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Consent Process Often Executed Poorly, Creating Risks and Costs

Obtaining patient consent is such a fundamental part of healthcare risk management that it would be easy to assume it is done consistently and properly in most cases, but that is a dangerous assumption.

Consent forms are regularly missing for many procedures and most healthcare organizations have room for improvement with this process, experts say.

A study from researchers at Johns Hopkins found that consent forms were missing for 66% of surgeries, which is especially problematic if timed antibiotics have been started. Missing consent forms delayed 10% of all surgical procedures and cost hospitals, on average, $580,000 each year, the study found. *(See the story on page 88 for more on the research.)*

> A STUDY FOUND THAT CONSENT FORMS WERE MISSING FOR 66% OF SURGERIES, WHICH IS ESPECIALLY PROBLEMATIC IF TIMED ANTIBIOTICS HAVE BEEN STARTED.

It can be surprisingly difficult to stay on top of all the informed consent requirements, says **Sue Dill Calloway**, RN, AD, BSN, MSN, JD, CPHRM, CCMSCP, president of Patient Safety and Healthcare Consulting and Education in Dublin, OH.

Clinicians must know which standards and guidelines apply to their situations, and often there are more than one to satisfy, she notes. Hospitals accepting Medicare and Medicaid must follow the Centers for Medicare & Medicaid Services (CMS) Hospital Conditions of Participation (CoPs), but there is a separate CoP for critical access hospitals, Calloway explains. There also are state laws on

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informed consent, plus requirements from accreditation organizations.

With CMS requirements for informed consent, the most frequently cited deficiencies are for Tag Numbers 131, 466, and 955, Calloway notes. The Joint Commission recently changed informed consent standards, deleting some and consolidating others, and many hospital leaders have not recognized the changes.

"How many doctors do you think know that they now need to talk about the risks of recuperation when obtaining informed consent? I bet you if I went in to a room of 100 doctors today and asked them to explain the risks and benefits of rehab after a total hip replacement, I don't think they'd know what I'm talking about," Calloway says. "That applies to every hospital accredited by The Joint Commission, but people are surprised when I tell them about a hospital being cited for the recuperation standard."

Work With Physicians

Risk managers can improve consent compliance by working with physician leaders to emphasize that much of the responsibility falls on the individual doctors, and incentivizing them to improve their consent processes, Calloway suggests. She has worked with one hospital that monitored consent form compliance closely and rewarded high compliance with better OR scheduling.

Physicians should be reminded that simply obtaining a signature on a form is not enough.

"When I first became a defense attorney I wondered why people don't get this, why informed consent is such an issue," Calloway says. "I still think there is a disconnect between what the legal requirements are and what is actually happening."

Calloway once was about to undergo a medical procedure when a nurse handed her a clipboard with a consent form and told her the physician would explain it when he came in. The physician entered the room, turned off the lights in preparation for the procedure, and asked if she had signed the form. Calloway said no and so he told her to sign it.

The incident opened her eyes to how the consent process can be marginalized.

"Having me sign a consent form in the dark, when no one had explained it to me, is not what any risk management professional would expect. But that is the kind of thing that happens every day," Calloway says. "And the record afterward said he had provided informed consent, so he dictated something he never did. The hospital is not supposed to

EXECUTIVE SUMMARY

The informed consent process still creates liability risks and unnecessary costs for healthcare organizations. Physicians may not be executing informed consent in the way risk managers assume and policies require.

- Work closely with physicians to improve their consent processes.
- Research has shown a high rate of missing consent forms in surgery.
- Requirements vary across different regulatory, accreditation, and state bodies.

be responsible for consent unless the physician works for the hospital, but the hospital relies on the physician to obtain consent in a proper way."

Calloway ran into the nurse soon after and mentioned the lack of informed consent, asking her if she had filed an incident report or otherwise reported it. She hadn't.

"So the nurse knew the physician had just waltzed in and had me sign a form in the dark without obtaining informed consent, but she didn't do anything about it. That doesn't show that we've made much progress in this," Calloway says. "Some hospitals are better than others. Those with good risk managers and counsel will do better, but they still could be surprised by what happens."

Frequent Claim in Lawsuits

Consent issues usually are wrapped up with negligence claims in malpractice cases, rather than being a standalone cause of action, says **Cynthia D. Grimes**, JD, senior counsel with the Clark Hill law firm in San Antonio. Consent issues arise in up to half of all medical malpractice claims, she says, often thrown in as a standard part of asserting negligence.

"We do see plaintiffs saying they didn't understand, and rarely they will say they didn't sign," Grimes says. "If people are not happy with the results of surgery they will often say they did not know that could be a consequence of the surgery. That is the responsibility of the physician and I tell them that they must be consistent with what they tell patients about specific procedures."

Grimes explains that when physicians are consistent with the informed consent process, they can say, "I may not remember the exact conversation I had with this patient but I can testify that this is what I say in every circumstance, so I am quite confident that I told this patient about this risk."

It also is important to have the consent document dated, witnessed, and especially to have the time noted, to show that informed consent was obtained before the administration of medications that could cloud the patient's judgment, Grimes says. Omitting any of those factors leaves an opening for the plaintiff to contest the consent, she says.

"In addition to the consent form itself, the medical record should have a note saying the doctor came in and explained the risks and benefits, and the patient agreed to have the procedure after understanding the risks involved," Grimes says.

"It is important that the doctor indicate he or she gave the patient information from which they could make a decision and give informed consent," she adds. "It is not enough

HFAP Finds Incomplete Consent Forms in Surveys

Consent forms missing one or more elements are a common problem found by surveyors with the Healthcare Facilities Accreditation Program (HFAP), based in Chicago.

The 2017 quality report from HFAP summarizes the consent form deficiencies regarding HFAP standard "Medical Records 10.01.16 — Informed Consent," saying the trending deficiency is one or more required elements missing from the consent form.

