Healthcare Risk Management™

Note: New CME procedures. See p. 83 for details.

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AHC Media

Specimen labeling still a major risk for ID errors and huge liability

Technology, focus on human factors can help

Patient identification errors continue to plague the healthcare industry despite years of efforts to eradicate this potentially disastrous problem. Understanding why patients and specimens are misidentified is key to reducing or eliminating errors, and risk managers can make progress by focusing on the human behavioral components of healthcare work.

Specimen labeling is one of the biggest risks for misidentification, with errors leading to delayed or wrong diagnoses, missed or incorrect treatments, blood transfusion errors, and additional laboratory testing. Literature reviews have identified specimen labeling error rates of 0.1% to 6.5%.

Recognizing this risk, The Joint Commission has implemented two hospital National Patient Safety Goals (NPSGs) for 2011 related to patient identification: NPSG.01.01.01 is "Use at least two ways to identify patients. For example, use the patient's name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment." NPSG.01.03.01 is "Make sure that the correct patient gets the correct blood when they get a blood transfusion." The College of American Pathologists also includes patient and sample identification as one of its five top patient safety goals.

Patient ID Errors

Phlebotomy is one of the fields most focused on labeling errors, and many health care providers take a punitive approach to errors, says **Fran Charney**, RN, MSHA, CPHRM, CPHQ, CPSO, FASHRM, director of edu-

Special Report: Patient identification errors

This month's *Healthcare Risk Management* includes a focus on the perennial and potentially disastrous problem of patient identification errors. Despite an intense focus on proper specimen labeling and other strategies for reducing identification errors, these problems still occur. Our special report provides tips and the latest advice for how to reduce identification errors in your own healthcare organization.

cational programs with the Pennsylvania Patient Safety Authority (PPSA) in Harrisburg, PA. Before joining the PPSA, Charney was a risk manager and patient safety officer.

"Many organizations talk about taking a systems approach, but when it comes to phlebotomy, they have a 'three strikes and you're out' approach," Charney says. "Then we ask if the problem went away when they fired that phlebotomist, and of course they say it didn't." *(The PPSA recently sponsored a multi-hospital blood specimen labeling collaborative that resulted in a 37% decrease in labeling errors. For more on that effort, see the story on p. 75.)*

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EXECUTIVE SUMMARY:

Patient identification errors continue to pose a serious threat to patient safety and liability. Almost one in 1,000 specimen labels are identified incorrectly.

- Human factors, such as workloads and distractions, are key contributors to identification errors.
- Bar coding technology can greatly reduce the chance of errors.
- A project in Pennsylvania reduced identification errors by 37%.

Charney encourages risk managers to look at specimen labeling errors as a system problem, treating them much like any adverse event and asking not just who made the error, but why that error was possible and how it could be prevented. "A lot of times we don't dig deep enough to see why the error occurred," she says. "We just say Sally the phlebotomist made a mistake and put that in her record. If she forgot to double check the ID because the phone was ringing off the hook, why was that? Because you were short staffed? And that was because you had a flu epidemic?"

Understanding human factors is a big part of reducing identification errors, says **Megan Shetterly**, RN, MS, patient safety liaison for the Northeast Region of the PPSA. When investigating an error, ask not only what happened and how, but why, she says. "We need to ask them why several times, to drill down and find out what led to this error, not the simple mechanics of how it happened," Shetterly says. "The nurse or phlebotomist might say she grabbed the wrong label, but you can't leave it at that. Why did she take the wrong label? What was going on, and what about your procedures made it possible for her to do that?"

Common causes are disruptions, interruptions, and increased work load, Shetterly says. The most often cited explanation is that the employee was not following procedures, but the next question must be why, she says. The answer also involves the workload. "They often say that to get the workload done, they don't have time to do the A, B, C, and D that are spelled out in the policies and procedures," Charney says. "So they decide C isn't really necessary, and they do a workaround. That sounds like an individual decision, but we put them in an unsafe place where that looks like the only way out."

Patients should be involved with confirming

their identification as much as possible, Charney says. Too often, she says, the caregiver enters the room and asks "Are you Mr. John Smith?" or says "You're Mr. Smith, right?" and the patient nods or mumbles a response. That is not an acceptable interaction, Charney says. "A much better way is to say, 'Can you state your name for me?'" she says. "That is a very different question, and you get a much better response. Sometimes you can go on and ask the patient to spell the last name. That kind of active participation by the patient is crucial."

Bar coding technology can significantly reduce patient identification errors but it is not a panacea, Shetterly says. She notes that the Centers for Disease Control and Prevention has recognized bar coding as a best practice for specimen collection. *(See the story on p. 77 for more on bar coding.)* "The technology is very good, but it's only as good as the person using it," Shetterly says. "You still have the human element, so errors can occur. We've seen people printing out labels ahead of time, for instance, which facilitates mixing up the labels." *(See the story on p. 76 for more solutions for reducing errors. See the story on p. 77 for identification errors related to cardiac monitoring.)*

Are you at risk for being sued?

