside-sponsored teleconferences	1	2	3	4	5
Outside-sponsored videoconferences	1	2	3	4	5
Web-based conferences	1	2	3	4	5
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