"While consent forms are used in legal proceedings to protect institutions (the documentation of consent), they are, first and foremost, evidence of an interactive process that should emphasize 'informed' — an act of intentional affirmation on the part of the patient," the report says. "To this point, informed consent is included in additional locations in the Conditions of Participation relating to patient rights and surgical services. To achieve the intent of the standard, consents must be written in simple language such that the meaning of the document is repeatable by the patient."

Because of the large percentage of the population with literacy deficits, and the larger percentage with medical literacy challenges, consent documents should be written so as to be understood by all, HFAP says.

The report cites the following examples of surveyor citations:

- missing consent for anesthesia;
- consent not written in simple sentences or at a fourth-grade level;
- consent missing alternative therapies;
- consent missing anticipated benefits and risks;
- procedure name abbreviated and not further documented for easy comprehension;
- date and time missing.

The HFAP report is available online at: https://bit.ly/2x5cNv3. ■

to say they signed a piece of paper. You need to state that you provided the information necessary for them to consider the risks and agree to the procedure."

Older Population Needs Attention

There can be special concerns with consent in treating older patients, says **Jane Carmody**, DNP, MBA, RN, program officer with The John A. Hartford Foundation (JAHF), a nonprofit, nonpartisan organization in New York City that works to improve conditions for the care of older adults in the healthcare system. Particularly with end-of-life care, patients must be fully informed of options, risks, and benefits, she says, and their wishes must be respected.

That depends on good communication, which does not happen often enough with this patient population, Carmody says.

"The healthcare community is oriented to providing treatment and making people better, though what that means can differ depending on who is talking," she says. "If you don't have a conversation with the patient or the patient doesn't have a family member who understands what the patient would want, you can end up providing treatment that is unwanted, unnecessary, and prolongs suffering."

Advance directives can help avoid such situations, but they are sometimes underused.

"A lot of times the advance directive has just become a box to check off on a form, yes or no," Carmody says. "There's no effort to document the directive, find out where it is, and what it says. A lot of times in the rush of an acute care setting they can be hard to find and apply to the care provided."

Carmody recommends risk managers audit conversations between physicians and patients to see what actually happens on the floor, rather than assuming a policy is being followed.

"Do the patients understand the risks and benefits, what this might mean for them in the long run? Is the health literacy taken into consideration appropriately?" she says. "Does the patient understand this might mean they will be under dependent care for the rest of their life, that they may never be able to play golf or go to church again?"

Accreditation Surveyors on Lookout

Accreditation surveyors are keen on the informed consent process, says **Bernard C. McDonnell**, DO, a surveyor with the Healthcare Facilities Accreditation Program (HFAP). Surveyors will look for evidence that a written informed consent is executed prior to a procedure or treatment, and information must be imparted by the provider performing the procedure or treatment prior to starting.

Specific requirements will vary among different accreditation bodies,

Study Finds 66% of Surgeries Lack Consent

Researchers at the Johns Hopkins University School of Medicine in Baltimore found that consent forms were missing for 66% of surgical patients, causing one-tenth of procedures to be delayed.

Because so many patients came to surgery without proper consent forms, it fell to a resident to obtain consent 43% of the time. The researchers also found that only 47% of residents reported that they felt comfortable obtaining consent for major procedures, and residents typically spent less time obtaining consent from patients than did attending physicians.

The difference in how much time they took obtaining consent was more pronounced when residents obtained a patient's consent at the last minute.

"The problem of lost or misplaced consents is both ubiquitous and extremely costly. It has been estimated that operating room delays resulting from these missing documents cost the average hospital $580,000 each year," the researchers wrote.

In addition to the inefficiency and increased cost from a missing consent form, the Hopkins researchers noted that obtaining consent in the hurried environment of the preoperative area may lead to miscommunication between "expected and achieved results."

That miscommunication can increase the litigation risk, they noted, citing previous research indicating that obtaining consent in the preoperative holding area does result in a marked increase in claims payments.

The study is available online at: https://bit.ly/2zuaRNx. ■

but surveyors generally expect the consent process to begin with a conversation that is followed up by an appropriately signed and executed form per hospital/facility policy and procedures.

McDonnell says the form must include, at a minimum, these elements:

- the name of the facility at which the care is being provided;
- the name of the specific procedure or treatment for which consent is given;
- the name of the responsible practitioner — usually the physician performing the procedure;
- a description of the benefits, risks, and alternative therapies, if applicable;
- the patient's signature or the signature of the patient's legal representative with date and time; witnessed.

"We also like to see inclusion of other practitioners participating in the procedure under the supervision of the operating practitioner," McDonnell says. "A separate anesthesia informed consent must be obtained by the anesthesia provider with similar content."

The following are the most common problems McDonnell says HFAP surveyors find regarding consent:

- missing document;
- incomplete document;
- missing witness;
- missing date and/or time;
- failure to complete all necessary parts of the informed consent process.

(See the story on page 87 for details on consent form deficiencies in the most recent HFAP quality report.)

"Although the physician is critical to the consent process, the document is often executed by ancillary staff," McDonnell says. "There must be documentation that the physician spoke with the patient and provided all the information necessary for the patient to give an informed decision and consent."

Informed consent documents should be written in the primary language of the patient and at a fourth-grade comprehension level, McDonnell says. For example, "cholecystectomy" should be written as "gallbladder removal" or "removal of a sac containing fluid that assists in the internal processing of food and nutrition."

It is important for healthcare providers to approach consent from the point of view of the patient, McDonnel says. Patients cannot give truly informed consent if the providers have not taken the time to confirm that the patient has understood the proposed treatment, he says.

Informed consent should have the same parameters and execution across all healthcare settings, McDonnell says. But each consent is being provided by an individual patient, so the specific situation and needs of the individual should be a primary focus.