The malpractice implications of a mislabeled specimen are significant, says **Laura A. Dixon**, JD, RN, CPHRM, director of the Department of Patient Safety for the Western Region of The Doctors Company, a malpractice insurer in Napa, CA.

A patient might receive care indicated for someone else, while the other patient does not receive needed treatment. "Some of these errors can have long term, lasting physical effects on the patient," Dixon says. "But in addition to the physical problems, the individual also may have emotional trauma. Of the claims we have from identification errors, the majority are about emotional trauma rather than physical injury."

The typical lawsuit involves a relatively young and healthy individual who underwent an unnecessary procedure and believed for some period that he had cancer or another serious illness, Dixon says. The potential liability will depend on how state law addresses claims of emotional distress, but the payout tends not to be in the millions of dollars, she says.

Delayed diagnosis is a bigger liability risk, Dixon says. A delayed diagnosis of cancer because of a specimen mixup, for instance, could result in a costly malpractice lawsuit, she says.

"Those cases tend to involve real injury and perhaps an impact on long term survivability, so they can be quite costly, both in terms of the payout and the cost to defend them," Dixon says.

SOURCES

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PA hospitals cut label errors by 37%

9 hospitals target blood specimens

A project designed to analyze labeling errors and devise solutions resulted in a 37% decrease in errors across nine hospitals in Pennsylvania.

From August 2009 through October 2010, the Pennsylvania Patient Safety Authority (PPSA) sponsored a multi-hospital blood specimen labeling collaborative. The PPSA worked with the hospitals to measure blood specimen labeling error rates, document hospital-specific interventions to reduce the labeling error rate, and measure the outcome of the interventions.

Patient ID Errors

Eight acute care hospitals and one rehabilitation hospital participated in the collaborative, says **Megan Shetterly**, RN, MS, patient safety liaison for the Northeast Region of the PPSA. Each hospital assembled a team to participate in the collaborative, and team members included laboratory directors, phlebotomy supervisors, patient safety officers, and risk management, quality and performance improvement, and regulatory compliance personnel. Some of the hospitals used bar coding technology in some areas but not throughout the hospital.

PPSA provided educational sessions about reli-

able design, just culture, and human factors engineering. Subsequently, each hospital team mapped its blood specimen labeling process, assessed the process for compliance through direct observation, and presented an overview of the processes to the rest of the collaborative participants.

This project was an opportunity for the collaborative participants to identify barriers to labeling compliance that transcended specific care areas and organizations, Shetterly says. Common barriers were those related to technology, communication, education, staffing, workflow, and leadership.

PPSA also trained participants in root cause investigations, and by October 2010 it had collected and analyzed 485 investigations. Facilities reported 520 contributing factors associated with the mislabeling errors. The top three contributing factors were procedures not followed, distractions and interruptions, and unplanned workload increase.

20 interventions address six domains

The collaborative participants implemented more than 20 interventions between April and July 2010. There were six major categories of barriers to blood specimen labeling accuracy: technology, communication, education, staffing, workflow, and leadership. The collaborative participants implemented several interventions within these domains to improve specimen labeling accuracy. Overall, there was a 37% statistically significant decrease in blood specimen labeling errors in the collaborative over the 18-month period, Shetterly says.

The PPSA project also involved patients by encouraging them to question caregivers about following proper identification procedures. Patients were given pens as a small gift that might be used and seen often, and signs were posted in rooms with the slogan "Did you ID me?" Shetterly also encourages hospitals to shadow staff doing blood draws and other specimen collection.

"We followed around some of these nurses who were doing the blood collection, and we saw things that the project managers in the hospital didn't see," Shetterly says. "Sometimes it takes a fresh set of eyes. If you're around the same place long enough, you don't notice that cobweb up in the corner anymore." *(The full PPSA article, "Reducing Errors in Blood Specimen Labeling," is available online at http://www.patientsafetyauthority.org.)* ■

Reduce ID errors with 24/7 phlebotomy

There are ways to minimize labeling errors. Top strategies include bar coding technology, firm policies and procedures, and accounting for the human factors that can prompt errors. Research also suggests that establishing a 24-hour, seven-days-a-week phlebotomy service can reduce errors by leaving blood draws to the people best trained and focused on the task.

Ana K. Stankovic, MD, PhD, MSPH, vice president of medical and scientific affairs and clinical operations with BD Diagnostics, based in Franklin Lakes, NJ, conducted research that involved reviewing more than 3.3 million specimen labels from 147 laboratories.[1] Labeling errors were identified at a rate of 0.92 per 1,000 labels. Two variables were statistically associated with lower labeling error rates: laboratories with current, ongoing quality monitors for specimen identification; and institutions with 24/7 phlebotomy services for inpatients.

