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Surgeon Sues Health System for 'Forced Referrals'

A Florida health system is facing a whistleblower lawsuit from a surgeon alleging the system violated federal law by requiring him to perform surgery and refer patients within its own facilities. The surgeon claims the health system fired him for not complying with the policy.

The mandatory self-referrals violate the Physician Self-Referral Law (Stark law), and other statutes, the lawsuit claims.

In the lawsuit, filed in January 2020, the orthopedic surgeon claims that he was fired for performing surgeries at a hospital unaffiliated with the health system that employed him, as well as for referring patients to radiologists outside of the health system. He is suing the

health system, two physician groups, and an imaging center.

According to the lawsuit, the health system created “an unbroken chain of financial relationships that renders these referrals as violations” of Stark. The surgeon also claims that physicians benefited financially from the arrangement.

The lawsuit says the surgeon was employed by a physician group for three years before the group was acquired by the health system, at which point in-network referrals were strongly encouraged but not required. But over time, the surgeon claims, he and other physicians began to feel more pressure to stay within the network.

He claims that at one point the health system

CEO encouraged another doctor to “show some loyalty to the system.”

ACCORDING TO THE LAWSUIT, THE HEALTH SYSTEM CREATED “AN UNBROKEN CHAIN OF FINANCIAL RELATIONSHIPS THAT RENDERS THESE REFERRALS AS VIOLATIONS” OF STARK.

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EDITORIAL QUESTIONS
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The orthopedic surgeon alleges that he was threatened with termination if he continued performing surgeries at other hospitals. When he resisted, the president of his physician group told him he was “sending a very negative message to [his] employer,” according to the lawsuit.

The health system also encouraged physicians to send patients to its imaging center, but the surgeon disputed the quality of care, citing difficulties in scheduling and long wait times, according to the suit.

Prioritize Best Quality Care

Although the case has not been resolved, there already are lessons for risk managers, says **Callan G. Stein, JD**, partner with Pepper Hamilton in Boston.

The first lesson is that hospitals and healthcare systems should clearly state and routinely emphasize to their physicians that the top priority is always ensuring patients receive the best medical care, Stein says.

“When talking about in-network referrals, the message should focus on the benefits to the patient of staying within a single network to get all necessary treatment. For example, the ease with which care can be coordinated across multiple physician and

specialties,” he says. “In this case, some of the worst-sounding allegations are those concerning directions or suggestions from the defendants to the physician to make in-network referrals without any reference to patient care.”

Hospitals and healthcare systems also should avoid broad directions that referrals “need to be” or “must” be made within network, Stein says. When making a referral, each patient’s situation must be evaluated individually to determine the best course.

“Blanket directions for in-network referrals can appear to deprioritize the patient’s needs when, in fact, the in-network referral is often what is best. Imposing broad directives also deprioritizes the patient’s right to choose his or her own care, which is imperative and must be emphasized,” he says. “Physicians must be made to feel confident in discussing what the patient’s preference is, so any statements concerning in-network referrals must include allowances when patients indicate a preference for an out-of-network provider.”

Do Not Punish Out of Network

Hospitals and healthcare systems should not punish or take negative

EXECUTIVE SUMMARY

A surgeon is suing a health system for allegedly requiring him to operate and refer patients within the network. The lawsuit claims violations of the Stark law.

- Hospitals and health systems should never explicitly require in-network referrals.
- The patient’s quality of care always should be the priority.
- It is possible to establish expectations of in-network referrals without violating Stark.

actions against physicians for referring patients out of network, Stein says. Often, there are valid reasons for doing so, such as complying with patient preference, a necessary specialist is out of network, or a piece of specialty equipment is only available at an out-of-network facility.

Hospitals and healthcare systems should endeavor to avoid even the appearance of taking negative action against physicians for out of network referrals, he says. For example, hospitals and healthcare systems should avoid overtly tracking individual physicians' in-network vs. out-of-network referral rates. They should never widely discuss or publish that information, he says.

Hospitals and healthcare systems can — and arguably should — ask physicians, in a nonthreatening way, why a particular referral was made out of network, Stein notes.

The information gathered from those discussions can be a valuable tool for identifying areas of the network that need strengthening, or geographic areas that need additional resources, he says. If physicians are hesitant to provide information in this manner, the facility might consider setting up an

anonymous mechanism to report such information.

“Under no circumstances should a physician’s compensation or job security ever be tied, directly or indirectly, to the number of in-network referrals he or she makes,” Stein says. “Such conduct could result in liability under the Anti-Kickback Statute, Stark law, or other laws. Again, hospitals and health systems should avoid even the appearance that this could be a possibility.”

Possible to Encourage In-Network Referrals

Depending on the circumstances, it is possible for the health system to expect that employed physicians will refer within the network, says **Geoffrey R. Kaiser**, JD, partner in the compliance, investigations, and white collar group with Rivkin Radler in Uniondale, NY.

If the surgeon is an employee of the health system, conditioning his continued employment on his agreement to refer his patients to the health system is not necessarily a violation of the Anti-Kickback Statute or the Stark law, he says, notwithstanding that employment

has remunerative value and might otherwise be viewed as an improper inducement to refer.

For example, Kaiser cites *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1050 (N.D. Ill. 2002), in which the court held that these statutes were not designed “to regulate typical hospital-physician employment relationships” and that “[t]here is nothing in either statute that prohibits hospitals from requiring that employee physicians refer patients to that hospital.”

“Outside the employee context, in a case involving an independent contractor, for example, the analysis would be different because the bona fide employee exceptions that exist in both statutes, and that protect such arrangements where the employee compensation formula is not directly based on referrals, would not apply,” Kaiser says. ■

SOURCES

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HHS, CMS Easing Some Abuse Rules, Will Reduce Compliance Burden

The Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) are continuing their plan to ease burdens on healthcare providers by amending the Stark law, the Anti-Kickback Statute (AKS), and the Civil Monetary Penalties Law.

