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TRICARE contracts can bring affirmative action requirements

Ruling: TRICARE contracts can subject hospitals to affirmative action

In this economy, every health care provider wants to say yes to a managed care contract that promises more revenue. A recent court ruling, however, shows that the money may come with strings attached.

A Labor Department Administrative Law Judge (ALJ) has found that a Florida hospital's TRICARE contracts trigger affirmative action obligations under federal law, handing down a ruling that is sending risk managers scrambling. This means that hospitals that are not otherwise required to have an affirmative action obligation must now develop one if they have a TRICARE contract.

The ruling came in *OFCCP v. Florida Hospital of Orlando*, DOL OALJ, No. 2009-OFC-00002. The ALJ upheld the position of the Office of Federal Contract Compliance Programs (OFCCP) that the hospital was a government subcontractor, explains **Stephanie Dodge Gournis, JD**, a partner with the law firm of Drinker Biddle in Chicago.

The case involves TRICARE, a federal health care program for active and retired military personnel that contracts with both health care providers and regional administrators to provide health care services to TRICARE participants, and Florida Hospital of Orlando, an acute care hospital that provides health care services to TRICARE participants through a care network managed by Humana Military Health Services (HMHS).

"This case is very significant to health care providers, because it provides

EXECUTIVE SUMMARY

A recent ruling by a Labor Department Administrative Law Judge (ALJ) means that providers with TRICARE contracts may be considered federal contractors. This obligates the provider to meet many requirements, including having an affirmative action program.

- Health care providers were considered exempt from the federal obligations in the past.
- The Office of Federal Contract Compliance Programs (OFCCP) has significantly increased its enforcement efforts.
- The decision could affect about 500,000 health care providers.

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us a definitive conclusion by an administrative law judge saying that, yes, this is sufficient to trigger affirmative action coverage,” Gournis says. “It changes the landscape pretty significantly for a lot of health care employers, because they have historically, largely believed they were exempt.”

After the ruling, the OFCCP began contacting health care providers to assert that TRICARE contracts subject them to affirmative action and non-

discrimination obligations, Gournis says.

“Hospitals, skilled nursing facilities, residential or special treatment centers, or other health care providers should conduct an immediate review of contracts and consult with legal counsel to determine whether they may now be deemed federal contractors or subcontractors under federal law,” Gournis says. “If qualifying contracts are discovered, employers should consult their attorneys as soon as possible to begin building affirmative action plans and complying with other affirmative action obligations.”

Gournis says the need for action is particularly acute given the OFCCP’s recent increase in funding and hiring of scores of new compliance officers, along with the Department of Labor’s focus on health care.

“The case is under appeal; but I don’t think health care providers should wait to assess their liability under this case, because I don’t think the appeal is going to come out in the hospital’s favor,” she says.

If the health care provider is only providing services pursuant to a subcontract for insurance, it might still fall into a very narrow exception spelled out in earlier rulings, Gournis says, but that will be the rare exception. More than 500,000 health care providers with TRICARE contracts are probably going to be providing medical services pursuant to a contract for providing medical services, which will make them subject to the affirmative action requirements, Gournis says.

Hospital had no federal contracts

The ruling clarifies the long debated and little understood issue of what constitutes a federal subcontract in the health care industry for affirmative action purposes, Gournis says. Florida Hospital has no direct federal contracts, so its leaders did not think it had to have an affirmative action program. It does receive more than \$100,000 annually in federal reimbursement pursuant to a managed care contract between HMHS and TRICARE, however. That led to the dispute that eventually resulted in the ruling.

Florida Hospital disagreed with the results of a 2007 audit, saying OFCCP had no jurisdiction, because its TRICARE agreements were neither federal contracts nor subcontracts under federal law. The OFCCP insisted they were and initiated compliance proceedings against the hospital when

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Editorial Questions

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it refused to hand over its affirmative action compliance plan.

“The ALJ determined Florida Hospital was a covered subcontractor, because it provided medical services to TRICARE’s beneficiaries, and these services were necessary to the performance of TRICARE’s contract with HMHS,” Gournis says. “The ALJ found irrelevant the fact that Florida Hospital’s agreement with HMHS contained no indication that the hospital would be deemed a federal subcontractor.”

The ALJ also ignored TRICARE’s assertion that it never intended for Florida Hospital to be a federal subcontractor, she says. It also rejected Florida Hospital’s argument that TRICARE was the functional equivalent of Medicare, which the OFCCP has consistently deemed to be a “grant” and not a federal contract. Consequently, health care providers receiving only Medicare and Medicaid reimbursements have not been subject to federal contractor obligations.

The ALJ distinguished Medicare by stating TRICARE “brings together the health care resources of the uniformed services and supplements them with networks of civilian health care professionals . . .” and is a “totally different program” from Medicare.

Law has been unclear

The recent ruling changes the scene only for hospitals that have a TRICARE contract amounting to at least \$50,000 in revenue and which do not have another federal contract, says **Kendra M. Allaband**, JD, an attorney with the law firm of Drinker Biddle in Chicago. Prior to the Florida Hospital of Orlando decision, case law was not altogether clear on TRICARE contracts, she says. In 2003, the Administrative Review Board issued a decision in *OFCCP v. Bridgeport Hospital*, ARB No. 00-034, 2003 WL 244810 (Jan. 31, 2003), which led the health care community to believe that providing health care for government employees would not trigger affirmative action obligations, she says.

In that case, Bridgeport Hospital had an agreement with Blue Cross/Blue Shield (BCBS) to provide medical services to persons eligible to receive health care benefits under any BCBS plan. This agreement provided for preferred rates at the hospital for all BCBS members. BCBS contracted with the U.S. Office

of Personnel Management (OPM) to provide federal employees with health insurance, and Bridgeport Hospital received over \$300,000 in payments from BCBS for services provided to federal employees and their dependents.

“The OFCCP argued that, by providing services to federal employees and their dependents, Bridgeport Hospital was providing a service necessary to the effectuation of BCBS’s federal contract and that the hospital was therefore a subcontractor,” Allaband says. “The Administrative Review Board disagreed and found that BCBS actually provided insurance — not medical services. Therefore, Bridgeport Hospital was not deemed a covered subcontractor.”

Six years after the Bridgeport Hospital decision, the Administrative Review Board substantially narrowed the effect of that holding, Allaband says. In *OFCCP v. UPMC Braddock*, ARB Case No. 08-048 (May 29, 2009), the University of Pittsburgh Medical Center (UPMC) had an HMO contract with the University of Pittsburgh Medical Center Health Plan to provide medical products and services to government employees pursuant to a contract between the Health Plan and OPM. This opinion stated that, unlike BCBS, the UPMC Health Plan was more than an insurer — it was an HMO, Allaband says. By its nature, an HMO arranges and provides for medical services through providers such as UPMC. UPMC was therefore found to be a federal subcontractor.

The holdings of Bridgeport Hospital and UPMC Braddock were difficult to reconcile and left the health care community with little guidance on which types of agreements would subject providers to affirmative action requirements, Allaband says. The OFCCP and the Florida Hospital of Orlando case clarify that more health care providers are subject to the requirements.

“This ruling serves as a wakeup call for risk managers and compliance officers that they really need to initiate a review and audit of their compliance standards and procedures,” Allaband says. “Too often, we find that health care employers lack a really consistent standard of practice for tracking federal contracts and don’t even recognize whether they have federal contracts or not. The risk manager or compliance officer should have a strong working knowledge of the OFCCP compliance standards and what constitutes a federal contract, and they should work with legal counsel on an

ongoing basis [regarding] what obligations arise as a result of those contracts.”