Most institutions had written policies for specimen labeling at the bedside or in outpatient phlebotomy areas (96% and 98%, respectively). Stankovic and her colleagues concluded that establishing quality metrics for specimen labeling and deploying 24/7 phlebotomy operations might contribute to improving the accuracy of specimen labeling for the clinical laboratory.

Patient ID Errors

"Dedicated phlebotomists are much better because they are better trained and they are not distracted by needing to do a hundred other things," Stankovic says. "We see hospitals transitioning back to dedicated phlebotomists because they are finding that the front-end costs are offset by the back-end costs of errors, redraws, and other problems."

In addition, patient specimens should include two distinct identifiers, and one should be a number, Stankovic says. For example, the label can include the patient's name and birth date, or name and Social Security number. Using both will help eliminate confusion when patients have similar names, she says.

Another common error occurs when a nurse prints labels at the nursing station, leaves the labels there, and then goes to a patient room to retrieve

a specimen. The nurse comes back with the specimen and grabs the wrong label. "The better way is to print the label at the nursing station, take the one label with you to the patient's room, confirm the identification is correct, and place the label on the specimen at the bedside," she says. "An even better solution is to use a specimen management system with a device that prints the label at the bedside, which can be combined with bar coding on the patient's wrist band."

REFERENCE

1. Wagar EA, Stankovic AK, Raab S, et al. Specimen labeling errors: A Q-probes analysis of 147 clinical laboratories. *Arch Pathol Lab Med* 2008; 132:1,617-1,622.

SOURCE

• **Ana K. Stankovic**, MD, PhD, MSPH, Vice President, Medical and Scientific Affairs and Clinical Operations, BD Diagnostics, Franklin Lakes, NJ. Telephone: (201) 847-4376. E-mail: Ana_Stankovic@bd.com. ■

Bedside barcodes reduce pharm errors

Barcoded wristbands can greatly reduce the opportunity for patient identification errors, says **David Grant**, RPh, MBA, vice president of pharmacy and clinical process improvement at Summit Health in Chambersburg, PA.

The barcoded wrist band is placed on the patient at admission and then is used for all specimen collection and medication administration, Grant says. Summit Health first began using the barcode technology about six years ago, when about 15% of U.S. hospitals were using it, he says. Now that figure is closer to 35%, he says.

Patient ID Errors

Summit's barcode system is used in the pharmacy when the medication is dispensed and also at the bedside before it is administered.

"The nurse uses a handheld scanner to read the barcode, and if they have the right patient, they are allowed to proceed with administering the medication," he says. "If they don't have the correct patient, it closes the medication administration record and notifies them that they don't have the right patient."

As a result of the barcode technology, "wrong patient administration errors have all but disappeared," Grant says. That success eliminates about 30% of all medication errors, he says, because administration errors make up about 15%, dispensing errors account for another 15%, and transcription errors result in about half of all medication errors.

Staff members have responded well to the new system, with more experienced nurses saying they would never want to go back to paper medication orders, Grant says. Summit spent about $1 million on the hardware and other infrastructure necessary for the barcode system. Planning took about two years, and the new system was rolled out over eight months.

"It's been a resounding success for us and we wouldn't go back," he says.

SOURCE

• **David Grant**, RPh, MBA, Vice President of Pharmacy and Clinical Process Improvement, Summit Health, Chambersburg, PA. Telephone: (717) 267-7998. E-mail: dgrant@summithealth.org. ■

ECRI PSO issues caution on cardiac monitoring ID

The ECRI Institute Patient Safety Organization (PSO) recently issued a warning about a patient safety issue involving cardiac monitoring of incorrect patients. The issue was brought to ECRI Institute PSO's attention in its analysis of reports submitted by participating healthcare providers.

ECRI Institute PSO reviewed numerous reports of cardiac monitoring of the wrong patients resulting in the deaths of unmonitored patients who experienced critical arrhythmias, says Clinical Director **Karen Zimmer**, MD.

"Ensuring positive identification of patients is a challenge in all healthcare settings," she says. "Reports submitted to patient safety organizations can help raise awareness of undetected risks occurring in hospitals and healthcare systems."

Zimmer says the potential for identification errors is significant in acute care settings, where a wide range of interventions are delivered in multiple locations by numerous staff who work in shifts. The extent of harm to patients caused by misidentification is unknown.

Although this problem is being seen in a cardiac monitoring situation, this caution applies to more situations throughout the healthcare system, she

says.