The HHS Office of Inspector General has proposed revisions to

ease requirements under existing AKS safe harbors. The proposed changes involve electronic health records (EHRs), warranties, local transportation, and personal services and management contracts.

This effort to reduce regulatory burdens is part of the HHS Regulatory Sprint to Coordinated Care, says **Jayme R. Matchinski**, JD, an officer

with Greensfelder in Chicago. That program aims to encourage value-based arrangements and patient care coordination, allowing some activities that otherwise might be considered forbidden by current law.

“This is good news for healthcare organizations,” she says. “This is an opportunity to pursue quality healthcare without having to face obstacles

that were meant to deter fraud but that, in practice, often got in the way of doing the right thing for the patient.”

The proposed changes would add new value-based exceptions to Stark, provide new safe harbors under the AKS, and revise some AKS safe harbors.

Healthcare Is Different Now

The proposed changes should reduce burdens for healthcare providers and allow greater flexibility while still discouraging fraud and abuse, Matchinski says.

A statement from HHS explained that “The Stark law’s new value-based exceptions, under the proposed rule issued by the Centers for Medicare & Medicaid Services, acknowledge that incentives are different in a healthcare system that pays for value, rather than the volume, of services provided. They include proper safeguards that ensure the Stark law will continue to provide meaningful protection against overutilization and other harms, while giving physicians and other healthcare providers added flexibility to improve the quality of care for their patients.”

The proposed changes would address “the longstanding concern

these laws unnecessarily limit the ways in which healthcare providers can coordinate care for patients,” HHS said. “The changes would offer flexibility for beneficial innovation and improved coordinated care through, for example, outcome-based payment arrangements that reward improvements in patient health. The changes also would make it easier for physicians and other healthcare providers to ensure they are complying with the law by offering specific safe harbors for these arrangements.” (*The statement can be found at: <https://bit.ly/39W3Y5z>.*)

Healthcare organizations have responded positively to the proposed changes. **Janis Orłowski**, MD, chief health officer of the Association of American Medical Colleges, issued a statement saying the group commends the “comprehensive efforts in this proposed rulemaking to increase opportunities for hospitals and physicians to engage in innovative arrangements to enhance care coordination, improve quality, and reduce costs. In this rulemaking, CMS takes a major step forward by addressing many of the real-world challenges that hospitals and physicians encounter when trying to structure arrangements that comply with the Stark regulations.” (*The statement can be read at: <https://bit.ly/3cX1C8n>.*)

The American Medical Group Association echoed those sentiments with a statement saying the group is “supportive of these exceptions, which would allow providers to take more innovative approaches in their financial arrangement while encouraging and removing barriers to value-based care.” (*The comments are available at: <https://bit.ly/39Okwvp>.*)

Home Dialysis Could Benefit

One proposed improvement cited by HHS and CMS involves in-home dialysis treatment. HHS says that health outcomes could be improved for patients with end-stage kidney disease by allowing a nephrologist, dialysis facility, or other provider to use telehealth to monitor and communicate with the patient.

Matchinski says this would be a huge step forward for these patients, and it is a good example of how the proposed changes could improve care by eliminating unnecessary roadblocks.

“Since the Affordable Care Act, HHS has strengthened its healthcare fraud and abuse oversight, so this is interesting that they are trying to move away a little bit from that,” she says. “The Affordable Care Act gave the federal government a stronger tool belt to go after fraud and abuse, but now HHS is putting in this value-based exception to the Stark law, adding these proposed additional safe harbors. They’re looking at how these value-based arrangements can improve care and easing some of the restrictions to provide a little more flexibility.”

There still will be penalties for persons or entities offering remuneration that violates Stark or other laws, but the proposed rules

EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) are trying to reduce regulatory burdens on healthcare organizations with rule changes that would protect some activities from anti-kickback allegations. The changes are intended to promote value-based care.

- The rule changes could give physicians more flexibility in treatment options.
- HHS and CMS are proposing new exceptions to the Stark law and other anti-kickback laws.
- Many healthcare organizations support the proposed changes.

alter the definition of remuneration and specifically allow some activities like telehealth for in-home dialysis, Matchinski explains.

“This new safe harbor would support that arrangement for end-stage renal disease and in-home dialysis, which would allow healthcare organizations to provide this service in the way that is best for these patients. They currently can’t do that without fear of violating Stark or other anti-kickback statutes,” she says. “They would have an exception so that it would not be considered remuneration under the Anti-Kickback Statute.”

With the proposed changes, an end-stage renal disease patient would not have to make a trip to the hospital or clinic for a face-to-face evaluation by a physician to receive dialysis, Matchinski explains.

“It can be a telehealth visit as long as there is documentation that the intention is not to steer the provider to a particular provider or supplier. My clients have been looking at this and making sure they have the right

forms showing the client understands how the patient care is going to be delivered,” she says. “Telehealth technologies cannot be an advertisement or a solicitation. Telehealth has to be about providing services for those end-stage renal disease patients, and the providers have to be aware of the change in technology. The provider has to document that this telehealth technology significantly adds to the provision of the patient’s care.”

Value, Freedom of Choice Required

In addition, the telehealth service cannot be of “excessive value.” Matchinski says this is the area that HHS and CMS will police closely.

“You can’t provide a \$600 smartphone when a \$300 smartphone would be adequate for the technology,” Matchinski says. “You have to use efficient telehealth technology, not necessarily the most expensive. You also can’t use duplicative technology, providing the

patient a smartphone if they already have one that will work with the technology.”

The healthcare organization providing the telehealth technology also must document that the patient has been informed of his or her right to obtain healthcare services from any provider, that the provision of technology does not bind the patient to that healthcare provider.