"For example, consent that is provided on behalf of a pediatric patient, or others who have a legal representative providing consent may take additional time and sensitivity in terms of finding language that meets the needs of the patient," he says. "Psychiatric patients and psychiatric facilities have many other and different informed consents, including those for voluntary and involuntary admission." ■

SOURCES

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Hospital Faces Class-action Lawsuit After Hepatitis C Outbreak

A hospital in Puyallup, WA, is facing a class-action lawsuit from patients possibly exposed to hepatitis C but is taking the right steps to mitigate the potential damage, says a malpractice attorney who is monitoring the case.

The case illustrates how notifying patients of such possible harm may actually create more exposure than the original incident, says **Benjamin J. Fenton**, JD, partner with the Fenton Law Group in Los Angeles. However, full notification is still the right move.

Up to 2,600 patients may have been exposed to the infection by a nurse at the hospital.

The class action lawsuit in Pierce County Superior Court alleges that the hospital and its parent company breached their care duties. Another

patient sued the hospital a week earlier with the same allegations.

The plaintiff was treated in the hospital's ED on Dec. 25, 2017, the lawsuit says, and later received a notice from the hospital saying she may have been exposed to hepatitis C. The hospital recommended she be tested.

The woman tested negative for hepatitis C, hepatitis B, and HIV, but may need to be tested later. The lawsuit claims the potentially exposed patients have been forced to endure worry, stress, inconvenience, and the "physical invasion and other effects of the testing process."

Two other patients tested positive for hepatitis, and the lawsuit notes that the hospital identified a 31-year-old nurse as the "common denominator" in the exposures. She was arrested but released without charges. The state nursing commission suspended her license for unprofessional conduct, the lawsuit notes.

The class-action lawsuit names the nurse and says she used needles on patients after first using them on herself with narcotics.

Hospital Improves Narcotics Process

The hospital issued a statement confirming some of the allegations, saying it conducted an investigation along with local and state health department officials and "determined that one of our nurses was removing higher-than-normal amounts of narcotics from our dispensing system and admitted to diverting medications intended for patients. She tested positive for hepatitis C and had treated both of the patients we know are infected."

The nurse no longer works for the hospital, it said.

As part of the investigation, the hospital "thoroughly examined its processes to identify areas for improvement to prevent this from happening again. One area identified is around reporting of narcotic use. A new report was added to our existing detailed reporting about medication use in the hospital. This new report will help identify employees who deviate from standard practices for medication use. This new report is now part of our ongoing narcotic monitoring program and will be closely reviewed on an ongoing basis."

The hospital faces significant liability but appears so far to be responding well to the crisis, Fenton says.

"When risk management learned of this situation, they jumped into action and notified pretty much every patient the nurse treated," Fenton says. "They provided a notification to all those patients even though most of them are not testing positive. Risk management acted in a conservative way, which I think is smart."

Notification Creates Risk

Notifying such a large number of patients opens the hospital up to more litigation than might otherwise have occurred, but Fenton says the hospital was right to avoid any impression it was trying to downplay the incident or neglect the safety of some patients.

"The lawsuit is seeking damages not necessarily for patients testing positive, because there aren't many, but for the emotional distress people might feel until such time as they have sufficient testing for them to be sure they're past the period in which they might test positive," Fenton says. "So the hospital was in a bit of a rock-and-a-hard-place situation. The hospital had to notify the patients, but that exposes them to lawsuits claiming this emotional distress from being notified."

The hospital could not have avoided that exposure without failing to notify even those patients at low risk of infection, Fenton says. In such situations, hospital risk managers should remember that the most significant exposure might stem from the notifications rather than the underlying event.

"Whatever you can do to minimize the emotional distress caused by the notifications will benefit the patient and the hospital as well. That may mean, in addition, sending a well-crafted letter that explains the potential harm but also makes clear how low the risk is," Fenton says.

EXECUTIVE SUMMARY

A hospital in Washington is responding to litigation involving exposure to hepatitis C from a nurse. The hospital notified 2,600 patients of a possible exposure.

- The notification created more liability exposure than the nurse's actions.
- Plaintiffs are claiming emotional damages from waiting to learn about possible infection.
- Hospitals should work to minimize the stress that can follow such notifications.

Fenton compares the situation to how hospitals must notify patients of a HIPAA violation but also provide credit watch services and similar aid to allay fears. Transparency and proactive assistance to reduce stress is the best strategy, he says.

"You could have people reach out by telephone to answer any questions and coordinate testing as soon as possible," he says. "The hospital could make its lab testing hours available longer in the day and add more staff, anything that would make the process easier and get the likely negative test results to the patient quickly." ■

SOURCE

- **Benjamin J. Fenton**, JD, Partner, Fenton Law Group, Los Angeles. Email: bfenton@fentonlawgroup.com.

Future of Risk Management Demands Broad Approach

The risk landscape of healthcare has changed drastically in the past decade, and consequently, the role of the healthcare risk manager has evolved tremendously, says **Diane Doherty**, CPHRM, senior vice president of Chubb Healthcare in New York City.

A successful career in risk management over the next 10 years will require anticipating changes and acting proactively, she says.

Today's challenging healthcare climate is marked by consolidation and unprecedented change from new delivery and alignment models, and Doherty says she is seeing risk managers take on a more elevated role in their organizations, working closely with senior leadership and other departments to develop a more strategic enterprisewide approach to risk management.

"In addition to focusing on patient safety, clinical care, regulatory compliance, and finance, they are dedicated to proactively addressing myriad liability threats on a day-to-day basis," she says. "This includes diagnostic and therapeutic errors, infections, alarm fatigue, violence, data breaches, social media missteps, and natural disasters, among other exposures. It makes risk managers a steady force in volatile times."

Risk managers touch nearly every corner of a healthcare enterprise, Doherty says, and they strengthen organizational operations, both proactively (by identifying, preventing and mitigating loss) and reactively (through real-time damage control).