The patient safety alert can be found online at https://www.ecri.org/PatientSafetyOrganization/Documents/E-lert_Patient_Identification.pdf. ■

Surgeon whistleblower awarded $4.7 million

Cedars-Sinai Medical Center in Los Angeles will have to pay almost $4.7 million to a surgeon who claims the hospital retaliated against him for blowing the whistle on unsafe practices in his department, unless the hospital manages to have the award overturned. The hospital already has spent as much as $1 million to appeal the arbitration decision, according to the informed estimate of the plaintiff's attorney.

In a 2009 arbitration, the hospital agreed to pay Hrayr K. Shahinian, MD, $4.7 million for economic, emotional and punitive damages, but then it asked a California appeals court to reverse that decision. The court recently denied Cedars-Sinai's request to strike down the arbitrated award.

Cedars-Sinai provided a statement to Healthcare Risk Management which says the hospital is considering a further appeal of the decision and claims that the surgeon's competence was an issue that was not adequately considered in the arbitration. "As a general rule, Cedars-Sinai does not believe it is appropriate to comment on matters pending in the judicial process. We are doing so now only to set the record straight in light of Dr. Shahinian's incomplete and inaccurate statements in his recent news release," the statement says. "Although this matter remains pending in the appellate system, Dr. Shahinian has made certain claims about the outcome of the process so far that are incorrect as to what both the arbitrator and Court of Appeal actually decided. He has also presented an incomplete and inaccurate picture, ignoring that the arbitrator rejected some of the very claims for which he says he was vindicated." *(See the story on p. 79 for more of the response from Cedars-Sinai.)*

The crux of the case was that the hospital did not follow its own bylaws when restricting the surgeon's privileges, says the plaintiff's attorney, **Robert C. Baker**, JD, a partner with the law firm of Baker, Keener & Nahra in Los Angeles. That action ultimately led the arbitrator to side with Shahinian, he says. *(For details on the dispute, see the story on p. 79.)*

Shahinian contends that the hospital punished him for complaining about patient safety and other concerns in the department. "Two witnesses testified that they targeted him because he complained," Baker says. Baker says he expects the hospital to appeal once more, this time to the California Supreme Court. The hospital's continued fighting almost defies logic, he says. Testimony from the Cedars-Sinai chief financial officer revealed that the hospital has $800 million in cash or cash equivalents, Baker says, an astounding sum which he says might explain why it is willing to continue fighting even after the arbitration.

"My educated guess is that since November 2009 they've spent probably at least a half million and maybe a million dollars on their appellate lawyers, and they've run up interest in the neighborhood of $600,000. That's on top of the $4.7 million the arbitrator told them to pay," Baker says. "They've got enough of a bankroll to continue pursuing this beyond anything that is remotely close to what everyone else would consider reasonable. They don't like this guy, and they're willing to spend a huge sum of money to get him."

EXECUTIVE SUMMARY:

A surgeon who complained that patient safety was threatened by inadequate administration support of his department alleges that his privileges were restricted by the hospital in retaliation. He subsequently won a $4.7 million settlement in arbitration.

- Cedars-Sinai Medical Center in Los Angeles denies the claim and says the surgeon was restricted for other reasons.
- An appeals court recently upheld the arbitration award.
- The plaintiff's attorney estimates that the hospital has spent as much as $1 million on appealing the case.

SOURCE

• **Robert C. Baker**, JD, Partner, Baker, Keener & Nahra, Los Angeles. Telephone: (213) 241-0900. ■

Clash with hospital led to restriction of duties

Court records indicate that Cedars-Sinai recruited Hrayr K. Shahinian, MD, to establish and direct its skull-base surgery program in

1996. The doctor's experience at the hospital was rocky from the start, says his attorney **Robert C. Baker**, JD, a partner with the law firm of Baker, Keener & Nahra in Los Angeles.

The hospital's neurosurgeons doubted his qualifications for the task, and even the chairman who had recruited him noted that he had alienated hospital management, Baker says. Shahinian stated in August 2002 that the hospital's lack of support for the program compromised patient care, and a month later he was notified that his position as a faculty physician and the program's director would end in one year.

Before that year was up, Shahinian registered complaints over the unavailability, malfunctioning, and inadequate reprocessing of surgical instruments, Baker says. Court records report that a hospital investigation bore out Shahinian's protests and revealed that certain instruments, which had been routinely flash sterilized, were contaminated with bioburden.

After his termination, Shahinian sued Cedars-Sinai for tortious discharge in violation of public policy, a suit that was settled in June 2005, Baker says. Under the settlement, the hospital agreed to extend Shahinian operating privileges in a non-retaliatory manner and to properly maintain its supply of surgical instruments, Baker says. The disputes continued, however. There was disagreement over who was responsible for maintaining the surgeon's custom instruments, and the hospital issued a 90-day moratorium on Shahinian performing any surgeries at the center while it investigated the surgeon's safety concerns. The parties then argued about the conditions Shahinian would have to meet to perform surgeries there. These conditions included providing his own sets of instruments, having his own employee clean them prior to sterilization, and personally inspecting the instruments before use or agreeing that the hospital's instrument handling process was satisfactory.

