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MARCH 2021 Vol. 43, No. 3; p. 25-36

Physician Judgment Case Might Mean More Risk from FCA

Clinicians make judgment calls every day that do not always turn out to be correct, even when they are made in good faith. A recent court decision regarding the medical necessity of hospice care could put clinicians and hospitals at risk of False Claims Act (FCA) allegations when judgment calls turn out wrong.

A recent federal court of appeals decision, *Care Alternatives v. United States (Care Alternatives)*, 952 F.3d 89 (3d Cir. 2020), opens new avenues of liability related to these judgment calls, says **Olivia R. King**, JD, associate with Foley & Lardner in Boston. *(The case text is available online at: https://bit.ly/3aBW033.)*

> "WHAT'S HAPPENING HERE IS THAT THERE ARE CASES BROUGHT CLAIMING THAT A PHYSICIAN'S JUDGMENT IS FALSE FOR THE PURPOSE OF THE FALSE CLAIMS ACT."

Plaintiffs alleged that hospice care physicians had improperly certified patients as terminal, and the patients then lived longer than expected. Four staff members at the New Jersey hospice center initiated a qui tam action claiming the center had submitted false claims to Medicare.

To support their claims, plaintiffs supplied the expert testimony of a physician who reviewed the patients' medical records. They claimed the certifying physicians' medical opinions were wrong in their assessment of the patients' conditions and qualifications for hospice care, thereby leading to false claims when the hospice facility sought reimbursement.

When the case went before the 3rd U.S. Circuit Court of Appeals, the

Financial Disclosure: Dr. Mackles, consulting editor, discloses that he is an author and advisory board member for The Sullivan Group and that he is owner, stockholder, presenter, author, and consultant for Innovative Healthcare Compliance Group. The relevant financial relationships listed have been mitigated. None of the remaining planners or authors for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

HEALTHCARE RISK MANAGEMENT™

***Healthcare Risk Management™*, *ISSN 1081-6534, including Legal Review & Commentary*,™ is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Healthcare Risk Management*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.**

GST Registration Number: R128870672

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defendant argued the claims should require proof of objective falsity and that a physician's judgment cannot lead to FCA liability. The court rejected those arguments, ruling a physician's judgment call can be the basis for liability under the FCA. The defendant is appealing to the U.S. Supreme Court, which is expected to decide in the next few months whether to hear the case.

Objective Falsity Debated

The issue of objective falsity is at the heart of this case. "There's a theory in the False Claims Act, and it's not written in the False Claims Act itself, that in order for a claim to be false, it must be objectively false," King explains. "That means that there are objective, verifiable claims to prove falsity. What's happening here is that there are cases brought claiming that a physician's judgment is false for the purpose of the False Claims Act. There is a circuit split on this question of objective falsity, which is what makes it particularly interesting."

Some circuits require that a claim be objectively false, some do not, and others have not ruled on the issue, King says.

Treatment settings such as hospice and rehabilitation are particularly vulnerable to this kind of claim, says **Michael J. Tuteur**, JD, partner with Foley & Lardner in Boston. He notes that while the FCA applies only to federal programs such as Medicare, commercial insurers could follow the lead of the courts in interpreting the need for objective falsity.

"You have to be able to qualify for hospice, with a finding by a physician that certain clinical requirements are met, including the likelihood of death within six months," he says. "Another clinician can come along, look at the records, and say there was no way this person could have thought that this person was going to be terminal. Sometimes, just going into hospice makes people live longer because it's calmer and they've decided to accept their condition."

A Supreme Court ruling favoring a requirement for objective falsity would greatly reduce the risk for healthcare organizations, Tuteur says. It could make the difference between shutting down a claim early in the process or a case dragging out for a long time.

"It could mean getting out of a case from the very beginning with a motion to dismiss, or — not quite as good — a motion for summary judgment," Tuteur says. "There is a whole lot less upheaval if you can do it at that stage rather than at the trial stage. By then, the provider probably has given up and tries to settle."

With objective falsity, the plaintiff would have to prove the clinical judgment was knowingly and

EXECUTIVE SUMMARY

A recent court decision regarding physician judgment could put hospitals at greater risk of liability. The decision involved the False Claims Act.