"It is critical that risk managers stay at the forefront of all healthcare changes, embrace those changes, identify the new related exposures, and be ready to implement strategic solutions to address them," she says. "New risks require new solutions and a strong risk manager to lead that charge. Today, a robust risk management program requires more than just a written plan; it requires a well-credentialed and qualified risk manager to execute and bring it to fruition."

To prepare for the future, and understand how much it might be different from the current risk management landscape, Doherty points to these three major changes in risk management over the past decade:

• **Violence.** Whether it's a hospital, outpatient facility, or physician office, the reality is that the healthcare setting is just as vulnerable to the same problems that afflict society as a whole, Doherty says.

"Healthcare violence continues to be on the rise and risk managers must vigilantly work to prepare their institutions to prevent situations that can result in costly losses or liability," she says. "For healthcare risk managers, violent incidents expose their organizations to not only critical safety issues but a wide range of insurance implications, including medical professional liability, workers' compensation, general liability, and property exposures. The key to stemming these exposures is rooted in a review of their workplace violence prevention program."

EXECUTIVE SUMMARY

Risk managers will fare best in the future by maintaining skills in a broad range of topics. New risks will emerge as the healthcare industry evolves.

- Risk managers are taking on more prominent roles in healthcare organizations.
- Violence and opioids will continue to be primary concerns.
- Successful risk managers will embrace technology.

Risk managers should ensure their program is based on an annual facilitywide assessment that surveys all shifts, pays particular attention to high-risk areas, and is overseen by a multidisciplinary committee, Doherty advises. Once the program is updated, risk managers should conduct unannounced drills and staff trainings that focus on identifying violence red flags, when to try and diffuse a situation, and when to retreat to safety.

• **Opioids.** The national opioid crisis has forced risk managers to wear more hats than ever before, Doherty says.

"The statistics are staggering, with the CDC reporting more than 115 people in the United States die every day after overdosing on opioids. They further recently reported a 30% increase in emergency room visits for opioid overdoses in all parts of the U.S. from July 2016 through September 2017," she says. "Risk managers are being called upon to do what they can to help curtail the crisis by taking a proactive approach to safeguard prescribing practices and minimize patient harm and associated liabilities."

• **Technology.** Risk managers today have to face the rapid influx of progressively complex and state-of-the-art technology that poses many challenges for healthcare organizations, Doherty says. In this environment, risk managers have to stay on the cutting edge of new technology, including telehealth technologies, and develop comprehensive risk management strategies that evaluate and respond to possible liabilities.

She cites the example of video monitoring technology, also known as telesitting, which is increasingly popular with hospitals.

"It is considered by some as a cost-effective solution to improve patient safety and lower staff costs associated with observing inpatients at risk for falls, wandering, pulling out tubes, and other types of self-harm," Doherty says. "From a risk perspective, there are many pros and cons of utilizing this virtual observation technology, as well as legal implications to consider."

Three areas of primary concern with video monitoring are informed consent, HIPAA, and record access. Risk managers should work with legal counsel, the leadership team, and frontline staff before implementing such a program, Doherty cautions. An effective telehealth partnership requires careful examination of professional liability issues, including contract protections, practitioner credentialing requirements, technology safeguards, network security, applicable practice standards, and insurance coverage, she says.

To minimize their exposures, healthcare organizations should create a comprehensive risk management program to address each of those issues, Doherty says. Given that each organization faces unique challenges, there is not a one-model-fits-all risk management solution, she notes.

"Hospital risk management teams should be familiar with these issues and should be empowered to take action to mitigate the risks. Because of the potential adverse consequences, hospital risk management teams should report directly to the top leadership — the chief executives as well as hospital boards," she says. "While risk managers are under constant pressure to do more with less, those that have the foresight to prepare for these emerging risks can reduce the chances of debilitating losses while strengthening their ability to deliver quality patient care." ■

SOURCE

- **Diane Doherty**, CPHRM, Senior Vice President, Chubb Healthcare, New York City. Phone: (212) 703-7120. Email: diane.doherty@chubb.com.

'Dry Run' for Radiology Improves Patient Safety

Radiology can be a complex process using the latest technology, and the results can drive the course of a patient's care. Getting it right the first time is not always easy, so one health network has found that sending patients through a "dry run" simulation before the actual procedure can improve outcomes and patient safety.

Steven Gresswell, MD, and colleagues in the division of radiation oncology at Allegheny Health Network in Pittsburgh implemented a "verification simulation" across its 11 radiation oncology clinics in 2014.

"It's an in-depth opportunity for the radiation therapist to own the plan. We bring the patient in a day beforehand and go through everything the radiation therapist does beforehand, all except actually delivering the radiation," he says. "This allows them to make sure the

beam angles and other parameters are correct, and that there's no potential collisions with the linear accelerator."

The team also verifies the prescription and double-checks all information related to the upcoming procedure.

"If there are any errors, this is an opportunity to fix them in an environment that allows the time to do it," Gresswell says. "We bring them in for 15-minute or 30-minute appointment slots depending on the complexity of the treatment plan. We saw this as a good opportunity to slow things down, look for any potential issues, and have the time to address them."

Fewer Incidents With Simulation

The team reported the results in a recent study. They compared success and incident rates with 965 patients in an 18-month period prior to implementation of the verification simulation and 984 patients treated in the same time period with the addition of the dry run.

The dry run typically was scheduled the day before a patient's first fraction of radiotherapy. Clinicians walked the patient through setup, imaging, and treatment, explaining the process without actual delivery of any radiation.

"The session is designed to allow staff time to verify that the parameters of treatment are accurate and troubleshoot problems in an organized team approach," Gresswell and his colleagues wrote in their report.

> "THE SESSION IS DESIGNED TO ALLOW STAFF TIME TO VERIFY THAT THE PARAMETERS OF TREATMENT ARE ACCURATE AND TROUBLESHOOT PROBLEMS IN AN ORGANIZED TEAM APPROACH."