Shahinian sued the hospital again in December 2006 and argued that the hospital had restricted his privileges and damaged his career without a fair hearing process. The surgeon and the hospital agreed to arbitrate the matter. In November 2009, the arbitrator concluded that the hospital's moratorium on Shahinian's surgeries was unlawfully retaliatory, Baker says.

The arbitrator pointed to the fact that no other surgeon was barred from operating or burdened with conditions because of concerns over the safety of the hospital's practices, and the arbitrator noted that the moratorium was enacted without a peer review or hearing process. Shahinian was awarded $508,124 in economic damages for breach of contract and interference with his practice, $1.6 million in emotional distress damages and $2.6 million in punitive damages, Baker says. Shahinian agreed to give up his staff privileges at Cedars-Sinai.

After agreeing to the arbitrated award, the hospital took it to court and argued that it exceeded the arbitrator's powers and violated public policy. The trial court rejected this claim, and the appeals court recently upheld that ruling.

"Defendant may be unhappy with the result, but defendant agreed to 'final and binding' arbitration, and that is what it got," the court wrote in its decision. "None of these rules of law or public policies is implicated when a hospital becomes embroiled in a dispute with a doctor that has nothing to do with the doctor's competence or the doctor's professional conduct that puts patient care and safety at risk." ■

Surgeon's competence claimed to be the issue

In challenging the arbitration award of $4.7 million to a surgeon whose privileges were restricted, Cedars-Sinai Medical Center in Los Angeles alleges that the doctor's competence was in doubt.

"The arbitrator found that Dr. Shahinian's competence was an issue," says a statement the hospital provided to Healthcare Risk Management after a court of appeals found in favor of the surgeon. "However, she refused to decide one way or the other whether the concerns that Cedars-Sinai harbored about Dr. Shahinian's competence were justified. Thus, she did not vindicate Dr. Shahinian on the question of competence — she did not decide the issue. But she did bar Dr. Shahinian from reapplying to Cedars-Sinai's medical staff until 2016."

The arbitrator found that parts of Shahinian's testimony lacked credibility, the hospital notes. "Her finding of lack of credibility is consistent with another recent judicial finding. Last year, in a case having nothing whatever to do with Cedars-Sinai (Dr. Shahinian had already left the Center and was practicing elsewhere), a Los Angeles Superior Court judge found against Dr. Shahinian for both professional negligence and fraud," the statement says. "It awarded over $950,000

against him, including $300,000 in punitive damages. Among other things, the judge found that Dr. Shahinian was negligent in performing a surgery; that he had falsely represented to his patient that the surgery had a 98% rate of success; that, in a 'failed attempt at subterfuge' Dr. Shahinian caused an altered pathology report to be sent to the plaintiffs in willful and conscious disregard for plaintiff's health and safety; and that he engaged in 'trickery' and 'was more interested in marketing than medicine as it relates to these plaintiffs.'"

The hospital also notes that "The arbitrator rejected Dr. Shahinian's allegations that Cedars-Sinai 'failed to adequately clean or sterilize instruments' and that Cedars-Sinai failed to supply non-custom instruments. The arbitrator found that Dr. Shahinian failed to live up to his obligation to provide sufficient custom instruments." ■

OIG advises caution with joint ventures

Red flag raised with startup

The Office of Inspector General (OIG) of the Department of Health & Human Services has clarified when certain health care joint venture arrangements might be problematic and in violation of federal health care statutes and regulations. Risk managers are advised to study the guidance in anticipation of their roles in vetting any future joint ventures, says **Brandy L. Rea**, JD, an attorney with the law firm of Lathrop & Gage in Overland Park, KS.

The OIG guidance came in OIG Advisory Opinion No. 11-03, in which the OIG discussed a proposed joint venture arrangement between existing companies and a startup. *(See the Resources on p. 81 for information on how to access the opinion.)* The OIG guidance omits the names of the actual companies involved and uses pseudonyms. A new long term care pharmacy (referred to as NewCo) owned by a company providing long term care (LTC Facilities) wished to enter a joint venture with an established long term care pharmacy (OldCo) that provided services for LTC Facilities. The OIG stated that this proposed arrangement might be in violation of the federal anti-kickback statute, Rea explains.

The requestor of the opinion was OldCo. The LTC Facilities and one pharmacist-employee of OldCo desired to own and establish a new long term care pharmacy (NewCo) that would engage in the exact same line of business as OldCo, Rea says. NewCo would provide services to the LTC Facilities and would operate in the same market at OldCo. NewCo and OldCo would enter into a management agreement in which OldCo would provide all personnel, operational, billing, inventory, storage, and all day-to-day services of NewCo.