“This changes the game for a lot of end-stage renal disease patients and eases the enforcement obligation for HHS,” Matchinski says. “Make sure you have good documentation for medical necessity, that the telehealth technology meets the requirements for multimedia communications, and the freedom of choice form must be reviewed and signed to show that the patient understands care can be obtained elsewhere.” ■

SOURCE

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Medical Record Retention Requires Good Policies, Strict Compliance

Records retention is a critical issue for risk managers, as the loss of important patient records and other documents could compromise litigation defense and threaten ongoing care. Healthcare organizations must create clear records retention policies and follow them closely, experts say.

Many healthcare organizations follow a policy of keeping medical records for seven years, says **Andrew Selesnick**, JD, shareholder with Buchalter in Los Angeles.

“However, we usually recommend 10 years because if there is a

dispute and the medical records are unavailable, defending on such a claim could be more problematic,” he says.

Without a medical record, defending a medical malpractice claim would be that much more difficult. This is why some insurance companies recommend keeping medical records for 10 years when the patient is an adult, 28 years for infants, and in the case of death, an additional five years, he explains.

The proper policy will differ according to the type of healthcare

organization, notes **William P. Dillon**, JD, shareholder with Gunster in Tallahassee, FL. A hospital must comply with state and federal legal requirements pertaining to records retention but also might have to follow guidelines set forth by accrediting bodies like The Joint Commission, he says. HIPAA also requires retaining records for six years.

A physician practice or group will follow federal and state laws, but those requirements should not always be considered ideal. In many cases, they should be seen as

only the minimum time physicians should retain records, Dillon says. For example, Florida law requires physicians to keep records for five years.

“We’re always telling them not to adhere to that because five years is just too short a time to retain medical records. That doesn’t comply with HIPAA, and it doesn’t protect you through the statute of limitations for medical malpractice in Florida,” Dillon says. “It also doesn’t protect you from a billing perspective if you’re billing Medicare or Medicaid patients because of the way the False Claims Act is interpreted.”

Follow Internal Policy

Healthcare organizations should assess the requirements and create an appropriate records retention schedule. This may mean keeping some records longer than required by one law or guideline to comply with another, he explains. The next step is important: actually following the retention schedule.

“A lot of people have the right retention policy that they’ve researched and put a lot of time into formulating, but then they don’t seem to follow it,” Dillon says.

The move to digital data in healthcare has changed how healthcare organizations look at records retention, Dillon notes. In previous years, retention policies

were driven in part by the high cost of storage for paper records, with hospitals, health systems, and physician groups eager to clear out old records as soon as it was practical. That meant policies often called for the destruction of records as soon as they passed thresholds set by law, he says.

“A LOT OF PEOPLE HAVE THE RIGHT RETENTION POLICY THAT THEY’VE RESEARCHED AND PUT A LOT OF TIME INTO FORMULATING, BUT THEN THEY DON’T SEEM TO FOLLOW IT.”

But now, with so many records stored digitally, and with digital storage much more cost-effective than physical storage, many healthcare organizations are comfortable with extending their retention policies to go beyond what is required, keeping records longer if they might potentially benefit the organization or the patient, Dillon explains.

“The question of storage space

and cost is not as pressing as it used to be, which raises the question of why we don’t just keep electronic records forever,” Dillon says. “There are competing schools of thought on that, with some saying it’s not going to hurt you to maintain the record for longer than required. But others argue that the longer you keep the record, the more you run the risk of it being exposed in a data breach, which would create potential liability over a record you had no obligation to maintain.”

Dillon advises healthcare organizations to err on the side of keeping records longer than required by any law or guideline. When in doubt, it is always better to retain records a little longer than necessary than to get rid of them too soon, he says.

“Humans are involved, and mistakes get made. I’d rather have a hospital hang on to the records a year or two longer than the statute says than run the chance of purging it too soon and then have to answer for that,” he says. “There’s no need to be aggressive and risk destroying documents too soon.”

But is there a risk that a record could be used against an organization if it is kept too long? “I don’t think you would find that’s much of a risk from a practical perspective,” he says. “It’s certainly possible in theory for a record to be used against you long after its retention period ended, but I don’t think I’ve seen the data to suggest that happens often at all.”

However, Dillon is doubtful of arguments that records should be kept indefinitely because they might be beneficial for patient care. Details from a patient encounter 10 years earlier are not likely to be helpful because relevant information would already have been carried forward to current records, he says.

EXECUTIVE SUMMARY

Medical records must be maintained for a minimum period defined by state and federal law, as well as other guidelines. It is important to have a records retention policy that accommodates all applicable requirements.

- It may be prudent to keep records longer than required by law.
- The retention period may be affected by the patient’s age.
- Retention policies should consider the ways a patient’s record is used.

Consider All Departments

Retention policies should be consistent among all similar facilities within a health system, Dillon says. For example, all hospitals in the system should have the same policy, and all physician groups should, too. It also is reasonable for a health system to use one universal policy that covers all types of entities and requirements for all states in which it practices, adhering to the longest applicable retention period, he says.

It is important to employ someone to oversee records retention policies who has a firm understanding of all applicable laws, guidelines, and the needs of various departments, notes **Clara Erman**, RHIA, director of the Health Information Technology Program at Plaza College in Forest Hills, NY. Retention policies may be influenced by the needs of clinicians, financial services, human resources, quality improvement, and risk management, she says.

“You want an individual who is savvy about all these areas, and how any single medical record has components that will be of concern to all these different people and departments,” Erman says. “Otherwise, you can have issues in

which you are destroying records that are still of interest to someone because you were looking only at the clinical data.”

A records retention policy also should be clear on how documents are to be purged, Erman says. A policy may be clear on what is expected and when records are to be destroyed, but it is not uncommon for the policy to stop there without specifying how to get rid of the documents, she says. That means individuals are left to determine how to destroy documents. This opens the possibility of many errors that can leave data still in your possession or in the hands of the wrong people, she says.