- A physician's assessment of medical necessity could be deemed false.
- Expert physician testimony may contradict the defendant's judgment.
- An "objective falsity" standard could reduce the risk.

deliberately false, Tuteur says. That is a high bar and would require proof, such as showing the physician never read the patient record on which the decision was made — an extremely unlikely circumstance.

"Here, there's no reason to think that the practitioner is doing anything other than making a clinical judgment," he says. "That should be the beginning and end of the matter."

Affects Many Treatments

King notes the issue involves more than just hospice and could affect any healthcare service that requires certification of medical necessity for reimbursement. Any providers and organizations participating in Medicare should be aware of the risks with these clinician assessments.

Tuteur says the dispute can involve not just whether a patient should be in the facility, but the details of prescribed services. "Think of all those patients in skilled nursing facilities who are getting physical therapy or occupational therapy, and whether they should get 60 minutes or 120 minutes. The government has brought claims in these cases because they all required a physician to certify this was the amount of rehab a patient needed," he explains. "If the answer is always going to be that you have an expert who says otherwise, those cases are going to be more difficult to resolve. If, on the other hand, absent showing bad faith on the part of the certifier, and the question must be answered objectively whether it is true or false, many more cases will be resolvable at the front end."

Depending on the federal circuit in which a healthcare organization is located, the risk of a false claim of this nature might already be included in the risk management system, King says. They have already been operating in a world in which medical necessity can be deemed false.

"But if the Supreme Court accepts the case, then the decision, whichever way it goes, can have implications for the entire country," King says. "If the Supreme Court decides that objective falsity is not necessary, then there will be increased costs associated with trying to avoid liability."

Those increased costs would come from more rigorous documentation and the associated paperwork. "Will you have one person doing the certifying, or two?" Tuteur asks. "You're making it more difficult for the qui tam relator to establish that there is anything there to dispute in the clinical determination. That might be good for healthcare because the unscrupulous will be driven out by the higher costs, but it's often the scrupulous who get driven out because they have to do more work, the cases go on longer, and they have to rely on physicians to certify." ■

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Changes to Stark Law Create Leeway for Inadvertent Errors

Significant changes to the Physician Self-Referral Law (Stark Law), the federal Anti-Kickback Statute (AKS), and the Civil Monetary Penalties (CMP) Law are on hold but could be good news to healthcare organizations if they are finalized.

The HHS Office of Inspector General (OIG) and CMS published final rules to take effect Jan. 19, 2021, but the U.S. Government Accountability Office disputed the validity of the rules because they did not include a 60-day delay to the effective date, as required by law. Then, the Biden administration instituted a regulatory freeze on all such rule changes on Inauguration Day. It remains to be seen what the new administration will do with the rules.

(The HHS proposed changes are available online at: https://bit.ly/39Vl3Py. The CMS changes can be found at: https://bit.ly/3jt5CRM.)

Welcomed by Healthcare Industry

The changes are a long time coming and would address some longstanding problems with existing law, says **Gretchen Heinze Townshend**, JD, partner with McGuireWoods in Chicago.

"They are changes that most in the healthcare industry have been clamoring for, for quite a while," she says. "There is, in general, bipartisan and industrywide support for the rules."

The proposed rules create more flexibility for providers to engage in relationships and various initiatives without violating laws, she says. A primary driver is the shift to value-based care, which prompts payers, including Medicare, to look for ways to compensate providers for quality and cost savings instead of paying fee-for-service.

"Another driver is the recognition that the strict liability nature of Stark has created a situation where even the best of intentioned providers screw up and have inadvertent violations. We call it a foot fault," Townshend explains, referring to the tennis foul in which a player inadvertently steps over the service line when serving. "If you don't check every single box on a particular Stark Law exception, you violate the law, full stop. Intentions don't matter, and ignorance doesn't matter."

Some of those violations are procedural and do not actually change the risk profile of an arrangement, she says. The violations can be discovered in business transactions, such as investments or mergers and acquisitions, when financial records are reviewed. For instance, documents may lack signatures or not specify a term of one year. That can be a Stark violation, which makes every referral by the physician under that agreement illegal and improper, triggering a refund and self-report.