Twenty-eight incidents — errors or potential errors during the dry run or the actual radiography process — were reported in the nonsimulation group, and 18 incidents in the verification simulation cohort. In the simulation group, more incidents also were detected before the day of treatment and fewer on the day of treatment. They concluded that a verification simulation can be an integral part of any radiation oncology QA program and a risk reduction strategy in the administration of radiotherapy.

Though it was not the aim of the project, they found that 83% of patients reported decreased anxiety because of the dry run.

"Error identification in radiation therapy is critical to maintaining a safe and efficient therapeutic environment," the authors wrote. "A verification simulation for patient information provides a dedicated time prior to treatment to duplicate steps of patient setup, imaging, and treatment processes as a final quality assurance step."

(An abstract of the report is available online at: https://bit.ly/2unjUKm.)

Gresswell notes that the findings were not exactly what he expected. There were fewer incidents reported in the simulation group, when he expected to see more just because there were two opportunities to spot errors — the dry run and the actual treatment.

"That might be because the errors were caught before they could lead to more errors down the road. They were caught in the simulation and addressed instead of going unseen and leading to other incidents on the day of treatment," he says. "When we have the dry run in place, that also gives the radiation therapists more time to do their jobs, and we found more of the incidents were detected by the radiation therapists. That was good to see." ■

SOURCE

- **Steven Gresswell**, MD, Division of Radiation Oncology, Allegheny Health Network, Pittsburgh. Email: steven.gresswell@gmail.com.

EXECUTIVE SUMMARY

Conducting a simulated radiography procedure with a patient helps reduce errors and relieves anxiety. The simulation also can encourage staff to report errors and process problems.

- Clinicians have a chance to identify issues before the procedure is performed.
- Patient satisfaction improves.
- Safety is improved when radiographic quality increases because of the simulation.

CMS May Address Regulatory Burdens of Stark

The Centers for Medicare & Medicaid Services (CMS) said it wants to make the physician self-referral law, the Stark Law, less of a burden for healthcare organizations. It is seeking input on how to make that happen.

The agency said it wants to focus in part on how the law may impede care coordination. CMS issued a request for information seeking recommendations and input from the public on how to address any undue impact and burden of the Stark Law.

CMS previously asked for comments on regulatory burdens, and one of the top areas of burden identified in the more than 2,600 comments received was compliance with the Stark Law.

CMS now is soliciting specific input on a range of issues identified with the Stark Law "to help the agency better understand provider concerns and target its regulatory efforts to address those concerns," it said. Comments can be made through August 24.

"We are looking for information and bold ideas on how to change the existing regulations to reduce provider burden and put patients in the driver's seat," CMS Administrator Seema Verma said in a statement addressing the law. "Dealing with the burden of the physician self-referral law is one of our top priorities as we move toward a healthcare system that pays for value rather than volume."

CMS said it is particularly interested in the public's input on the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, the need for revisions or additions to exceptions to the physician self-referral law, and terminology related to alternative payment models and the physician self-referral law. ■

Staff Workarounds Pose Medication Error Risk

Patient safety is compromised when healthcare workers use workarounds to speed things up when they are busy, or to overcome roadblocks that make it difficult or impossible for them to follow proper procedures in the medication process, warns a report from the Pennsylvania Patient Safety Authority (PPSA) in Harrisburg.

The good news is that recognizing those workarounds provides quality leaders the opportunity to redesign the work process so that clinicians are not tempted to deviate from the procedure.

In its work with Blue Mountain Health System in Lehighton, PA, to identify barcode medication administration (BCMA) risks, PPSA found a pattern of near-misses involving a commonly used drug administration check tool that uses point-of-care barcode technology to automatically validate and document the medication administration process. The system is intended to improve patient safety by reducing medication errors.

The health system's data indicated multiple instances of barcode scans of the wrong patient as the nurse administered medication at the bedside, which generated error reports for each one. When the health system and PPSA investigated, they found that these incorrect barcode scans were intentional: nurses were not clearing the previous patient from the barcode scanner because it was faster and easier to leave the previous patient info in the system. Following the proper procedure to clear one patient before scanning the next required too many mouse clicks and slowed down their work, the nurses reported.

"To understand the nurses' barcode scanning workflow better, the team surveyed nursing staff about their scanning process, including whether they scan the medication or the patient first. The existing policy set an expectation that the patient is scanned first, then the medication," the PPSA report explains.

"However, nurses would engage a workaround in certain circumstances (e.g., when the same medication was ordered for multiple patients [e.g., acetaminophen], nurses would first scan the medication). This workaround contributed to some of the wrong-patient scan totals. In addition to policy re-education, nursing directors affixed a STOP sign visual reminder to the mobile computers, which reinforced the proper scanning sequence. This reminder helped reduce the number of wrong-patient scan errors."

Lack of internet connectivity also led to staff employing workarounds that they thought were the best alternative to following the standard procedures.

"For example, the health system noted certain patient rooms

had greater numbers of barcode scanning events than others, which was associated with limited or no internet connectivity," the report says. "Internet connectivity was expanded to include those areas." ■

CAPTURE Focuses on Coordination, Gait Support

This summary of the CAPTURE Falls program is provided by **Katherine J. Jones**, PT, PhD, associate professor in the Division of Physical Therapy Education at the University of Nebraska Medical Center in Omaha.

CAPTURE Falls includes the idea that there are eight "rights" of fall risk reduction. A good risk reduction program must include:

• **The right frame of reference.** The CAPTURE Falls solution depends on collaboration and proactive teamwork to improve the structure and coordination of organizational processes, as well as to standardize definitions for reporting and benchmarking. This approach views fall risk reduction as an organizational goal that multiple teams coordinate to achieve.