SOURCES

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Affirmative action includes impact analyses

If your hospital is now subject to affirmative action requirements because of a TRICARE contract or any other federal contract, what does that involve?

The requirements are found in Executive Order 11246, Section 503 of the Rehabilitation Act of 1973, and the Vietnam Veterans' Readjustment Assistance Act of 1974, explains **Stephanie Dodge Gournis**, JD, a partner with the law firm of Drinker Biddle in Chicago.

The rules specify that federal contractors and subcontractors are required to develop a written Affirmative Action Plan (AAP) for each of their establishments within 120 days from the start of a federal contract, if the contract is worth \$50,000 or more annually.

Additionally, Gournis says the hospital may also be subject to these requirements:

- conducting adverse impact analyses for hires, promotions, and terminations;
- engaging in outreach activities;
- performing compensation analysis;
- ensuring nondiscrimination in employment;
- filing an EEO-1 report;
- filing a Vets 100/100A report;
- participating in E-Verify;
- complying with certain record-keeping responsibilities;
- allowing OFCCP access to the contractor's/subcontractor's facilities and records;
- posting of certain notices;
- including a non-discrimination statement in job postings;
- posting job vacancies with the state unemployment agency;
- providing reasonable accommodations; and
- prohibiting retaliation. ■

Surprise! You might be a federal contractor

Prior to the ruling in *OFCCP v. Florida Hospital of Orlando*, DOL OALJ, No. 2009-OFC-00002, most hospitals did not worry about being a federal contractor — and all the obligations that can trigger — unless they were engaged in specific business with the federal government. Now, you might be a federal contractor and not even realize it.

Being a federal contractor is no small deal. As with most endeavors with the government, being a contractor requires keeping extensive data and statistics on your affirmative action efforts, says **Monica M. Fanning**, JD, a shareholder with the law firm of Polsinelli Shughart in Kansas City, MO. And to make matters worse, the Office of Federal Contract Compliance Programs (OFCCP) is now increasing its oversight of these requirements, she says.

“During the Bush administration, the OFCCP was so underfunded that it was rare that a federal contractor would be audited,” Fanning says. “The information you had to collect was not submitted to anyone; you basically just put all the data together and put it on a shelf, then hoped you wouldn't get audited. Because the reports were onerous and expensive, federal contractors began to say there was no point in putting the reports together until they got an audit letter.”

The Obama administration shifted priorities and increased the budget for federal contractor oversight by about 40%, Fanning says. The OFCCP has increased its staff of investigators by 50%, she says.

Among federal contractor clients at Fanning's firm, the number of audits by the OFCCP has gone from one in three years to 18 that she has handled in the past year and a half.

“The OFCCP went from being something that nobody worried about to now being extremely, extremely aggressive,” she says. “We're finding that not only are they being aggressive with typical federal contractors — those who knew in the past they were contractors — but also with people who are just now realizing they have to follow these rules. They don't really care that you're new to this and may not even realize what you have to do.”

An audit by the OFCCP is a big deal. The hospital receives an audit letter from the OFCCP

saying it wants to see the provider's affirmative action plan. But the audit letter actually is more onerous than that. In addition to checking your affirmative action plan, the OFCCP can visit your site and study your I-9 employment eligibility verification forms, and even pay stubs for wage and hour issues.

"It opens you up to a lot of liability," Fanning says.

The potential consequences range from increased oversight by the government for a specified period to debarment, which means the provider is not eligible for a government contract of any type for a certain period of time or forever. It is not clear whether that could impact Medicare and Medicare participation, Fanning says, but many providers are worried enough about that possibility that they will comply with the contractor obligations for that reason alone.

Although there is some chance that the ruling could be overturned, Fanning says she wouldn't count on it. In the meantime, risk managers need to get to work, she says. The first thing to do is to determine if you have a contract with TRICARE, she says, and a great many hospitals do.

Even if you do not have a written contract with TRICARE, you may still be involved and be considered a federal contractor, Fanning says.

"There are many providers who are network providers with TRICARE but who do not have actual written contracts," she says. "In that case, you need to figure out your relationship to TRICARE. Many providers know they are somehow involved with TRICARE, but they've never had a reason to figure out the exact relationship. You need to figure it out now, so that you can see if it is enough to trigger your obligations."

Some providers with TRICARE contracts are deciding to risk the penalties and forego all the compliance documentation until they get audited, a move that may be pragmatic, but which could result in serious penalties, Fanning says. Other providers are taking the steps to comply as thoroughly as possible, because the TRICARE contracts are too valuable to give up, and they aren't willing to risk non-compliance.

"It's a balance between how much it is going to take to comply and be a federal contractor and how much you are getting under these contracts," Fanning says. "I've seen a hospital do the numbers and see that they're only getting \$60,000 a year from the contract, so they decided it wasn't worth it. They let the contract go rather than comply with the contractor obligations."

SOURCE

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Court ruling: TRICARE not like Medicare

The defendant hospital in *OFCCP v. Florida Hospital of Orlando*, DOL OALJ, No. 2009-OFC-00002, argued that rather than being a contract with the federal government, TRICARE was merely another form of "federal financial assistance," just like Medicare.

If Medicare doesn't trigger affirmative action obligations, the hospital said, why should TRICARE?

The court didn't buy it.

"The Plaintiff does not disagree with the Defendant that OFCCP lacks jurisdiction over businesses if their only relationship with the federal government is as a recipient of federal financial assistance, be it from Medicare or other federal programs," Administrative Law Judge Jeffrey Tureck, JD, wrote in his ruling. "Thus, if Defendant's only receipt of federal funds was through Medicare or other federal financial assistance programs, Plaintiff does not contend that the statutes would be applicable to the Defendant. However, this case does not concern a program of federal financial assistance."

Tureck went on to say that the hospital's "argument that TRICARE and Medicare are 'essentially indistinguishable' is simply wrong. As OFCCP contends, Medicare is an insurance program. Medicare does not provide medical services to its beneficiaries — it simply pays for such services. On the other hand: TRICARE is the uniformed services health care program for active duty service members and their families. TRICARE's primary objectives are to optimize the delivery of health care services in the direct care system for all Military Health System (MHS) beneficiaries and attain the highest level of patient satisfaction through the delivery of world-class health care benefits.

"That Medicare may be considered federal financial assistance has no relevance to TRICARE. They are totally different programs."

For the full ruling by the court, go to http://www.polsinelli.com/publications/labor/resources/Florida_Hospital_of_Orlando.pdf. ■

Volunteers a great asset until they cost you

Volunteers are a key component to the success of many health care organizations, but how often do you consider the risks they bring? No one wants to turn away people offering their time for free, but at the same time, risk managers must consider the potential downside.

Many organizations rely on volunteers to enhance services provided by staff, improve the quality of life for clients, or simply to meet the goals of their mission. Based on a recent study by the Bureau of Labor and Statistics, almost 65 million people volunteer their time each year, and that number continues to grow.

However, without a good risk management plan, volunteer programs can expose your organization to additional risks of a loss, damage to your reputation, or even imperil operations, says **Tim Folk**, a producer at The Graham Company, an insurance broker and consulting firm in Philadelphia. Folk works with the Health and Human Services Industry Practice Group, a group established to address the risk management challenges specific to behavioral health, senior services, home health, addictive services, and mental health businesses.

“This is something that slides under the radar a little bit,” Folk says. “Most nonprofit providers are operating on a shoestring budget, which is the very reason they value their volunteers. And then everyone in administration is wearing multiple hats and working very hard, so the volunteers are just appreciated, but forgotten about in terms of any potential downside.”