“It needs to make sense all the way through, so that when you write a policy calling for the destruction of data at a certain point you also describe exactly how to go about doing that,” Erman says. “We have to remember that we write a policy, we’re not writing it for ourselves and assuming all the knowledge that we have of a particular subject. We’re writing that policy to be read by someone else who may not know the proper steps to be taken unless you include them in the policy.”

Erman does have concerns about keeping records longer than required by applicable laws or guidelines. As long as records are retained,

hospitals will be obligated to produce them when they are subpoenaed or requested by a patient, Erman says.

There is no gray area in which hospitals can have possess records but not turn them over because the required retention period has passed, she explains.

“If you are going to keep the records longer, either because you did not follow your own policy or you have some other reason, you have to know that there is that risk of the records being subpoenaed and you having to turn over records you wish you had destroyed,” Erman says. “It can come back to hurt you. That is why you want to make sure you have individuals who understand all the different aspects of a record and how it can be used, not just the clinical side, and it could impact the organization if you retain it.” ■

SOURCES

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Fall Prevention Always Is a Concern; Innovative Products Help

Fall prevention is a perennial concern for risk managers but it is important not to get complacent about the challenge. Look for new ideas and ways to improve fall prevention efforts, as well as fall investigations.

Good data collection is essential to the proper investigation of fall incidents and long-term prevention efforts, says **Bette McNee**, RN, NHA, clinical risk management consultant at insurance broker Graham Company in Philadelphia. Data collection should go beyond the basics of how the patient slipped on a wet floor, she says.

“We need to record the clinical circumstances, such as the patient’s blood pressure, any new meds they were on, the first time out of bed — the information that can be useful when the hospital is investigating fall trends and what can be done,” she says. “This can help with identifying the risks that are unique to your patient population, because the fall risks are going to be different for a patient population with a majority of patients over 80 vs. a postoperative general surgery population.”

Healthcare organizations also are using more environmental design and innovative devices to prevent falls, McNee says. For instance, some

hospitals are avoiding the sudden overhead light when a patient goes to the bathroom at night by using motion-activated, underbed lighting to illuminate the floor area instead, she says.

“WHEN THEY ARE ALREADY LOOKING AT RENOVATING ROOMS, HOSPITALS ARE STARTING TO LOOK MORE AT INNOVATIVE DESIGNS, ESPECIALLY WITH FLOORING AND THE BATHROOMS.”

“When they are already looking at renovating rooms, hospitals are starting to look more at innovative designs, especially with flooring and the bathrooms,” McNee says. “In many hospitals, the design of the bathroom is increasingly important, with more attention to how to

contain splashing that will leave water on the floor, for example. They’re using poured floors with grit to improve the slip coefficient, many things like that.”

Cord management also is a big concern. Some bed manufacturers are responding with options such as retractable cords and cord lines that run along the underside of the bed, she adds.

Healthcare risk managers should encourage consideration of these innovative product designs to reduce falls, says **Alan Abrams**, MD, a geriatric clinical advisor and member of the board of directors for Senior Helpers, a company based in Towson, MD, that provides in-home services to seniors.

“There are a number of devices that can help support older adults to reduce the risk of falls and to alert to the risk of fall. Some of them need better proof points but people should be on the lookout for some of these,” he says. “There are some interesting, innovative products that are being developed, such as balance monitoring devices, but the mainstay of fall reduction is that it is multifactorial and it includes environmental issues.”

Those environmental issues include lighting for vision cues, assist bars, elevated toilets, reducing clutter, removing potential trip and slip obstacles, reducing fall-associated medications, using proper footwear, and proper use of assistive devices such as walkers and canes, he says.

Other new products can monitor the restlessness of patients, McNee says. Patients tend to get restless and move about before they attempt to get out of bed and risk a fall, so this new technology can monitor how

EXECUTIVE SUMMARY

There has been progress in fall prevention, but there is much more room for improvement. Some organizations are finding success with innovative products that can help reduce falls.

- Data collection should include clinical information.
- Falls may be reduced at meal times.
- Hip protectors can help prevent fractures from falls.

active a patient is in bed and prompt a nurse intervention before a fall, she says.

Hospitals also can borrow risk management strategies from senior care facilities to reduce fall risks, McNee says. For example, facilities caring for older patients often serve several meals a day, and serve items in ways that require slower eating.

“A lot of times, hospitals will find that when they track their trends in falls, they will find that there are fewer falls during meal times. Why? It’s because we have something to do when we’re eating and so we’re not moving about,” she says. “Speech therapists and occupational therapists are good at finding ways to slow down consumption, and this can be useful even if there is no need to prevent choking or otherwise slow down that patient’s eating. If a community hospital is seeing a lot of older people at risk for falls, doing something like that can be an effective way to address falls.”

An Ongoing Challenge

There has been progress in addressing falls, partly because of

campaigns like the one led by the National Council on Aging (NCOA), says **Linda Rowett**, BSN, RN, risk consultant with liability insurer Coverys in Morristown, NJ. (*The NCOA offers evidence-based fall prevention programs online at: <https://bit.ly/39HRcHI>.*)

Another promising fall prevention method was implemented by the Veterans Administration (VA), Rowett says. The VA is using external hip protector devices designed to decrease fractures. Manufacturers offer multiple types of hip protectors, some with soft shells designed to absorb the energy and redistribute the force of the fall, and others with a hard shell that distributes the energy of the impact.

Rowett notes the VA has developed a toolkit for providers to aid in the implementation of hip protectors. “Although the scientific evidence is mixed, some large, randomized, controlled trials have demonstrated their usefulness in nursing home settings for preventing hip fractures in older adults,” the VA’s National Center for Patient Safety reported. (*The toolkit is available online at: <https://bit.ly/38RHdyw>.*)

The need for fall prevention will

not decrease even as progress is made, Rowett says. The number of falls is large enough, and the effect of falls on individuals and organizations is significant enough that fall prevention will always be a top priority for risk managers, she says.