• **The right team.** The Coordinating Team typically consists of a quality improvement leader, a nurse champion, a certified nurse anesthetist, a pharmacist, a physical therapy or occupational therapist, and a senior organization leader. This team manages resources, coordinates the fall risk reduction program and interventions, and holds the core team accountable for reliably implementing evidence-based interventions. The team should span locations, status/hierarchies, and knowledge boundaries across disciplines.

• **The right coordination of the program.** The Coordinating Team oversees other component teams of the program that: achieve proximal goals and organizational goals; develop and coordinate the fall risk reduction program; conduct and implement targeted and universal interventions at the bedside; and make real-time adjustments to the care plan. The nursing team, for example, assesses fall risk based on observations and implements interventions at the bedside, while the pharmacy team assesses fall risk based on medication side effects and medication debridement. The physical therapy and occupational therapy team assesses fall risk based on performance and ensures competency in safe transfers and mobility.

• **The right training.** Clinicians and others in the organization must be trained in the overall fall risk reduction program (purpose, interventions, outcomes), administration of the fall risk assessment tool, safe transfers and mobility, mechanical lifts, and post-fall huddles.

• **The right risk assessment.** The program uses these questions to improve risk assessment: Does it facilitate critical thinking about targeting interventions to risk factors? Do you know the sensitivity, specificity, and predictive value of your tool?

• **The right event reporting and learning system.** CAPTURE Falls encourages the reporting of falls in four categories: unassisted falls that result in injury, unassisted falls that do not result in injury, assisted falls that result in injury, and assisted falls that do not result in injury. Unassisted falls represent a system failure and are more likely to result in injury, while assisted falls that do not result in injury to patients or staff represent system success.

• **The right interventions.** These include universal, purposeful hourly rounding, toileting schedules, and using gait belts. The organization should make it easier to assist mobility.

• **The right response to a fall.** The post-fall huddle is the key component of responding to a fall. Members from various teams should conduct a post-fall huddle immediately after a fall to determine what happened, why it happened, and what will be done differently in the future to prevent such a fall. The goals of the post-fall huddle are to decrease the risk of future falls for an individual patient, apply what is learned to decrease risk across the system, build trust, and share knowledge.

More information on the CAPTURE Falls program, including free tools and guidelines for implementing it in any healthcare facility, is available online at: https://bit.ly/2rddVqX. ■

COMING IN FUTURE MONTHS

- Reducing slip-and-fall liability
- Coordinating with counsel effectively
- Mitigating EHR liability risks
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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **A study from researchers at Johns Hopkins found that consent forms were missing for what percentage of surgeries?**
   a. 26%
   b. 46%
   c. 66%
   d. 86%

2. **What does Cynthia D. Grimes, JD, advise regarding how physicians explain treatment to patients when obtaining informed consent?**
   a. Be consistent and tell patients the same information for particular procedures; the physician later can say that is his or her routine even if unable to recall a specific conversation.
   b. Be purposeful in making each discussion unique rather than telling patients the same information for particular procedures.
   c. Use only printed information describing the potential risks and benefits and avoid open discussions with the patient.
   d. Have a nurse provide the information required for informed consent but be available to answer questions.

3. **In the case involving potential hepatitis C exposure at a Washington hospital, what does Benjamin J. Fenton, JD, say about how the hospital responded?**
   a. It was wrong to notify all patients potentially exposed, even those for whom the risk was low.
   b. It was correct to notify all patients potentially exposed, even though that increased the number of potential plaintiffs.
   c. It should not have notified patients potentially exposed until legal issues involving the nurse were resolved.
   d. It should have notified many more patients and not just those treated by the nurse in question.

4. **In the dry run radiography program at Allegheny Health Network in Pittsburgh, what was one likely reason for fewer reported incidents after the simulations began?**
   a. Errors were caught at the dry run stage, before they could create more incidents.
   b. Staff were more focused on detecting errors before the simulations began.
   c. The patient mix was different after the dry runs began.
   d. Radiologists were more directly involved in the process when the dry runs began.

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Physician Defeats Liability for Prescribing Without In-person Consultation

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News: In 2014, a middle-aged man contacted a plastic surgeon with whom he had an existing friendship. The patient indicated he suffered from chronic pain in his back, shoulders, and other areas, first informally and then in a phone consultation with the plastic surgeon, who prescribed medication to treat the pain. At no point did the patient meet with the plastic surgeon in person to discuss the treatment or symptoms.

On a subsequent trip, the patient consumed many alcoholic beverages, which interacted with the medication. He was found dead the following morning. His daughter brought suit against the plastic surgeon and his employer, alleging that the physician engaged in malpractice by failing to meet with the man in person. An autopsy report revealed that the level of medication was therapeutic and that the cause of death was cardiac in nature. After a six-day trial, the jury found for the defendant, in part because the physician testified that he cautioned the patient against drinking while on the medication.

Background: On Sept. 29, 2014, a 54-year-old self-employed contractor contacted a plastic surgeon, with whom he had been friends for more than 20 years, regarding persistent pain in his neck, back, shoulder, and upper arm. The contractor had multiple phone conversations with the physician the week prior, informing the physician of his symptoms and claiming that the pain would not subside with over-the-counter medication and rest.

During one conversation, the physician prescribed a powerful narcotic, Vicoprofen (hydrocodone and ibuprofen), and a muscle relaxant, Soma. At no point did the patient come in to the physician's office for an examination. A few days following the phone call, the patient went on a trip and drank a substantial amount of alcohol before he went to sleep. The patient's friends discovered him dead the following morning.

AN AUTOPSY REPORT REVEALED THAT THE LEVEL OF MEDICATION WAS THERAPEUTIC AND THAT THE CAUSE OF DEATH WAS CARDIAC IN NATURE.

A medical examiner performed an autopsy, which revealed that the contractor had an enlarged heart and coronary artery disease. Toxicology tests revealed a blood alcohol content of .13 and therapeutic levels of the two medications prescribed by the physician. The autopsy report concluded that the primary cause of death was cardiac in nature, but with contribution from the combination of drug and alcohol toxicity.