In addition, NewCo would purchase from OldCo most of its non-controlled medications. In exchange for these services, NewCo would pay OldCo a certain amount per prescription and would pay OldCo for all medications it purchased from OldCo for its customers. NewCo's services would be reimbursable by federal health care programs.

Seeing the potential for trouble, the companies asked the OIG for guidance. The OIG stated that the proposed arrangement might be in violation of the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)). *(See the story on p. 81 for details on why the OIG reached that conclusion.)* The federal anti-kickback statute prohibits the offering, soliciting , receiving or paying of any remuneration in exchange for the referral of any item or service that is payable by a federal healthcare program.

"Remuneration includes the transfer of anything of value, directly or indirectly," Rea says. "To violate the anti-kickback statute, at least one purpose of the payment of remuneration must be to reward or incentivize referrals. A violation of the anti-kickback statute is a criminal offense and is subject to both criminal and civil penalties."

Risk managers should be aware of healthcare joint venture arrangements that might be problem-

EXECUTIVE SUMMARY:

A recent opinion from the Office of Inspector General (OIG) of the Department of Health & Human Services urges caution with some types of joint venture agreements. The case involves a pharmacy that would provide services similar to those already provided by an existing company to a long-term care provider.

- The OIG said the plan could violate the federal anti-kickback statute.
- The ability to refer patients among joint venture participants is a red flag for the OIG.
- Risk managers might be involved with vetting such arrangements and should be familiar with the potential problems.

atic and a violation of federal healthcare laws, Rea says. In particular, be cautious of arrangements in which one entity expands into a related line of business and contracts out substantially all of its operations to a potential competitor in exchange for a portion of the profits. *(See the story on p. 82 for risk factors that could signal trouble with a joint venture.)*

The scenario in the recent opinion is only one example of this problematic type of joint venture arrangement. Another common example, Rea says, would be a hospital wanting to start a durable medical equipment (DME) subsidiary and contract all the services to an established DME provider in the area. The hospital would refer all its patients to this subsidiary, and the DME would be paid based on the volume of referrals. The hospital, as the owner of the subsidiary, would receive compensation based on the referrals.

"This opinion brings to light that these types of joint venture arrangements are under heightened scrutiny," Rea says. "A risk manager should know that if your organization is trying to get involved in a joint venture like this, the OIG is going to take a particularly close look at it. They would be well advised to know the potential risks and be prepared to advise their organization before deal gets too far along."

SOURCE/RESOURCES

• **Brandy L. Rea**, JD, Associate, Lathrop & Gage, Overland Park, KS. Telephone: (913) 451-5108. E-mail: brea@lathropgage.com.

• ***OIG Advisory Opinion No. 11-03*** regarding joint ventures is available at www.oig.hhs.gov. Select "Compliance" from the drop-down menu at the top of the page, and then select "Advisory opinions." The opinions are listed in order on that page. No. 11-03 was released on April 14, 2011. ■

Referrals are obstacle in joint venture plans

The Office of Inspector General (OIG) stated in its recent opinion that it has "longstanding concerns" about joint venture arrangements between a party that is in a position to refer patients to receive certain items or services and a party that is already in the business of providing such items or services, explains **Brandy L. Rea**, JD, an attorney with the law firm of Lathrop & Gage in Overland Park, KS.

Those concerns are especially important when the party in a position to make such referrals is anticipated to be a significant source of patients for the joint venture, she says.

"The OIG has expressed its concern about these particular types of joint venture arrangements since 2003," Rea says. "When one party is in a position to refer the business, and another party is responsible for furnishing items or services that are reimbursable by a federal program, the OIG is going to be skeptical."

In the recent opinion involving a new long term care pharmacy (NewCo) owned by a company providing long term care (LTC Facilities) that planned to enter a joint venture with an established long term care pharmacy (OldCo) that provided services for a long term care provider, the OIG discussed the elements of the proposed arrangement that create a possible violation of the anti-kickback statute:

- The LTC Facilities are expanding into a related line of business (long term care pharmaceuticals) that would be dependent on referrals from the LTC Facilities.
- The LTC Facility owners would not participate in the operation of NewCo but would contract out substantially all of the NewCo operations to OldCo.
- The LTC Facility owners would not be exposed to any business or financial risk because they would control the business that would be referred to NewCo.
- OldCo provides the exact same services as NewCo and is in the position to provide all of the services that it would provide as a manager of NewCo to its own clients.
- Payment to OldCo would vary with the volume of referrals from the LTC Facilities.
- The LTC Facility owners' income would vary with the volume of referrals from the LTC Facilities.
- OldCo and the LTC Facility owners would benefit from the formation of NewCo.