Folk says the risks associated with volunteer programs can be summarized in three categories:

- injury or loss to a volunteer while performing services for the organization;

EXECUTIVE SUMMARY

Volunteers can pose a liability risk that often is overlooked or underestimated. Health care providers should address these risks with volunteer-specific policies and procedures.

- Providers may insure volunteers for injuries, or if not, should warn volunteers about the consequences of being injured.
- Requiring volunteers to sign a waiver and release can reduce General Liability costs.
- Volunteers should be provided health and safety training.

- claims filed against the organization resulting from harm or loss caused by a volunteer while performing services for the organization;
- claims filed against the volunteer that resulted from harm or loss caused by a volunteer while performing services for the organization.

An important issue is who is expected to pay for a volunteer’s medical expenses for injuries sustained while volunteering, Folk says.

Your employees are provided workers compensation for their medical expenses and lost wages arising from injuries sustained while working for the organization. Volunteers are not typically included on a workers compensation policy, and you are not typically required by law to provide any benefits to volunteers. Some organizations choose to protect their volunteers with an accidental death and dismemberment Policy as a way of attracting and communicating their commitment to their volunteers, Folk says.

This type of policy provides a benefit amount (such as \$25,000) if a volunteer is injured in an accident and it results in the death or dismemberment of the volunteer. It also pays a medical expense benefit for medical services incurred due to injury to a volunteer from an accident. Note that this medical expense coverage is typically in excess of the volunteer’s own medical health insurance, Folk says.

Some organizations choose not to carry any insurance to protect volunteers for their medical expenses for injuries sustained while volunteering, Folk says. In this situation, it is critical to make sure your volunteers understand what to expect if they get injured.

In considering whether to provide coverage to volunteers, Folk suggests asking these questions:

- What is the cultural message we send to our volunteers if we don’t provide some level of benefit?
- What are the costs as weighed against the potentially negative cultural impact?
- Will an AD&D policy help prevent significantly greater exposure (i.e., a lawsuit by a disgruntled volunteer)?

Will volunteers sue you?

Another important issue is whether a volunteer can sue your organization if he or she gets hurt while volunteering, Folk says.

Employees are prevented from suing for their injuries, because workers compensation benefits are their sole remedy for their injuries. Since volunteers

are not employees, they are entitled to sue you for their injuries just like any other third party, Folk says. (You would typically be covered for this lawsuit by your general liability policy, he notes.)

Some organizations minimize their exposure to these types of lawsuits by requiring their volunteers to sign a waiver and release. These types of agreements explain to the volunteer that because of the hazards and risks associated with volunteering, the organization requires every volunteer to be alert for his/her own safety and to sign a written agreement releasing the organization of any and all responsibility in connection with all risks encountered while volunteering, Folk explains. This helps protect the general liability loss experience, which then helps control the cost of purchasing insurance.

Some organizations are not comfortable with this approach and do not request their volunteers to restrict their right to sue.

Folk advises risk managers to ask these questions regarding exposure to lawsuits by volunteers:

- Do we currently use waiver and release forms?
- How will existing and new volunteers react to the request to sign one?
- What are the leadership methodologies we can employ to create a balance between the need to manage risk and maintain volunteer relations?

Need to screen, evaluate volunteers

For claims filed against the provider and resulting from harm or loss caused by a volunteer while performing services for the organization, you would typically be covered by your general liability policy, Folk says.

“However, the last thing an organization wants is a volunteer who turns out to be a bad apple,” Folk says. “Your organization’s loss experience, reputation, and ultimately, bottom line are all at risk. In order to protect your organization, good risk management practices should be followed and documented, including volunteer screening, training, and evaluations.

Screening practices may include criminal background checks, DMV records, sexual predator histories, and even credit reports, says **Martin Irons**, CPCU, CIC, ARM, vice president, Technical Development Department, with The Graham Company. Even a claim with little to no merit can become cause for serious concern if a third party is able to substantiate a lack of diligence in your selection and screening processes, especially for those individuals in direct contact with patients, he says.

“The training can be a real challenge for some organizations, because they already are stretched thin just trying to keep their employees trained and up to date, and plus they don’t have the same kind of control over volunteers in terms of scheduling and requiring them to do certain things,” Irons says.

Training is important to minimize both the physical risks to volunteers and clients, as well as non-physical risks, he says. Safe lifting, patient handling, restraints, and similar safety issues are all important. But so is training in regard to patient interaction, dispute resolution, and harassment, he says.

Note, however, that performing evaluations and reviews of volunteers may place a burden on the time of management and supervisors.

“But it also allows for a continuous screening process and helps ensure you have the best of the best helping you complete your mission,” Folk says.

Volunteers can hurt each other

With claims filed against the volunteer, resulting from harm or loss caused by another volunteer, the volunteer who caused the injury would typically also be covered by your organization’s general liability policy for these types of claims, since volunteers are included as “Insureds” in the standard ISO policy form, Folk says. This means the volunteer would also receive defense coverage from your policy. In most cases, this is beneficial to your organization, because your insurance carrier can coordinate the defense of your volunteer and your organization, since you would also typically be named in a lawsuit if the volunteer is alleged to be liable, he notes. In addition, it is another way for your organization to protect and value your volunteers.

“However, many insurance carriers use non-standard general liability forms for Health and Human Services clients,” Folk says. “The definition of who is insured should be carefully scrutinized, as you may not have the coverage you assumed you had.”

Don’t forget automobile coverage

Another area that is a difficult exposure to manage is when a volunteer is using their own automobile while performing services for the organization. In this situation, only the volunteer’s personal auto policy would protect the volunteer, Folk says. The

organization's business auto policy only protects the organization.

An option some organizations consider is adding volunteers as "Insureds Endorsement" to provide excess auto liability coverage to the volunteer under the organization's auto policy, Folk notes. Since your organization would also typically be named in a lawsuit, this could again be beneficial to your organization for coordination of defense, he says.

In addition to making these internal decisions, Folk says you should work with your insurance broker to ensure that your insurance program is properly tailored to respond to volunteers. Irons and Folk note that management of volunteers — and the risks they bring — can be a "hot potato" that administrators try to avoid, but they say the risk manager should take responsibility for controlling the risks.

"Volunteers bring numerous benefits to organizations. However, they also bring additional risks," Folk says. "Having a good risk management plan for your volunteer program is key to coming out on the winning side."

SOURCES

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Compliance officer hat could take you far

If you are a risk manager who also serves as the compliance officer, that second title could be your ticket to advancement within the organization, says **Roy Snell**, CHC, CCEP, CEO of the Health Care Compliance Association (HCCA) in Minneapolis and a former Mayo Clinic administrator, consultant, and compliance officer.

Snell says health care compliance officers will continue to grow in stature within health care organizations, because the government is increasing oversight and regulation in the industry. Compliance officers will report to higher levels in the health care organization in the near future, he says.

"There will be higher paying jobs and more opportunities to learn and improve your skills," he says. "Compliance officers will become more effective at their jobs. It will be easier, because you

have more authority; but it will be harder, because you're going to get more responsibility."

Other functions may be rolled into the compliance job description, such as safety and quality of care.

"Instead of the compliance functions being spread out across the organization, they will be consolidated, and that will make a stronger group of people who will be more effective," Snell says.

On the other hand, there is a risk that the compliance position will become diluted by the addition of other functions, Snell says.

"If the organization adds a lot of non-compliance related risk to the role, such as audit functions that are not for problems that the company could be causing others but are for the risks that others could be causing the company, the compliance function could be compromised," he says.