The patient's daughter sued the physician and the plastic surgery center that employed him, alleging they were negligent in the treatment of her father and in issuing the prescriptions. She further claimed that this negligence amounted to medical malpractice and caused the patient's wrongful death. The surgery center was voluntarily dismissed before trial, and the case proceeded to trial against the physician only.

At trial, the plaintiff's pathology expert (and the same physician who performed the autopsy and issued the autopsy report) testified about his findings and the basis for his conclusions regarding the cause of death. He further testified about how he determined that the combination of drug and alcohol toxicity contributed to the contractor's death. The plaintiff's counsel argued that, while it was true that the patient was contributorily negligent for drinking while on pain medication, the physician was negligent for prescribing the medicine in the absence of an actual physical exam, and thus liable.

The plaintiff's internal medicine expert testified that California law precludes a physician from issuing a prescription for medication, especially narcotics, to an individual without a face-to-face patient encounter and a good faith physical examination. Thus, the expert opined, it was below the standard of care to prescribe Vicoprofen and Soma without first performing an examination.

In response, the defense's plastic surgery expert stated that the physician gathered all pertinent medical information during the phone conversations to determine that the two prescriptions were justified. The expert testified that the conversations did, in fact, satisfy the patient examination required by California law. Moreover, the expert pointed out that even in retrospect, there were no medical conditions present that would have made the prescriptions contraindicated even if a face-to-face examination had taken place.

The defense's pathology and cardiac pharmacology experts both testified that the cardiac event was triggered by the binge consumption of alcohol and explained that there was no drug "toxicity" in this case, as all medications were at therapeutic levels and did not trigger any type of cardiac event. The physician testified that he advised the patient not to take the medications with alcohol. Defense counsel argued that the man caused his own death by consuming alcohol while taking the prescriptions.

After a six-day trial, the jury found in favor of the physician.

What this means to you: Notwithstanding the defense verdict, this case still illustrates the importance of implementing procedures to prevent unlawful medical practices. Hospitals need robust compliance teams that remain abreast of changing case law and statutory law, as well as changes to the applicable standards of care. These compliance teams also must implement an enforcement program that can develop a complaint procedure.

Hospitals are required by licensing and accreditation agencies to maintain performance improvement and risk management programs. These programs include peer review activities that guide physician practices and deal with divergent behaviors under state and federal guidelines that also include strict protections to preserve the confidentiality of any disciplinary proceedings. Enforcement programs should set up procedures that govern the methods by which complaints are received, reviewed, investigated, evaluated, and resolved.

Hospitals also should implement mandatory reporting procedures for instances such as the death of a patient, the conviction of an employee on a felony charge, the observation of unlawful activity during the course of duty, and any activity that may reasonably be the subject of a malpractice proceeding. For best practices, and contemplating that medical malpractice litigation will eventually occur (even if meritless), hospitals also should strongly consider working closely with attorneys to consider the rules of evidence and facilitate insulation from intrusive discovery requests to the extent possible.

Another notable lesson from this case is the potential danger of a medical professional's provision of services to friends, family, or even himself or herself. An analogous adage from the legal practice applies: A lawyer who represents himself has a fool for a client. Multiple issues may arise from such a provision of services, including questions concerning the physician's judgment and diagnoses given the personal connection to the client. While it may not be illegal to self-prescribe, many will readily recognize that this practice can quickly evolve from a well-intentioned one to a vicious cycle of abuse. Self-prescription with controlled substances should be expressly prohibited by hospitals, and a similar prohibition should be implemented against prescriptions for controlled substances for anyone with whom physicians have a close personal relationship.

Fortunately for the physician in this case, he informed the patient about the dangers related to consuming alcohol with the prescription. Physicians and medical professionals must ensure that patients are informed of — and understand — such dangers, including those related to prescription medications mixing with different activities (consuming alcohol, operating motor vehicles, interactions with other medications or specific foods, etc.).

For example, the effectiveness of blood pressure and heart medications may be reduced when combined with alcohol, especially beta-blockers and angiotensin-converting enzyme. Over-the-counter and prescription painkillers may even pose serious health risks when used concurrently with alcohol. Maintaining medical

records with the specific information given to patients concerning medication use restrictions is paramount if a medical malpractice case ensues, as it is difficult to prove that warnings were provided if they were not documented.

Prescribing medications over the phone is generally not malpractice in and of itself. In fact, with the expansion of telemedicine, it is becoming more common. The physician here was a close friend of the decedent and therefore had knowledge of his general health and current medical condition, and warned him appropriately. The pharmacy where the patient filled the prescriptions also has a legal requirement to put warning labels on all medications that interact with or potentiate the effects of alcohol. It is unfortunate that many patients disregard these verbal warnings from prescribing physicians and the written warnings on the medication bottles in their hands, but as evidenced by this case, medical professionals who correctly provide these warnings may avoid liability for malpractice. ■

REFERENCE

Decided on April 19, 2018, in the Superior Court of Orange County, Orange, CA; case number 30-2015-00811876-CU-MM-CJC.

Injuries From Fall at Hospital Lead to Patient's Death, $3 Million Verdict

News: In late 2014, an elderly man went to a hospital for the implantation of a pacemaker. He was given zolpidem to help him sleep; however, it was ineffective, and a nurse was required to help him into a chair beside his bed. The medication made him drowsy and lose motor control, and he fell out of his chair.

The man suffered a laceration on his ear, and later scans indicated he also suffered a subdural hematoma. He was later transferred to hospice care, where his condition deteriorated and he eventually passed away. His wife and daughter brought suit against the hospital, alleging that it was negligent in monitoring him. The jury found in favor of the plaintiffs and awarded them $3 million for the wrongful death.