“Falls in 2017 were the second highest category of sentinel events, according to The Joint Commission. In 2015, they were the No. 1 cause of root cause analysis, according to the National Center for Patient Safety,” Rowett notes. “One-fourth of Americans aged 65 or older fall each year, and falls cause 2.8 million injuries annually. I don’t believe there will be a reduction in falls significant enough to mean we can take our focus off of this problem.” ■

SOURCES

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Patient Selection, Standardization Can Reduce Surgical Liability

One-quarter of all malpractice claims in a recent closed claim study involved surgical allegations, second only to diagnosis-related allegations. The authors of the study said standardization and practice contribute to successful outcomes. Routine and rigor also are vitally important.

Coverys, a malpractice insurer based in Morristown, NJ, conducted a study of five years of closed

malpractice claims data from 2014 through 2018. The researchers were surprised that performance and technical skills remain the largest risks in surgery, says **Sharon Gilmore**, MHA, BSN, RN, CPHRM, CPHQ, senior risk specialist in the risk management department at Coverys.

“For technical risks, we’re thinking that homing in a little bit more on credentialing and privileging would

help, to be sure that the surgeon has performed those types of surgeries before and has done so successfully,” she says. “We’re also thinking of the impact from surgeons being pressured to do more with less time, being encouraged to move more patients through the OR in less time and with fewer resources.”

The study authors also determined that 78% of surgical allegations were

related to practitioner performance during surgery. Forty-seven percent of claims from more than 50 surgical specialties involve three specialties: general surgery (22%), orthopedic surgery (17%), and neurosurgery (8%).

Distractions in the OR

Gilmore says the research indicates specific process vulnerabilities at each stage in the surgical episode of care and unique challenges related to the top three specialties. Risk managers can help surgeons understand those issues and improve outcomes, she suggests. (*The report is available online at: <https://bit.ly/2xmKOat>.*)

“Distractions are always a major concern. As we do on-site visits, we often see high traffic in and out as they’re bringing in equipment, possibly because the OR was not prepared appropriately beforehand,” Gilmore says. “Conversations also can be a distraction, as they are talking about their weekend or what’s happening on the floor. Cellphones can be a problem, and we see that especially in anesthesia providers because there are long periods while they are monitoring the patient and may spend that time on their phone instead of aggressively monitoring the patient.”

Coverys recommends limiting cellphones in the OR. Gilmore knows of one hospital that requires all clinicians to drop their phones in a collection basket before entering the OR.

For technical performance concerns, Gilmore recommends strong peer review and performance evaluations of surgeons and their teams.

“We need to identify if there are any lapses in technical knowledge or performance, and that is not necessarily going to come from the standard review process when a surgeon is credentialed. If you think there is any reason to doubt proficiency, there should be a focused effort to evaluate more thoroughly and more frequently,” Gilmore says. “Ongoing reviews can reveal a lot of opportunities for improvement.”

Standardization is important in improving surgical outcomes, Gilmore says. Not only should the surgical team be following best practices, but standardization helps highlight any deviations that can affect outcomes, she says. Gilmore recalls working with a surgeon whose motto was “Same way every day, team. Let’s go.”

“Patient selection is another big issue. The patient may want to use

this provider and the surgeon may want to do the procedure, but does the hospital have the resources? Does the provider have the skill level to serve this particular patient well?” Gilmore says. “No two patients are the same. We have to consider the challenge afforded by this patient, this procedure, this facility, and this surgical team. If they are not a match we are setting ourselves up for failure.”

Patient handoffs and communication also are key to reducing surgical liability, Gilmore notes.

The data presented in the closed claim study present an opportunity for risk managers to assess their own programs. “A lot of people know that these issues are hot spots, but they lose focus over time when they get into the daily routine of providing surgery,” Gilmore says. “The data in the report can be used as a way to look at how your own facility is doing in these areas and to get surgical teams focused on these key areas that have a real impact on quality improvement.” ■

SOURCE

- Sharon Gilmore, MHA, BSN, RN, CPHRM, CPHQ, Senior Risk Specialist, Risk Management, Coverys, Boston. Phone: (800) 225-6168.

Causation Difficult for Plaintiff in ED Malpractice Claim

To prevail in a malpractice claim, plaintiffs must meet four specific criteria: a patient/physician relationship existed, there was a breach of standard of care, negligence occurred while the practitioner was acting within the scope of employment, and negligence was a proximate cause of the injury.

The first three criteria are straightforward in most ED cases. **Gary Mims**, JD, cannot think of a case in which there was no patient-physician relationship, or a case in which one party claimed such a relationship did not exist.

“This would be a dangerous

approach for a defendant in many states like Virginia,” says Mims, managing partner at Fairfax, VA-based Frei, Mims, and Perushek. This is because state damage caps protect physicians from large judgments. “If a defendant successfully claimed there was no patient-physician

relationship, he would lose protection of the cap,” Mims adds.

Generally, plaintiff attorneys find some aspect of care that was arguably beneath the standard of care. Likewise, they can show the ED provider was acting in the scope of his or her employment. However, causation “is often a difficult problem,” Mims says.

For example, in missed stroke cases, the EP did not cause the stroke, but rather failed to diagnose it. “If the ED defense can prove the injury would have happened regardless of the ED physician’s treatment, even if the treatment was negligent, the ED physician would get off because the negligence would not be a proximate cause of the injury,” Mims explains.

The plaintiff may struggle to prove the failure to diagnose caused the bad outcome (e.g., permanent brain injury). First, the plaintiff has to prove the patient visited the ED in time to meet criteria for tPA and that tPA likely would have changed the outcome. “I have rejected many cases where the patient arrived at the ED with signs of stroke and tPA wasn’t given. In those cases, there were notes showing that tPA was considered and why it was ruled out,” Mims reports.