Based upon these factors, the OIG concluded that the proposed arrangement might be in violation of the anti-kickback statute because it permitted the parties to be paid based upon the volume or value of referrals to items and services that might be reimbursed by federal healthcare programs, Rea explains. In particular, OldCo would be indirectly paying the LTC Facility owners a share of the profits from their referrals. ■

Watch for risk factors in a joint venture

When helping to vet a proposed joint venture, watch for these red flags that government regulators have said will receive their attention, suggests **Brandy L. Rea,** JD, an attorney with the law firm of Lathrop & Gage in Overland Park, KS:

• The healthcare provider is seeking to expand into a new but related line of business. This new business will provide services to the provider's existing patients.

• The joint venture professes to benefit existing patients, but there is no bona fide attempt to expand the patient base. The new venture will be based almost entirely on referrals from the one provider.

• All or substantially all of the items or services are contracted out to a third party that is already established in this line of business.

• The contractor or third party that is going to provide the items or services normally would be a competitor to the new entity created by the joint venture, but instead is the recipient of referrals.

• The contractor could provide all the services or items to the patients directly rather than working through the subsidiary created by the joint venture.

• The compensation from the joint venture to the owner and/or the contractor takes into account the volume of referrals.

• There is an exclusivity or non-compete clause that prohibits the contractor from serving other patients in the area. ■

AHRQ: Good teamwork but weak in handoffs

When it comes to measuring patient safety, hospitals tend to receive good scores for teamwork and education, but there still is considerable room for improvement with handoffs and other concerns. Those are some of the findings from the fifth annual edition of the Hospital Survey on Patient Safety Culture 2011 User Comparative Database Report from the Agency for Healthcare Research and Quality (AHRQ).

The first annual comparative database report was released in 2007 and included data from 382 U.S. hospitals. This year's report displays results from 1,032 hospitals and 472,397 hospital staff respondents. The 2011 report also includes a chapter on trending that presents results showing change over time for 512 hospitals that administered the survey and submitted data more than once.

Results are expressed in terms of percent positive, which is the percentage of positive responses (agree, strongly agree) to positively worded items such as "People support one another in this unit" or negative responses (disagree) to negatively worded items such as "We have safety problems in this unit."

Three areas of strength emerged in the 2011 results:

• **Teamwork within units (average 80% positive response)** — This composite is defined as the extent to which staff support each other, treat each other with respect, and work together as a team. This composite had the highest average % positive response.

• **Supervisor/manager expectations and actions promoting patient safety (average 75% positive response)** — This composite is defined as the extent to which supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems. This composite had the second highest average % positive response.

• **Patient safety grade** — On average, most respondents within hospitals (75%) gave their work area or unit a grade of "A — Excellent" (29%) or "B — Very Good" (46%) on patient safety.

There also were three areas that showed potential for improvement:

• **Nonpunitive response to error (average 44% positive response)** — This composite is defined as the extent to which staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file. This composite had the lowest average% positive response.

• **Handoffs and transitions (average 45% positive response)** — This composite is defined as the extent to which important patient care information is transferred across hospital units and during shift changes. This composite had the second lowest average % positive response.

• **Number of events reported** — On average, most respondents within hospitals (54%) reported no events in their hospital over the past 12 months. It is likely that events were underre-

ported. This is an area for improvement for most hospitals, the AHRQ report says, because underreporting of events means potential patient safety problems might not be recognized or identified and therefore might not be addressed.

Breaking down the results by hospital and individual characteristics also yielded interesting results. These are some of the highlights from the report:

• Very small hospitals (6-24 beds) had the highest overall average % positive response on the patient safety culture composites.

• Small hospitals (25-49 beds) had the highest percentage of respondents who gave their work area/unit a patient safety grade of "Excellent" or "Very Good" (81% positive for 25-49 beds vs. 70% for 400 beds or more).

• Nonteaching hospitals had a higher average percent positive response than teaching hospitals on Teamwork Across Units (60% positive compared with 55% positive) and Handoffs and Transitions (47% positive compared with 42%).

• Non-government-owned hospitals had a higher percentage of respondents who reported one or more events in the past year (47%) than government-owned hospitals (42%).

• East South Central and West South Central hospitals had the highest average percent positive response across the composites (66% positive); New England hospitals had the lowest (59% positive).

• Mid-Atlantic, East South Central, and West South Central hospitals scored highest on the percentage of respondents who gave their work area/unit a patient safety grade of "Excellent" or "Very Good" (78%).

• Pacific hospitals had the highest percentage of respondents who reported one or more events in the past year (51%). The lowest percentage of respondents reporting events was in the West South Central region (43%).

• Respondents in rehabilitation had the highest average percent positive response across the composites (69% positive). Emergency had the lowest (57% positive).