SOURCE

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Mediation effective, but many skeptical

Mediation can not only reduce the costs of malpractice litigation, but also has the potential to offer closure to plaintiffs and ensure that procedures are changed in hospitals to prevent recurrences of the error that sparked the lawsuit, according to a recent study. However, too often that potential goes unrealized, because doctors and hospitals are often reluctant to participate.

Barriers put up by doctors, hospitals, and their lawyers often stand in the way of mediation being employed effectively, says author **Carol Liebman**, JD, a professor at the Columbia Law School in New York City. The study was published in the *Journal of Health, Politics, Policy and Law*.¹

Her study found that mediation can not only reduce the costs of litigation, but it also has the potential to offer closure to plaintiffs and ensure that procedures are changed in hospitals to prevent recurrences of the error that generated the lawsuit. However, too often that potential goes unrealized, she says.

"Change will require medical leaders, hospital administrators, and malpractice insurers to temper their suspicion of the tort system sufficiently

to approach medical errors and adverse events as learning opportunities — and to retain lawyers who embrace mediation as an opportunity to solve problems, show compassion, and improve care,” Liebman says.

Liebman, an internationally recognized expert on mediation and negotiation, directs the Law School’s Mediation Clinic. Co-author Chris Stern Hyman, JD, was formerly an Adjunct Research Scholar at the Law School.

The study looked at 31 cases from 11 nonprofit hospitals in New York City in 2006 and 2007 that went to mediation. About 70% of the cases settled either during or after mediation, resulting in monetary settlements from \$35,000 to \$1.7 million.

On the surface, Liebman says, the case for mediation would appear to be compelling in medical malpractice cases. She cites these reasons:

- The outcome is under the parties’ control.
- Plaintiffs can receive payment soon after the harm instead of waiting years.
- Defendants do not have to pay outside lawyers to try the case.
- Members of the medical staff do not have to prepare for discovery and a trial.
- Even if the mediation does not resolve the case, it may create enough momentum to lead to a settlement.

In spite of those benefits and the fact that many of the mediated cases settled, Liebman says “major challenges” remain for mediation to gain greater acceptance in malpractice suits.

“Most significantly, in none of the cases studied did a doctor take part in the mediation,” she says. “It is possible that plaintiffs would have been even more satisfied with the process had their physicians demonstrated respect and caring” by attending the mediation.

Defense lawyers often cited the doctors’ work schedules to explain their absence, Liebman says. Others did not want to subject the doctors to being verbally attacked by the plaintiff. This “deprives them and their patients of the opportunity for healing, understanding, forgiveness, and repair of broken relationships and failed communication,” the study concluded.

The authors cited research that found patients expect an apology after a medical error, and that most doctors want to oblige, but they — and their lawyers — refrain from doing so out of fear of legal liability. However, the confidentiality of mediation would obviate that, Liebman says.

“Anecdotes abound of injured patients and their

family members who have continued to seek care from — and even recommended to their friends — hospitals that apologize for medical errors and adverse events,” according to the study.

The absence of doctors in mediation also limits the ability, the authors write, for doctors and hospitals to learn from the medical errors and improve the quality of care.

REFERENCE

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SOURCE

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More than \$9 billion recovered from fraud

Since January of 2009, the Justice Department’s Civil Division and the U.S. Attorneys around the nation have recovered more than \$9 billion in cases alleging false claims, fraud against the government, and violations of the Food, Drug and Cosmetic Act.

Cases alleging fraud or false claims against government health care programs are the largest portion of these recoveries, and during this period the Justice Department has opened more health care fraud cases, secured larger fines and judgments, and recovered more dollars lost to health care fraud than in any other period: more than \$5 billion, the Justice Department reports.

Criminal fines, forfeitures, restitution, and disgorgement under the Food, Drug and Cosmetic Act have yielded another \$3 billion — again, a record number.

In some of the biggest recoveries recently, Abbott Laboratories Inc., B. Braun Medical Inc. and Roxane Laboratories Inc. (now known as Boehringer Ingelheim Roxane Inc.) and affiliated entities have agreed to pay \$421 million to settle False Claims Act allegations, the Justice Department announced recently. These settlements resolve claims by the United States that the defendants engaged in a scheme to report false and

inflated prices for numerous pharmaceutical products knowing that federal health care programs relied on those reported prices to set payment rates. The actual sales prices for the products were far less than what defendants reported, the Justice Department says.

The difference between the resulting inflated government payments and the actual price paid by health care providers for a drug is referred to as the “spread.” The larger the spread on a drug, the larger the profit for the health care provider or pharmacist who gets reimbursed by the government, Tony West, JD, assistant attorney general for the Justice Department’s Civil Division, explained when announcing the settlement. The government alleges that Abbott, Roxane, and B. Braun created artificially inflated spreads to market, promote, and sell the drugs to existing and potential customers.

Because payment from the Medicare and Medicaid programs was based on the false inflated prices, the government alleged that the defendants caused false claims to be submitted to federal healthcare programs, and as a result, the government paid millions of claims for far greater amounts than it would have if Abbott, B. Braun, and Roxane had reported truthful prices.

Abbott is paying \$126.5 million to resolve the claims against it in two *qui tam* cases. In the first, the United States intervened and filed suit against Abbott in May 2006. This case initially was filed in the Southern District of Florida before being transferred for pre-trial proceedings to pending multi-district litigation in the District of Massachusetts. In this case, the United States alleged violations by Abbott of the False Claims Act with respect to its pricing of dextrose solutions, sodium chloride solutions, sterile water, and vancomycin. The second lawsuit was filed by a whistleblower and involved Abbott’s pricing of the drug erythromycin, an oral antibiotic.

“With these settlements, the Department of Justice has now recovered more than \$1.8 billion from pharmaceutical manufacturers arising from similar unlawful drug pricing schemes,” West said. “By offering their customers one price and then falsely reporting a greatly inflated price to the lists the government uses when determining how much to pay for the drugs, we believe pharmaceutical companies created an incentive for the purchase of their drugs, since buyers could obtain government payment at the inflated price and pocket the difference.” ■

Hospital CEO guilty of six felony counts

In a case that should frighten every hospital administrator who thinks he or she won’t be held personally responsible for criminal fraud, the former CEO and president of Archbold Medical Center and Archbold Memorial Hospital in Thomasville, GA, is facing a potential 105 years in prison after being convicted of six felony offenses related to Medicaid fraud and obstruction of justice.

The United States Attorney for the Middle District of Georgia, Michael J. Moore, JD, announced the trial results recently. Ken B. Beverly was convicted after a 7-day jury trial. Beverly had served as CEO and president of the hospital for 20 years.

Beverly was convicted on all six counts against him: conspiracy to falsify records, two counts of falsification of records, two counts of obstruction of justice, and one count of misleading statements.

Prosecutors alleged that Beverly participated in a conspiracy to falsely portray Archbold Memorial Hospital as a public hospital, controlled and owned by a governmental authority, in order to qualify for additional Medicaid funds. In fact, Archbold Memorial Hospital is, and always has been, a private not-for-profit hospital, Moore said.

Beverly conspired with former CFO William Sellers to create fictitious documents showing the City of Thomasville Hospital Authority owned and controlled Archbold Memorial Hospital, according to Moore. Beverly directed Sellers to send these fraudulent documents to the Georgia Department of Community Health in order for Archbold Memorial to receive funds as a public, rather than a private hospital, Moore said. Federal Medicaid officials had requested proof of Archbold’s public status.

“Mr. Beverly’s conduct is an example of extraordinary greed,” Moore said. “He was willing to try and fraudulently obtain money from a public program specifically designed to guarantee that those who need medical care — but can’t afford it — have a way to receive treatment. With the crisis in our health care system, this type of fraud and abuse is simply reprehensible.”