Causation in Missed Diagnosis Hard to Prove

Causation often comes up in ED malpractice claims alleging missed or delayed diagnosis, says **Sean P. Byrne**, JD, an attorney in the Richmond, VA, office of Hancock, Daniel & Johnson. For a plaintiff to prevail, they have to prove a breach of the standard of care that proximately caused damages. “With delayed diagnosis cases, the damages claimed can take many forms,” Byrne says.

It can be a worsened condition, death, a prolonged hospitalization, or less-than-full recovery. “At times, the impact of the diagnostic delay can be more difficult to define,” Byrne notes.

The plaintiff may allege the negligence reduced or eliminated the odds of a positive outcome for the patient. Under this theory, the plaintiff has to prove the provider’s negligence took away the possibility of a better outcome for the patient. “Valuing this damage is challenging,” Byrne observes.

For example, in a delayed diagnosis wrongful death case, the plaintiff might claim the patient’s chance of survival was reduced by 50% due to the EP’s negligence. “The defense might argue that the claim is unduly speculative, given the probability that the patient would have died regardless of the care provided,” Byrne explains.

Legally Complex

These cases are legally complex because the bad outcome has two or more causes. Delayed ED care is one cause, but the underlying condition is another. There may be additional causes. “The traditional ‘but for’ causation test does not squarely fit this type of case,” Byrne notes.

For example, the ED provider is not responsible for the underlying condition. Often, the courts apply a “substantial factor” test. This

looks at whether the EP’s care was a substantial factor in bringing about the result. “This relaxed causation standard is used in some cases that recognize this damages a theory,” Byrne says.

The plaintiff need only show the defendant’s actions increased the risk of harm to the plaintiff. “Other states will apply a stricter standard, asking the jury to decide whether they find a probability that the defendant’s negligence was a cause of plaintiff’s injury,” Byrne says.

Defending these cases requires careful analysis of medical causation. “The defense must develop an evidentiary argument, through expert witnesses, as to the patient’s chances for recovery, and how those chances were impacted with the passage of time,” Byrne says.

The plaintiff maintains the legal burden of proof. However, says Byrne, “it can be a practical reality that the defense in a delayed diagnosis case has the burden of persuasion, if their defense theory is that the delay caused no appreciable harm.”

That is because jurors start with the general presumption that “sooner is better” when it comes to diagnosis in the ED. A defense attorney trying to convince them the delay really caused no harm is going to be viewed with skepticism. “But it is a challenge that defendants must take on when the medical causation analysis is on their side,” Byrne adds. ■

CE OBJECTIVES

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

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



HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. Regarding the surgeon suing a Florida health system over claims he was forced to operate and refer patients in-network, what does Callan G. Stein, JD, say is the first lesson from this case?

- a. Hospitals and healthcare systems should clearly state to their physicians that the top priority is always ensuring patients get the best medical care.
- b. Surgeons will rebel at any policies regarding where they operate.
- c. It is unlawful to give any guidance to surgeons regarding where they can operate or where they can refer patients.
- d. Hospitals and healthcare systems should require their employed surgeons to operate only at their own facilities and refer patients only to in-network facilities.

2. Under the proposed rule that would allow more telehealth services for end-stage renal disease patients, which is one limitation imposed by the Department of Health and Human Services?

- a. Both the patient and physician must be in the same county.
- b. The patient must be within 100 miles of a hospital in which the

physician has privileges.

- c. The patient must sign a document acknowledging he or she is free to seek healthcare from any provider, not just the one providing telehealth technology.
- d. The provider must provide telehealth technology at no cost to the patient or an insurer, including Medicare and Medicaid.

3. What does William P. Dillon, JD, advise regarding records retention?

- a. Keep records only as long as required by law and destroy them immediately when that time runs out.
- b. Know the required maintenance periods, but keep records a bit longer than strictly required by law.
- c. Allow individual facilities or physicians to determine their own records retention policy.
- d. Keep records only for the six years required by HIPAA.

4. In a surgical closed claim study, what percentage of claims were tied to the performance of the surgical team?

- a. 28%
- b. 48%
- c. 58%
- d. 78%



LEGAL REVIEW & COMMENTARY

EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Severe Hypoxia During Delivery Results in Permanent Brain Damage, \$15 Million Verdict

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Elena N. Sandell, JD
UCLA School of Law, 2018

News: A newborn suffered permanent brain damage, cerebral palsy, severe developmental delays, and other significant injuries because of a hypoxic-ischemic brain injury during a natural birth. During the delivery, physicians failed to adequately inform the mother about the risks of vaginal delivery, failed to monitor the infant's heart rate, and failed to act timely when signs of hypoxia were observed.

The newborn's mother filed a malpractice suit alleging the physicians' and staff's negligence caused the child's injuries, as the child was otherwise healthy throughout the pregnancy. Following a trial, the judge awarded the patient \$15 million.

Background: Less than a year before the incident, a woman gave birth to her first child at the hospital. During labor, medical personnel detected the fetus was experiencing bradycardia, which was resolved by repositioning the mother. However, physicians observed the patient's cervical dilation was not progressing; thus, physicians performed an emergency cesarean section.

Four months after giving birth to her first child, the patient returned to the hospital because she was pregnant with her second child. The second pregnancy was monitored properly, and all standard prenatal tests were performed, including ultrasounds, fetal heart rate monitoring, and bloodwork. The fetus appeared to be healthy and developing at an ordinary rate. Because the second pregnancy occurred so shortly after her first, it was classified as a "closely spaced pregnancy."

During the second pregnancy, the patient began considering delivery through natural birth, which is known in her case as vaginal birth after cesarean (VBAC), instead of undergoing another cesarean section. When successful, VBAC is associated with shorter recovery times, less blood loss, and fewer infections. However, if unsuccessful, VBAC can result in major maternal and fetal complications, including hysterectomy, uterine rupture, fetal injury, and death of infant and/or mother.