Background: On Dec. 26, 2014, an 84-year-old man underwent a procedure for pacemaker implantation. Shortly before midnight on Jan. 2, 2015, the man was administered zolpidem to help him sleep while recuperating from the surgery. A few hours later, at approximately 1:30 a.m., a nurse moved the man to a chair beside his bed, as he was still unable to sleep. At some point that night, the man fell out of the chair and hit his head, suffering a laceration to his right ear that required stitches.

After the injury, a CT scan showed a subdural hematoma and, in the days following, the man's brain swelled and bled. The hematoma caused brain tissue to push onto his spinal cord, rendering him paralyzed on the left side of his body.

On Jan. 7, a craniotomy was performed to relieve the swelling in the patient's brain, and he remained intubated until Jan.10. His family reported that he complained of head pain and exhibited outward signs of discomfort. On Jan. 20, the patient was transferred to hospice care where he died two days later.

The patient's wife and his daughter sued the hospital and its parent company, alleging a failure to monitor. The plaintiffs claimed that the patient, who had exhibited signs of memory impairment and was deemed a high fall risk, was negligently placed in a chair without any fall precautions, such as an alarm. They further contended that the patient attempted to get out of the chair without assistance when he fell, likely in attempt to get back into bed or to use a urinal on a side table.

The plaintiffs' nursing expert testified that the man experienced forgetfulness and short-term memory impairment prior to the incident. The expert further testified that this was documented by the nurse on duty at least 16 times in the nursing records. According to the expert, zolpidem amplified his memory issues and impaired his motor functions, thus increasing his fall risk. The nursing expert did not fault the hospital for administering the medication, but argued that the chair should have had an alarm, since he was prone to falling. An alternative was to have him sit next to the nurse's station in the hall, so that the nurse could have monitored him while she worked at her computer.

The defendant argued that chair alarms do not reduce the risk of falls, and the patient did not need one. The defense also testified that older patients commonly fall and not every fall is preventable, nor does every fall cause serious injury. Moreover, an alarm can unnecessarily restrict the movements or choice of older patients who understand instructions and

the need to ask for assistance. The hospital's geriatric medicine expert stated that the zolpidem did not affect the patient's motor function or overall condition, and that it did not contribute to his fall.

The jury deliberated for four hours after a four-day trial, finding in favor of the plaintiffs. The jury awarded a total of $3 million for wrongful death.

What this means to you: Many elderly patients die from fall-related injuries each year. Chair alarms came into use in response to the ban on physical restraints in the 1990s. They are pressure-sensitive pads that are placed on chairs and sound an alarm when a patient shifts his or her weight, indicating they are getting up. Research has suggested that these alarms may pose a risk to patient safety because their use can result in staff complacency. By the time nurses respond to the alarm, patients likely have already fallen to the floor, rendering the alarm useless for its intended fall prevention purpose.

Some medical facilities have begun phasing out alarms and other fall prevention methods to prioritize attentive care. These facilities focus on learning patient routines and accommodating patients who wish to move about freely. They also focus on changing bathroom schedules, rearranging rooms, and providing more mental stimulation to patients to help them regain autonomy and dignity.

While these changes are preferable for overall patient well-being, there is concern that they will inflate the number of falls, exposing care facilities to liability — especially, like in this case, where an alarm may have prevented the fall or minimized the injuries.

Other medical care facilities strike a balance by moving to discreet sensors that alert nursing staff of the patient's movement without causing embarrassment or other negative effects. These sensors communicate with nursing staff directly and alert them of the need to assist the patient.

Other fall prevention methods include lowering beds when patients sleep, placing fall mats, or softening flooring. Hospitals should train staff to actively search out hazards that could increase fall risks and injuries, such as power cords, boxes, loose rugs, loose floorboards, spilled liquids, and clothing. More lighting can help prevent falls, including nightlights in bathrooms.

Medical professionals also should be keenly aware of fall risk factors, including a history of falls, decreased strength, gait or visual impairment, psychoactive medication use, dizziness, low body mass index, cognitive impairment, arthritis, and undertreated pain.

In this particular case, the injury that caused the patient's death, a subdural hematoma, is characterized by a collection of blood between the dura mater of the brain and the surface of the brain. This bleeding fills the brain area quickly, compressing brain tissue, and is among the deadliest head injuries. The most common cause of subdural hematoma is severe head trauma.

The symptoms depend on the location and size of the hematoma and can include confused or slurred speech, balance issues, trouble walking, headache, lack of energy, seizures, nausea or vomiting, and vision problems.

Subdural hematoma typically is diagnosed via a head CT or MRI, and is often treated through a craniotomy or medications such as diuretics and corticosteroids to reduce swelling, and anti-seizure medications. Subdural hematoma is an emergency condition that requires prompt treatment. In the event of a fall, medical professionals must be cautious for any resulting emergent conditions — and the failure to do so may constitute medical malpractice.

Injury-causing falls are not limited to the elderly; younger patients are also at risk because they do not realize the limitations on mobility caused by surgical procedures and drugs, including antihypertensives, sedatives, hypnotics, analgesics, and psychotropics. These drugs have additional effects on the elderly, who metabolize them at a variable rate, making it difficult to determine when their effects will subside. Zolpidem is known to cause sleepwalking in some cases and should be used with caution, as should all medications given to seniors.

Patient falls occur in every healthcare setting, and there is no way any facility can prevent all of them. All patients who fall should be carefully assessed for occult injuries, especially if there are external bumps, bruises, or broken skin with bleeding. X-rays and scans should be done without hesitation, even if only to confirm that no injury occurred.

Of concern in this case is the delay to intervene once the patient fall was discovered. The fact that there was a laceration to the ear means that the side of his head most likely hit the floor. A CT scan should have been ordered that night, and if negative, repeated in four hours. Any evidence of a bleed should have been addressed medically or surgically on an emergent basis. In this case, the craniotomy was performed five days later, by which time the harm had already occurred. ■

REFERENCE

Decided on April 6, 2018, in the Delaware County Court of Common Pleas; case number 2016-6622.