Beverly was accused of attempting to induce Sellers to remain silent about Beverly’s role in the conspiracy in exchange for Beverly’s efforts to protect Seller’s retirement benefits. The convictions carry possible prison terms of up to 20 years each, for a total of 105 years possible, plus monetary penalties. ■

Tort reform doesn't alleviate doctors' fear

Physicians' fears of being sued for malpractice are out of proportion to their actual risk of being sued, according to a recent study by a University of Iowa researcher and colleagues.

The study also suggests that tort reform legislation aimed at controlling malpractice costs has not lessened physician concerns about malpractice lawsuits, and it may not be effective in altering defensive medicine practices — like ordering unnecessary lab tests — that can drive up the cost of health care, says senior study author **David Katz, MD**, associate professor of medicine with University of Iowa Health Care.

“We found that both generalist and specialist physicians fear being sued for malpractice, even in states where their risk of being sued is relatively low,” Katz says. “One likely explanation is that physicians' concerns about malpractice are driven more by their perception that the malpractice tort process is unfair and arbitrary — and less by their actual risk of getting sued.”

Katz, who also is a research investigator in the Center for Research in the Implementation of Innovative Strategies in Practice at the Iowa City Veterans Affairs Medical Center, conducted the study with colleagues from the Center for Studying Health System Change in Washington, DC, and the Harvard School of Public Health. The findings were published in the September issue of the journal *Health Affairs*.¹

The research team surveyed a nationally representative sample of physicians and found high levels of concern about being sued for malpractice among all physicians regardless of specialty or geographic location.

Physicians in the highest-risk states, however, expressed only modestly higher levels of concern than physicians in low-risk states (4.3 points on a 100-point scale). This small difference was particularly surprising given that physicians in the least risky states have less than one-third of the malpractice risk as those in the most risky states, Katz says. The researchers used objective measures of risk, such as malpractice premium rates and risk of incurring a paid malpractice claim, to calculate physicians' actual malpractice risk.

“The high levels of malpractice concern, even among physicians in relatively low-risk environ-

ments, is striking,” Katz says. “One possible explanation is that most physicians do not have the information to accurately access their actual risk of being sued.”

Many tort reform efforts are driven by the idea that fear of being sued leads physicians to practice defensive medicine, which raises health care costs, he says.

The study showed that several types of state tort reforms, such as caps on total damages, are individually associated with significantly reduced malpractice concerns, but the results were mixed.

Overall, Katz says the study suggests that current tort reform efforts aimed at reducing malpractice risk would be relatively ineffective in alleviating physicians' concern about lawsuits and therefore may not alter defensive medicine practices.

REFERENCE

1. Carrier ER, Reschovsky JD, Mello MM, et al. Physicians' fears of malpractice lawsuits are not assuaged by tort reforms. *Health Affairs* 2010;29:1585-1592. ■

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe the legal, clinical, financial and managerial issues pertinent to risk management;
- explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
- identify solutions to risk management problems in health care for hospital personnel to use in overcoming the challenges they encounter in daily practice. ■

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CNE QUESTIONS

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity with the **June** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue in order to receive a letter of credit. When your evaluation is received, a credit letter will be mailed to you.

5. What was the ruling in *OFCCP v. Florida Hospital of Orlando*, DOL OALJ, No. 2009-OFC-00002?

- A. A Florida hospital's TRICARE contracts trigger affirmative action obligations under federal law.
- B. A Florida hospital's TRICARE contracts do not trigger affirmative action obligations under federal law.
- C. A Florida hospital's TRICARE contracts are irrelevant to the question whether the hospital has affirmative action obligations under federal law.
- D. A Florida hospital may determine internally whether TRICARE contracts trigger affirmative action obligations under federal law and federal authorities must abide by its decision.

6. According to Monica M. Fanning, JD, a shareholder with the law firm of Polsinelli Shugart in Kansas City, MO, how is the Office of Federal Contract Compliance Programs (OFCCP) addressing its monitoring of the requirements for federal contractors?

- A. It is decreasing its oversight of the requirements.
- B. It is increasing its oversight of the requirements.
- C. It is neither increasing nor decreasing its oversight of the requirements.
- D. It is claiming that it has no jurisdiction that another federal department take responsibility for oversight of the requirements.

7. According to Tim Folk, a producer at The Graham Company, an insurance broker and consulting firm in Philadelphia, which is true when a claim is filed against a volunteer, resulting from harm or loss caused by another volunteer?

- A. The volunteer who caused the injury would not typically be covered by your organization's General Liability Policy.
- B. Federal law prohibits the health care organization from providing any insurance coverage or defense to the volunteer who caused the injury.
- C. State law typically provides a defense fund for volunteers who are sued in the course of their volunteer work, and this defense extends to the organization.
- D. The volunteer who caused the injury would typically be covered by your organization's General Liability Policy for these types of claims since volunteers are included as "Insureds" in the standard ISO policy form.

ANSWERS: 5. A; 6. B; 7. D.

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Alleged Failure to Perform Adequate Follow-Up Care and Investigate Cause of Pain Leads to \$500,000 Settlement

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NEWS: At the age of 69, a woman underwent rectal prolapse surgery. After conducting a preoperative history and physical exam on the woman, her internist released her for surgery. The preoperative lab results showed that the woman had a hemoglobin lower than usual, indicating possible anemia. The internist informed the surgeon of the hemoglobin level, but no additional blood work was requested on the woman. Two days after the surgery, a hospital resident saw the patient, who was complaining of severe abdominal pain. The resident prescribed a muscle relaxer and discharged the woman. Two hours after discharge, the woman died. During the fourth day of trial, the hospital settled with the plaintiff for \$500,000. The other defendants in the case received a directed verdict in their favor.

BACKGROUND: A 69-year-old woman underwent rectal prolapse surgery at an area hospital. This surgery is meant to treat a condition in which the rectum falls, or prolapses, from its normal anatomical position because of a weakening in the surrounding supporting tissues. Risks associated with rectal prolapse surgery include potential complications associated with anesthesia, infection, bleeding, injury to other pelvic structures, recurrent prolapse, and failure to correct the defect. The surgery was performed by a colorectal surgeon after receiving clearance from the woman's internist. Prior to the surgery, the woman had visited her

internist, who had performed a presurgical history and physical and lab work. The lab work indicated that the woman's hemoglobin was 7.4, lower than usual and a possible indication that the woman may have been suffering from mild anemia. The results were discussed with the colorectal surgeon, but no additional tests were ordered by either physician, as the physicians attributed the numbers to the woman's bleeding rectal prolapse. During the surgery, the woman received multiple blood transfusions due to the ongoing loss of blood. Two days after surgery, a resident physician employed by the hospital visited the woman, who was complaining of severe abdominal pain. The resident believed that the pain was due to spasms that may have been caused by the position the woman was forced to lie in during the surgical procedure and prescribed the woman a muscle relaxant. The woman was discharged by the resident. Two hours after discharge, the woman died.

An autopsy revealed hemorrhagic pancreatitis, which caused internal bleeding and shock, resulting in the woman's death. The plaintiff alleged that the woman's hemoglobin was well below normal ranges and should have been at least 10 to allow for the loss of blood during surgery, but allowing the woman to survive. The plaintiff further argued that the colorectal surgeon should have ordered more blood during the surgery to combat the blood complication, and that the resident should have further investigated the abdominal pain.

The internist physician argued that no additional testing was required based on the low hemoglobin and that it was not his responsibility to ensure that adequate blood transfusions were accomplished during the procedure. Both the colorectal surgeon and the resident claimed that their actions were reasonable and met the standard of care. All three defendants further contended that the hemorrhagic pancreatitis complication could not have been diagnosed in advance and that no treatment is available for the condition, such that death was the inevitable outcome.