According to the patient, physicians did not accurately describe to her the specific risks of VBAC associated with her situation. In fact, while in general the

odds of a successful VBAC are approximately 60-80%, the patient's closely spaced pregnancies, short physical stature, pelvic measurements, and the complications during the delivery of her first child should have indicated to physicians that she was not a good candidate for VBAC. Also, physicians should have explained in greater detail the specific risks associated with her case.

Nevertheless, physicians did briefly discuss the general complications of VBAC. The patient expressed her intention to attempt VBAC and forgo a second cesarean

IF UNSUCCESSFUL, VBAC CAN RESULT IN MAJOR MATERNAL AND FETAL COMPLICATIONS INCLUDING HYSTERECTOMY, UTERINE RUPTURE, FETAL INJURY, AND DEATH OF INFANT AND/OR MOTHER.

section. After about 39.5 weeks, the patient went into labor and presented to the hospital two hours after her contractions started.

The patient alleged the hospital staff were negligent in allowing her to walk the halls of the hospital without continuous monitoring of the fetal heart rate. After arriving to the hospital and undergoing an initial check, the patient was encouraged to ambulate, and the fetal heart rate was left unmonitored for approximately one hour. The hospital's standard procedure required an obstetrician be notified as soon as the patient presented to the hospital in labor. However, the obstetrician was not notified until well after the initial complications had begun. In fact, approximately two hours after the patient entered the hospital, the fetal heart rate reached a state of bradycardia and further signs arose indicating poor fetal oxygenation. Staff failed to act promptly, and it was not until the fetal heart rate reached a level associated with fetal injury that a cesarean section was performed. At birth, the newborn appeared blue, could not breathe, and required resuscitation.

Following a trial, the judge found in favor of the plaintiff and awarded \$15 million: \$6.4 million for future medical expenses based on a life expectancy of 57 to 60 years, \$2.2 million for future lost earnings, \$1.5 million for past and future pain and suffering, and \$5 million for past and future loss of enjoyment of life.

What this means to you:

This case presents a multitude of breaches of the standard of care that cumulatively gave rise to the liability and significant verdict in this matter. In the complaint, the patient alleged the physicians breached their duty of care on multiple factual bases, including by failing to disclose all the

risks associated with VBAC, violating the hospital's standard operating procedure for failing to notify an obstetrician when the patient presented in labor, failing to monitor the fetal heart rate continuously, allowing the patient to ambulate, and failing to identify early signs of fetal hypoxia and appropriately treating the condition.

Acquiring a patient's informed written consent is critical. The failure to do so produces significant risk for physicians and care providers. According to hospital records in this case, the patient signed the consent to VBAC forms on three separate occasions throughout the course of her pregnancy. These standard forms contained language indicating that, on average, 60-80% of women experience successful VBAC. However, only one of the three consent copies was signed by a physician who testified that he did not believe the patient's history placed her at a higher risk of suffering complications. The physician further explained that because he believed another physician had more thoroughly discussed the risks, he personally did not provide any detail besides the general risks indicated in the consent form. The plaintiff's expert witnesses opined the plaintiff's previous experience during delivery, as well as her physical characteristics, clearly indicated she was not an appropriate candidate for VBAC. Furthermore, the short time between her two pregnancies exacerbated the risk of complications from VBAC compared to an individual who had a longer period to recover from the cesarean section.

Because the consent form was only signed by one physician, the court determined the overview of the risks provided was insufficient given the nature of the specific case.

Furthermore, the physician relied too heavily on the presumption that "someone else" would have discussed specific risks with the patient, which did not occur. The fact that there were unsigned informed consent forms in the medical record indicates it is possible the patient was asked to sign the forms as part of a hospital's standard office procedure, rather than after an informative discussion with the physician.

When there are multiple physicians providing care to the same patient, a clear delineation of labor is important. Ultimately, it is in each physician's own best interests to ensure he or she abides by the applicable standards and provides sufficient information to the patient to acquire informed consent, even if someone else also may be providing the same or similar information. When in doubt, it is better to err on the side of caution on this point, as two physicians providing full information to the patient is far better than the patient left wondering about the potential risks and alternatives. Thus, care providers must be self-sufficient in this regard, and protect both patients and their own interests by providing adequate information to patients.

The hospital argued that standard procedures required staff to notify an obstetrician as soon as the patient entered labor, but this patient presented to the hospital in "early labor," and it was not yet necessary to notify an obstetrician. However, the obstetrician was not notified for more than two hours after the patient entered the hospital, which was an inappropriately long wait.

The events that took place following the patient's arrival at the hospital is an example of a perfect storm. Every safety standard developed by the American College of

Obstetricians and Gynecologists for the safe management of VBAC was disregarded. Each physician who saw the patient during her prenatal care was obligated to know how their colleagues were advising her about the high risk to her and her unborn child should she choose to deliver vaginally. In fact, it would be acceptable for a physician in such a circumstance to decline involvement, as physicians can remove themselves from situations that present an unnecessary risk to both patient and physician.

All VBAC deliveries are considered high risk. These deliveries require close monitoring and continuous communication between the physician and nursing staff until the physician arrives. Allowing a patient

to wander the hospital while in labor is dangerous, and falls below the applicable standard of care. Placing fetal monitors on the patient but not interpreting or reporting readings that are indicative of fetal distress is even worse. Obstetrical units must be high-performing, intensive care departments where all providers are team players who train together, are comfortable with each other, and work side by side as colleagues without fear of hierarchical reprisals or pulling rank.

According to the judgment, these delays clearly constituted material deviations from the standard of care. The judge explained that if the possibility of a cesarean section been discussed with a physician when the

initial signs of fetal distress began to appear, it was likely the injury would have been avoided. Based on the evidence provided by the expert witnesses, the judge concluded the infant's injuries were a direct consequence of oxygen deprivation during labor. Since the injury was caused to a newborn child, who would require significant future medical care and would suffer lifelong debilitation, the size of the verdict was unsurprising, as it directly correlates to the substantial injury. ■

REFERENCE

Decided on Jan. 28, 2020, in the United States District Court for the Middle District of Tennessee, Case Number 3:15-cv-01073.