• Rehabilitation had the highest percentage of respondents who gave their work area/unit a patient safety grade of "Excellent" or "Very Good" (84%). Emergency had the lowest (63%).

• Intensive care units (any type) had the highest percentage of respondents reporting one or more events in the past year (63%). Rehabilitation had the lowest (42%).

• Respondents in administration/management had the highest average percent positive response across the composites (74% positive). Pharmacists had the lowest (60% positive).

• Administration/management had the highest percentage of respondents who gave their work area/unit a patient safety grade of "Excellent" or "Very Good"(86%). Pharmacists had the lowest (67%).

• Pharmacists had the highest percentage of respondents reporting one or more events in the past year (72%). Unit assistants/clerks/secretaries had the lowest (18%). ■

CNE INSTRUCTIONS

Nurses participate in this CNE/ CME program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. *First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.*
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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.

COMING IN FUTURE MONTHS

■ How to work best with compliance officers

■ Roadmap to reducing OB liability

■ Fleet insurance: Are you getting the best deal?

■ Improving ED on-call response

CNE QUESTIONS

1. What does says Fran Charney, RN, MSHA, CPHRM, CPHQ, CPSO, FASHRM, director of educational programs with the Pennsylvania Patient Safety Authority (PPSA), advise regarding identification errors made by phlebotomists?
   A. Enforce a "three strikes and you're out" policy.
   B. Disregard any errors that do not result in patient harm.
   C. Investigate the cause of the error thoroughly, asking why the error occurred, not just how.
   D. Document the nature of the error, but no further investigation is needed.

2. In the study by Ana K. Stankovic, MD, PhD, MSPH, vice president of medical and scientific affairs and clinical operations with BD Diagnostics, what was one factor associated with lower rates of errors in specimen labeling?
   A. A 24/7 phlebotomy service
   B. An emphasis on blood draws being done by the unit nurses
   C. Smaller healthcare facilities
   D. Teaching hospitals

3. According to Robert C. Baker, JD, a partner with the law firm of Baker, Keener & Nahra, representing the surgeon who sued Cedars-Sinai Medical Center, how did the hospital err in restricting his privileges?
   A. The crux of the case was that the hospital did not follow its own bylaws when restricting the surgeon's privileges.
   B. The hospital took too long to notify the surgeon of concerns about his performance.
   C. A court had ordered the hospital not to restrict the surgeon's privileges, but it did so anyway.
   D. An administrator failed to sign the documents restricting the surgeon's privileges.

4. What does Brandy L. Rea, JD, an attorney with the law firm of Lathrop & Gage, say is one scenario that might signal a problem with a joint venture agreement?
   A. The involvement of a third party that is not typically involved in providing healthcare.
   B. An arrangement in which one entity expands into a related line of business and contracts out substantially all of its operations to a potential competitor in exchange for a portion of the profits.
   C. Any deal in which the larger healthcare provider is expected to provide remuneration to a smaller entity in a related field of work.
   D. The formation of a subsidiary that functions under the same corporate framework as the hospital but has separate and distinct billing procedures.

Dear *Healthcare Risk Management* Subscriber:

This issue of your newsletter marks the start of a new continuing nursing education (CNE) semester and provides us with an opportunity to tell you about some new procedures for earning CNE and faster delivery of your credit letter.

Healthcare Risk Management, sponsored by AHC Media, provides you with evidence-based information and best practices that help you make informed decisions concerning eucational options. Our intent is the same as yours: the best possible patient care.

The objectives of *Healthcare Risk Management* are for participants to 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 educators commonly encounter in their daily activities;
- Identify solutions to risk management problems in health care for hospital personnel to use in overcoming the challenges they encounter in daily practice.

The American Medical Association, which oversees the Physician's Recognition Award and credit system and allows AHC Media to award *AMA PRA Category 1 Credit™*, has changed its requirements for awarding *AMA PRA Category 1 Credit™*. Enduring materials, like this newsletter, are now required to include an assessment of the learner's performance; the activity provider can award credit only if a minimum performance level is met. AHC Media considered several ways of meeting these new AMA requirements and chose the most expedient method for our learners.

HERE ARE THE STEPS YOU NEED TO TAKE TO EARN CREDIT FOR THIS ACTIVITY:

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3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
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This activity is valid for 24 months from the date of publication. The target audience for this activity is healthcare risk managers and other professionals.

If you have any questions about the process, please call us at (800) 688-2421, or outside the U.S. at (404) 262-5476. You can also fax us at (800) 284-3291, or outside the U.S. at (404) 262-5560. You can also e-mail us at: customerservice@ahcmedia.com.

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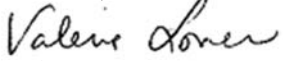
Sincerely,



Valerie Loner
Continuing Education Director
AHC Media