The resident and the hospital settled with the plaintiff on the fourth day of trial for \$500,000. With regard to the remaining defendants, the colorectal surgeon and the internist, the court found that the alleged deviations from the standard of care were not the proximate cause of the woman's death and directed a verdict in their favor.

REFERENCE

Cook County (IL) Circuit Court, Case No. 06L-11429

WHAT THIS MEANS TO YOU: This case of a 69-year-old woman who died two hours after hospital discharge following rectal prolapse surgery raises questionable assessment, diagnosis, and monitoring concerns. While the litigation outcome resulted in defense verdicts and a hospital settlement, what this case means to you is the importance of implementing assessment, risk-prevention, and risk-reduction strategies for all those involved in providing safe patient care. To discharge a two-day postoperative patient complaining of severe abdominal pain, with a prescription of a muscle relaxant and no diagnostic studies to confirm the source and/or cause of the pain, is a prescription for high-risk scenarios, litigation potential, and negative outcomes.

One of the risk factors in this case began with the patient's pre-op low hemoglobin result of 7.4; a normal hemoglobin range for adult females is 12-16 and for elderly females, 11.7-13.8. Physicians frequently consider blood transfusions for those with a hemoglobin level of 8 or 9. A low hemoglobin may indicate anemia, recent hemorrhage, or fluid retention which dilutes hemoglobin in the body. This test measures the severity of the anemia and also monitors response to interventional therapy. Although proceeding with surgery in a patient

with such a low hemoglobin rests within the surgeon's professional judgment, reducing risks by repeating the test and considering provision of interventional therapy prior to surgery would have been prudent in minimizing bleeding risk. In addition, hematocrit levels (which also detect anemia and other abnormal blood conditions) serve as a monitor for blood loss and evaluation of blood replacement, and are important in assessing patient status and potential blood replacement needs.

It was noted in the case summary that the patient required and received multiple units of blood during the surgical procedure. This is another risk factor that might have been prevented, but still should alert all staff monitoring the patient postoperatively to the potential of subsequent additional bleeding. Signs and symptoms of bleeding can include tachycardia, tachypnea, hypotension; bleeding in the abdomen may include severe abdominal pain, tenderness, guarding, distention, rigidity, diminished or absent bowel sounds; clinical signs of hemorrhagic pancreatitis may include all of the above plus vomiting, diarrhea, fever, and basilar rates — especially in the left lung.

Hemorrhagic pancreatitis is a potentially fatal inflammation of the pancreas characterized by formation of necrotic areas on the surface of the pancreas and omentum, which may lead to bleeding. Statistics related to acute pancreatitis indicate such a diagnosis in 40 cases per year per 100,000 adults. In 20% of those presenting with acute pancreatitis, there is a mortality rate of 30%. In the case presented here, the post-mortem findings of hemorrhagic pancreatitis benefited the defendants and overshadowed the failure to determine/diagnose and attempt to treat the cause of the severe abdominal pain. In a failure to order diagnostic tests case, *Steeves v. United States*, physicians failed to perform tests and diagnose a patient's condition; the court pointed out that "a wrong diagnosis will not in and of itself support a verdict of liability in a lawsuit. However, a physician must use ordinary care in making a diagnosis." In *Steeves v. United States*, failure to perform additional diagnostic studies was found to be a breach of good medical practice.

Severe abdominal pain, particularly in that of a two-day post-op patient, warranted and required thorough and methodical assessment and monitoring. What does this mean to you?

To provide a prescription for pain medication at discharge in a patient with unresolved and undetermined severe abdominal pain, with no opportunity to clinically monitor the effects of the prescribed medication in respect to the pain, was careless. To discharge a post-surgical patient who was experiencing severe abdominal pain was reckless; such actions do not serve to prevent or minimize risks for the health care provider and health care organization. Most importantly, such actions do not promote safe patient care. In spite of the favorable defense verdicts, this case gives pause for reflection as to what could have been done differently to achieve a more positive outcome for the patient. While it is true the post-mortem diagnosis rendered the deviations from the standards of care not proximate to the cause of death, and ultimately the patient's diagnosis may have been fatal, to die two hours after discharge with a noted complaint of severe abdominal pain is tragic. ■

Nursing Home Resident Dies After Fall; \$900K Verdict

NEWS: An 83-year-old man was admitted to a nursing facility after suffering a broken hip and a stroke. The hospital, prior to discharge, determined that the man required 24-hour stand-by assistance for all movement. The admitting nurse at the nursing facility, however, assessed the man and determined that he was independent in ambulation and needed no assistance for daily routine activities. Shortly after being admitted, the man fell. On the third day after being admitted, a fire broke out in the facility. During the evacuation process, the man fell again and dislocated his previously fractured hip. The man was taken to a hospital, where his hip was dislocated six additional times. The man died three months after first being admitted to the nursing home of complications from the hip fracture and dislocations. A verdict in favor of the plaintiff was entered in the amount of \$915,397.

BACKGROUND: An 83-year-old man was admitted to the hospital for the repair of his broken hip. While in the hospital following surgery, the man suffered a stroke, leaving him paralyzed

on his left side. The stroke and subsequent paralysis left the man with significant problems ambulating. It was at this time that the man was assessed, and it was determined that he required 24-hour stand-by assistance for all movement.

Subsequently, the man presented to a local nursing home. At the time of admission, the admitting nurse assessed the man as being independent in ambulation and needing no assistance for daily routine activities. It was also noted that the man had made a good recovery from the stroke and only needed around-the-clock supervision. Shortly after being admitted to the facility, the man fell. Three days after admission, a fire broke out during the night shift in the nursing facility, requiring evacuation of the residents. The man was not assisted in the evacuation, as there was only one nursing aide on the floor that evening for 24 residents. During the evacuation, the man fell, despite use of a four-point walker. The man's previously dislocated hip was fractured. The fractured hip was identified by nursing home staff at the time residents were allowed to reenter the building. The man was taken to the hospital, where he suffered six additional dislocations. Due to the circumstances, the man's condition further deteriorated, and he suffered kidney failure, underwent surgery on the hip, and contracted a hip infection. The man ultimately died.

The plaintiff in this case alleged many errors on the part of nursing home personnel. Specifically, the plaintiff contended that the man was admitted to the facility without proper evaluation. Additionally, the plaintiff claimed the nursing home's failure to conduct another evaluation of the man after the first fall was a deviation from the standard of care. With respect to the second fall that occurred during the fire evacuation, the plaintiff alleged that the man was overmedicated, which contributed to his fall and the complications leading ultimately to his death.

The defendant countered the plaintiff's claims and contended that the nursing home was not provided with the man's medical records upon admission. The defendant also denied that the man was overmedicated or that his hip was fractured because of the fact that the man never complained of pain when he was carried out of the facility by a firefighter attending to the situation.

The jury in the case returned a verdict in favor of the plaintiff in the amount of \$915,397.

REFERENCE

Portage County (WI) Circuit Court, Case No. 06 CV 63.

WHAT THIS MEANS TO YOU: In this case of an 83-year-old gentleman with a history of hip fracture and subsequent stroke, who was discharged from a hospital to a nursing facility, appropriate and ongoing assessment is central to the verdict for the plaintiff. Considering life expectancy, his age and death were most likely primary factors in determining the amount of the verdict, particularly in light of the breach of duty, resulting injuries, and causation in this case. The failure to adequately assess the resident, resulting in multiple dislocations, complications, and ultimate death could otherwise have led to a higher dollar verdict.