Appellate Court Affirms \$6 Million Medical Negligence Arbitration Award

News: A state court affirmed an arbitration award of \$6 million for a child who suffered a brain injury caused by a nurse's failure to reinsert a tracheotomy tube to ensure proper oxygenation to the child's brain. On appeal, the defendant care providers argued the patient waived her right to arbitrate, the arbitration agreement was not enforceable, and the neutral arbitrator acted with misconduct. The appellate court found in favor of the patient on all counts, and affirmed the award.

Background: A child was born with a congenital respiratory condition requiring intubation and constant medical care. In October 2015, while the child was under the care and medical supervision of a nurse, the nurse failed to provide appropriate care and to properly reinsert the patient's tracheotomy tube in a timely manner. The delay

in reinserting the tube caused the patient to suffer oxygen deprivation to her brain, which led to significant and permanent damage.

In January 2016, the mother filed a medical malpractice action in state court against the nurse and the nurse's employer. That complaint alleged the nurse's delay constituted negligence and directly resulted in the child's permanent brain injury. The patient sought to recover damages for physical pain and impairment, mental suffering, loss of enjoyment of life, emotional distress, past and future medical expenses, and loss of earning capacity.

Four months after filing the lawsuit, the patient sought to enforce an arbitration agreement instead, moving the matter to a private arbitration rather than a public court. The defendant nurse and employer opposed the motion. The

arbitration clause was included in a contract between the patient and the medical service provider that stated any dispute regarding allegations of medical malpractice was to be resolved through arbitration, and that the state's law applicable to healthcare providers governed the arbitration. The state court granted the motion, and halted all further proceedings with the court to enable the private arbitration to move forward. The case proceeded to arbitration in front of a panel of three arbitrators: one selected by the patient, one selected by the care providers, and a third selected by both of the first two arbitrators.

During the arbitration, the issue of liability was largely undisputed, as the panel unanimously agreed the nurse breached the standard of care and caused the patient's injuries. However, on the issue of damages,

the panel was divided. The patient-selected arbitrator advocated for an award of \$14 million, based on a life expectancy of 20 years. The care provider-selected arbitrator advocated for an award of \$2 million, based on a life expectancy of two years. Because of the disagreement among the panel, the decision was up to the neutral arbitrator, who awarded \$6 million, based on a life expectancy of between five to seven years.

After the issuance of the arbitration award, the defendant care providers appealed, arguing that the matter should not have been in arbitration and arguing that the neutral arbitrator was biased. The appellate court denied the appeal, and affirmed the \$6 million award for the patient.

What this means to you: The issue of liability in this case was unanimously decided by all three arbitrators in favor of the patient. The facts of the case leave little space to argue the nurse acted in conformity with the necessary standard of care, particularly because of the significance of the delayed medical intervention. The patient's medical condition and her reliance on the tube to deliver steady oxygen to her brain was known to the nurse, and was the entire basis for the provision of medical care. The nurse knew or should have known that leaving the patient without the tube for several minutes would cause oxygen deprivation with the likely consequence of significant brain injury. Even during the arbitration proceedings, the defendant-appointed arbitrator found in favor of the patient.

Rather than substantively challenging the basis for the negligence, the defendant care providers singled out aspects of the arbitration proceeding. First, the care providers argued the proceeding

should have never been allowed because the patient delayed seeking the arbitration. Nevertheless, the court explained the burden of proving the arbitration proceeding could not be enforced rests on the party challenging the proceeding and, when doubt exists as to whether an arbitration clause is enforceable, the law will resolve in favor of arbitration. The defendants failed to raise a timely challenge to the motion to compel arbitration, and had also failed to provide any evidence as to why the arbitration agreement was unenforceable. Thus, the care providers waived their right to challenge the arbitration. As a general legal principle, regardless of venue, the law favors resolution of disputes on the merits, and disfavors dismissal of actions on technical or procedural grounds. Even if the challenge to the arbitration forum was successful, the matter would have proceeded in the state court.

Second, the care providers challenged the validity of the arbitration, alleging the neutral arbitrator exhibited prejudice. Two specific instances were cited: the arbitrator's denial of the care providers' motion to declare a mistrial when it appeared clear that their expert witness would be unable to testify due to illness, and a conversation where the arbitrator referred to the case as "tragic." The appellate court found that the mere comment by the arbitrator did not indicate he had decided the case based on preconceived ideas. Furthermore, there was no evidence the arbitrator acted with misconduct and, even in the decision of the award amount, the arbitrator applied a clear and logical standard drawing his conclusions from information presented by experts. The court noted that all but one of the arbitrator's

decisions questioned by the care providers were unanimous decisions of the panel, and in no occasion did the other panel members question the neutral arbitrator's fairness or good faith.

Finally, the nurse defendant argued that since the arbitration agreement was between the medical service provider — her employer — and the patient, and because she was not a signatory of the agreement, the arbitration clause could not be enforced against her individually. The appellate court did not address the substance of the nurse's argument because it determined that she waived such arguments by failing to oppose the patient's motion to compel arbitration brought at the state court.

Because the evidence on liability was clear in this case, the defendants challenged nearly every procedural aspect of the proceeding. Unfortunately, their challenges were too late, as they failed to oppose the motion to compel arbitration brought by the patient at the initial trial court hearing. If the care providers opposed the motion, the procedural aspects of this case may have changed significantly. Those procedural aspects, including the change of venue, could have altered the substantive outcome. Whether such changes would have been favorable to the care providers is difficult to say, but one item is largely indisputable: Courts generally proceed slower than private arbitrations. Those delays inure to the benefit of defendants rather than plaintiffs. ■

REFERENCE

Decided on Jan. 14, 2020, in the Court of Appeal of the State of California, Fourth Appellate District, Case Number G056386.