The hospital assessment indicated the patient required 24-hour stand-by assistance for all movement. The fractured hip history, followed by a stroke and subsequent left-sided paralysis, were but a few of the risk factors for falls. The nursing facility's claim of not being provided the patient's medical records upon admission to the nursing facility was a poor excuse — inappropriate and unacceptable. According to the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission, it is the responsibility of the health care organization, whether in an acute or long-term care setting, to adequately and appropriately assess and periodically reassess the patient or resident. This is not optional. The nursing facility was responsible for performing an intake assessment prior to admission to determine if they could accept the patient and meet his needs, and were responsible for performing an admission assessment once the patient was discharged from the acute care setting and became a resident of the nursing facility. One would certainly question the validity of the initial nursing home assessment, especially in consideration of the patient's history, when he was assessed to be independent for ambulation and activities of daily living.

The Joint Commission's National Patient Safety Goals (NPSG) for Long Term Care include the requirement to reduce the risk of falls, as it does in the acute care setting. Long Term Care's NPSG.09.02.01 requires accredited facilities to "reduce the risk of resident harm from falls" and provides the following rationale for this goal: "Falls account for a significant portion of injuries in hospitalized patients, long-

term care residents, and home care recipients. In the context of the population it serves, the service it provides, and its environment of care, the organization should evaluate the resident's risks for falls and take action to reduce the risk of falling, as well as the risk of injury, should a fall occur. The evaluation could include a resident's fall history; review of medications and alcohol consumption; gait and balance screening; assessment of walking aids, assistive technologies, and protective devices; and environmental assessments." The Elements of Performance for NPSG.09.02.01 are (1) Assess the resident's risk for falls (2) Implement interventions to reduce falls based on the resident's assessed risk (3) Educate staff on the fall reduction program in time frames determined by the organization (4) Educate the resident and, as needed, the family on any individualized fall reduction strategies and (5) Evaluate the effectiveness of all fall reduction activities, including assessment, interventions, and education.

As noted, the responsibility for assessment, particularly falls risk assessment, clearly rests on the shoulders of the health care organization. There are tools, however, to assist in the assessment process. One such tool is the Morse Fall Scale, developed by Janice M. Morse in 1985 and deemed by many health care organizations as a falls risk assessment standard. The Morse Fall Scale scores the variables of history of falling, secondary diagnosis, ambulatory aid, IV or IV access, gait, and mental status; the higher the score, the higher the risk. Low-, medium-, or high-risk prevention interventions are then to be implemented in correlation with the score.

The assessment issues in this case were compounded by the nursing facility fire, but they still did not excuse the organization from initially performing an adequate and appropriate assessment. It is sad and frightening to think this resident was left to his own devices to evacuate the facility and that one nursing assistant was responsible for 24 residents. The "no complaint of pain" used as a determination of a non-fracture was frivolous on the part of the defendant. Nonetheless, a second falls assessment was required after the first fall in the nursing facility, which may have helped to prevent or reduce the risk of a second fall during the fire and the resident's subsequent health complications and death. A verdict for the plaintiff was not a surprise in this case. ■

Importance of security risk assessments rise with advent of electronic health records

Millions available for hospitals that meet meaningful use requirements

A landmark study conducted by the Poneman Institute Reference shows that 70% of hospitals say that protecting patient data is not a top priority and 67% have less than two staff members dedicated to protection management.¹ (See page 3 for more study results.)

Hospitals and other covered entities have a new incentive to step up efforts to protect patient data and conduct annual security risk assessments now that meaningful use and incentive payments under the Health Information Technology for Economic and Clinical Health (HITECH) Act are available. The meaningful use regulations require organizations to conduct or review a security risk analysis and implement security updates as needed, along with correcting identified security deficiencies as part of their risk management process.

“People have ignored the need for a decent risk assessment and have chosen to accept the risk of a breach as less costly than the investment needed for thorough risk assessment,” says **Feisal Nanji**, executive director of Techumen, a consulting firm focused on securing health care information. Incentive payments for meaningful use of elec-

tronic health records (EHRs) are significant and will make the risk assessment more important for organizations, he says.

“The incentive payments are a significant source of funds to offset the implementation of electronic health records, but to be eligible, your risk assessment must be based upon National Institute of Standards and Technology’s [NIST] guidelines,” says Nanji. (See resources, page 2 for guidelines.) The financial incentives for hospitals are based upon an initial base payment of \$2 million, plus an amount per Medicare patient discharge for the year, with a four-year cap of \$11 million. Physicians and other eligible professionals can receive incentive payments up to \$18,000 per year with a maximum payout of \$44,000.

The last day that hospitals can register and attest to receive an incentive payment for the federal fiscal year 2011 is Nov. 30, 2011, so there are a number of steps hospitals can take to be sure they are able to participate in the program, says **Sandra E. Quilty**, JD, attorney, Baudino Law Group, Des Moines, IA. (See page 3 for all deadlines.) “Larger hospital systems have the technical, legal, and op-

Executive Summary

Information security has moved up the priority list for hospitals that want to participate in the Center for Medicaid & Medicare Services’ meaningful use incentive program. Security risk assessments that meet specific standards are required to qualify for payments of up to \$11 million over four years to offset the cost of implementing electronic health records.

- Risk assessments must be based upon National Institute of Standards and Technology’s guidelines.
- A need to improve data protection is evident, according to a Poneman Institute study that shows 70% of hospitals say that patient data protection is not a top priority.
- Hospitals should evaluate who is in charge of monitoring information security, and ensure that operations and compliance are separate functions in separate departments to improve integrity of monitoring function.

erational support needed to comply with meaningful use requirements, but small or rural hospitals may find the regulations burdensome,” she says.

The Department of Health and Human Services’ Regional Extension Centers are designed to provide some of the technical assistance that critical access and rural hospitals need to convert from paper-based medical records to certified EHR technology, she says. (*See resources, this page.*)

The security risk assessment should include all of the key players in implementing and ensuring the security of an EHR system, says Quilty. Information technology, compliance officers, clinical leaders, legal counsel, and key managers of departments that will use or support the system should be involved in identifying and evaluating potential security risks, she says.

An EHR system poses different security challenges than many information systems, says Nanji. While you can control the number of individuals who access different types of information throughout a hospital, electronic medical records must be easily accessed by a wide range of providers to ensure quality care, he explains. “This increases the opportunity for unauthorized access or use of information so the assessment must be thorough to identify and minimize risks,” he adds.

Another issue that many hospitals need to address to ensure security on an ongoing basis is the identification of the right person to monitor the integrity of information systems, says Nanji. “In most hospitals, the chief information officer or someone who reports to the chief information officer is often the person designated to monitor the security of the system, even if he or she reports to a person who serves as the overall compliance officer,” he says. This means that hospitals are asking an operations person, the CIO, to also monitor and ensure security — two tasks that may be at odds with each other, he says.

“As an operations manager, the CIO must meet budget restrictions and keep the information systems up and running efficiently,” he points out. “As a security officer, the CIO may identify upgrades or enhancements to the system that may not be within budget parameters or will not be as convenient for system users,” he says. In most cases, the CIO will make decisions that favor operations if the security risk is not deemed as important as the need for cost-efficiency, he adds.

“I always ask compliance officers if they are sure they are getting the information they need from their CIO,” says Nanji. Enhanced criminal, civil, and monetary penalties that are in place with the passage of HITECH increase the importance of

Resources

- National Institute of Standards and Technology’s free Special Publication 800-30, Risk Management Guide for Information Technology, can be accessed at csrc.nist.gov/publications/nistpubs/800-30/sp800-30.pdf.
- A list of Department of Health and Human Services’ Regional Extension Centers can be found at <http://healthit.hhs.gov>, selecting “HITECH Programs” on the left navigation bar and choosing “Health Information Technology Extension Program.”
- A list of certification rules and programs for electronic health records can be found at <http://healthit.hhs.gov>. Select “Regulations and Guidance,” then “Standards and Certification,” and “Certification Programs.”
- The health information technology association, Healthcare Information Management and Systems Society (HIMSS) offers the Meaningful Use OneSource, a compilation of documents, tools, and links to other resources related to Meaningful Use and Certification Criteria and Standards. Go to http://www.himss.org/ASP/topics_meaningfuluse.asp, and choose from the left navigation bar.
- Free tools to help health care organizations track the requirements for EHR incentive payments can be found at www.hitechanswers.net. Select “Free EHR Tools” at the bottom of the page.

compliance officers getting the right information at the right time, he says. “A hospital governance structure that places responsibility for information security separately from information operations is the best approach,” he says. “I also recommend that compliance officers be able to understand the information they need and to obtain advice from outside consultants if necessary,” he adds.

The security risk assessment is only one part of the requirements for Phase I of the meaningful use of electronic health records, points out Quilty. The other requirements include the use of technology certified by the Centers for Medicare & Medicaid Services (*see resource box on page 2 for information about certification agencies*), core clinical measures

that must be reported, basic requirements of the system including computerized physician order entry and e-prescribing, and patient communication capabilities. “Other phases of the meaningful use rule will expand upon these requirements and will be published in 2013 and 2015,” she says.

Throughout all phases of electronic medical record implementation, security will continue to be important, says Nanji. “The security risk assessment is critical, but a hospital’s responsibility doesn’t end with the assessment. You must be prepared to identify your risk and explain how you will address the risks on an ongoing basis.”

REFERENCE

1. Ponemon Institute, Benchmark Study on Patient Privacy and Data Security 2010. Traverse City, MI.

[For more information about security risk assessment for meaningful use, contact:

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Patient data protection not a top priority

Hospitals report too few resources to be effective

Data breaches cost health care organizations more than \$6 billion annually, and 71% of the respondents to a study released by the Ponemon Institute say they do not have enough resources to prevent or to quickly detect a loss of patient data.¹

The study surveyed 65 hospitals in the 100- to 600-bed range, with researchers interviewing an average of 3.25 senior-level personnel in each organization.

Study findings include the following:

- The majority of responding organizations have less than two staff dedicated to data protection management (67%).
- Hospitals say that protecting patient data is not a top priority (70%).
- Most at risk is patient billing information and medical records.
- Patients are typically first to detect a significant number of breaches at health care organizations (41%).

Meaningful use incentive program dates

- Oct. 1, 2010 — Reporting year began for eligible hospitals and critical access hospitals (CAHs).
- Jan. 1, 2011 — Reporting year began for eligible professionals.
- Jan. 3, 2011 — Registration for the Medicare EHR incentive program began.
- Jan. 3, 2011 — For Medicaid providers, states may launch their programs if they so choose.
- April 2011 — Attestation for the Medicare EHR incentive program begins.
- May 2011 — EHR incentive payments expected to begin.
- July 3, 2011 — Last day for eligible hospitals to begin their 90-day reporting period to demonstrate meaningful use for the Medicare EHR incentive program.
- Sept. 30, 2011 — Last day of the federal fiscal year. Reporting year ends for eligible hospitals and CAHs.
- Oct. 1, 2011 — Last day for eligible professionals to begin their 90-day reporting period for calendar year 2011 for the Medicare EHR incentive program.
- Nov. 30, 2011 — Last day for eligible hospitals and critical access hospitals to register and attest to receive an incentive payment for federal fiscal year (FY) 2011.
- Dec. 31, 2011 — Reporting year ends for eligible professionals.
- Feb. 29, 2012 — Last day for eligible professionals to register and attest to receive an incentive payment for calendar year (CY) 2011.

- 60% of organizations had more than two data breaches in the past two years. The average number for each participating organization was 2.4 data breach incidents.

- The average number of lost or stolen records per breach was 1,769. A significant percentage of organizations either did not notify any patients (38% or notified everyone [34%]) that their information was lost or stolen.

- The top three causes of a data breach are: unintentional employee action, lost or stolen computing devices, and third-party mistake.

- 41% discovered the data breach as a result of a patient complaint.

- More than half (58%) of organizations have little or no confidence that their organization has the ability to detect all patient data loss or theft.

- 63% of organizations say it took them between one to six months to resolve the incident.

- 56% of respondents have either fully implemented or are in the process of implementing an EHR system. The majority (74%) of those who have an EHR system say it has made patient data more secure.

REFERENCE

1. Poneman Institute, Benchmark Study on Patient Privacy and Data Security 2010. Traverse City, MI. ■

Pay attention to content of phone messages

Honor patient requests for phone privacy

Calling to remind patients of their appointments, instructions on how to prepare the night before a procedure, or to see if patients have questions prior to surgery are important ways to keep your outpatient surgery or diagnostic testing departments' schedules on track. With the renewed focus on privacy and security of patient information, how much information can you leave on a voice mail service that may be accessed by people other than the patient?

According to a FAQ on the Office of Civil Rights website, you can leave information for patients on answering machines or voice mail systems, but to safeguard their privacy, you should limit information to only what is needed to confirm an appointment. If more information is needed, ask the patient to return the call.

Although you can leave a message, pay attention to some diagnoses that are covered by more stringent privacy laws, says Vicki Hohner, MBA, senior HIPAA consultant, Fox Systems, a Scottsdale, AZ-based consulting firm specializing in health information technology implementation in health care. "Some diagnoses, conditions and services, such as HIV/AIDS, reproductive health, and mental health or drug and alcohol diagnoses and treatment are covered under more stringent state and federal privacy laws and may restrict what, if anything, can be communicated by phone," she says. "Other considerations such as domestic violence and protective orders may also restrict what communica-

tions can be made via phone," she adds.

It is not a bad idea to ask your patients how they want you to handle messages, either on voice mail or with another family member who answers the phone. Although the privacy rule allows providers to disclose limited information to family or friends not involved in the patient's care, it is up to the provider to use professional judgment to determine what is best for the patient.

"If other persons living in the household are involved in the patient's care and treatment, the provider may provide additional details subject to professional judgment," says Hohner. "The patient can also specifically authorize access to other persons who would potentially answer the calls," she says. Of course, if the person who would potentially receive the calls is a personal representative of the patient, through power of health care attorney or power of attorney, that person has the legal authority to access any of the patient's information as if he or she were the patient for as long as they hold that legal power, she adds.

Permissions to give information or messages to other people are not normally needed for each individual visit, but are not necessarily permanent either, says Hohner. "Time limits on each approach can be set independently and as determined by the physician and/or patient," she explains. "However, the patient has the right to revoke any of these permissions for any reason at any time," she says.

"Verification of the individual who answers the telephone is not necessarily required under HIPAA, but many providers have instituted verification practices, at least in the office setting, to avoid medical identity theft and other potential inappropriate disclosures such as those related to domestic violence or child abuse," says Hohner. "It is at the discretion of the provider to obtain further verification if desired or required by other law or professional practice," she says. Some providers only leave messages when the patient is identified by name on the voice mail or answering machine.

[For more information about HIPAA privacy rules, contact:

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RESOURCE

To see answers to frequently asked questions related to HIPAA privacy and security, go to <http://www.hhs.gov/ocr/privacy/hipaa/faq/index.html>, and enter keywords to search for answers. ■