"Several years ago, CMS put in the self-disclosure protocol for inadvertent violations, and they have thousands of entries. Lots of reports like, 'Whoops, we failed to amend an agreement that was in place with the updated compensation, and we paid different than what was in our contract,'" she explains. "There was no kickback, no perverse or improper incentives are in place there, just inadvertent violations. CMS has been bogged down by these self-disclosures."

More Flexibility to Comply

The proposed rules would give providers more flexibility to comply with Stark and reduce the CMS burden of handling so many self-disclosures, Townshend says. For example, the rules would allow 90 days to complete documentation of an arrangement after it is in place. Inadvertent financial payments could be resolved within 90 days of discovering the error.

"It's basically softening the rules a little bit under Stark to give a

EXECUTIVE SUMMARY

Proposed changes to the Physician Self-Referral Law (Stark Law) and other laws would give healthcare organizations more ability to avoid self-disclosure and refunds. The changes are expected to be finalized soon.

- Many of the changes are aimed at inadvertent violations that do not pose real risk of improper activity.
- Under current laws, inadvertent errors can be an automatic Stark violation.
- Organizations could address innocent errors without needing to self-disclose.

better defense to the idea that a foot fault is a per se violation of the law," Townshend says. "They were trying to give providers, hospitals, compliance officers, and physicians more arrows in their quiver to both be innovative in their relationships going forward but also to defend any inadvertent violations without having to go through self-disclosure and say you owe a bunch of money."

In a statement announcing the changes, HHS offered these examples of the potential benefits:

• "In an effort to coordinate care and better manage the care of their shared patients, a specialty physician practice could share data analytics services with a primary care physician practice.

• "Hospitals and physicians could work together in new ways to coordinate care for patients being discharged from the hospital. The hospital might provide the discharged patients' physicians with care coordinators to ensure patients receive appropriate follow-up care, data analytics systems to help physicians ensure their patients are achieving better health outcomes, and remote monitoring technology to alert physicians or caregivers when a patient needs healthcare intervention to prevent unnecessary ER visits and readmissions.

• "A physician practice could provide smart pill boxes to patients without charge to help them remember to take their medications on time. The practice also could provide a home health aide to teach the patient and the patient's caregiver how to use the pill box. The pill box could automatically alert the physician practice and caregiver when a patient misses a dose so they could follow up promptly with the patient."

(The HHS announcement is available at: https://bit.ly/3jyYQtJ.)

> THE PROPOSED RULES WOULD GIVE PROVIDERS MORE FLEXIBILITY TO COMPLY WITH STARK AND REDUCE THE CMS BURDEN OF HANDLING SO MANY SELF-DISCLOSURES.

No New Obligations

Townshend says she is confident the rules will take effect soon, once the Biden administration reviews the changes and all the administrative obligations are fulfilled.

The changes will not create any new obligation for healthcare organizations. Everything that is compliant with Stark and AKS now will be compliant once the final rule becomes effective. The changes do create opportunities for compliance officers when they are conducting audits or evaluating physician relationships, she says. Inadvertent mistakes can be corrected without the need to disclose a Stark violation.

The changes also will open the way for more value-based care arrangements because inadvertent errors will not be automatic Stark violations that can sour a proposed business arrangement.

"Risk managers and compliance officers should be happy reading the proposed changes. They have new opportunities both to protect historic conduct and also to participate in new and innovative arrangements, and to have those protected more fully and more clearly than they were under the old rules," Townshend says. ■

SOURCE

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Closed Claims Study Shows Pain Management Risks as COVID-19 Contributes

An analysis of closed medical malpractice claims related to pain management identifies common areas of risk and reveals the COVID-19 pandemic has created new possibilities for liability.

The Doctors Company, a professional liability insurer based in Napa, CA, studied medical malpractice claims that closed between 2008 and 2018. A top contributing factor in 90% of all closed claims was insufficient consent between the physician and the patient or family. The most common injuries alleged in claims were adverse reaction to medications (16%), punctures/perforations (11%), and nerve damage (11%).

The spinal cord was the area most often involved in these claims. Improper performance of treatment or procedure was the most common case type. Technical performance was the leading factor that led to claims, followed closely by patient factors. *(The study is available at this link: https://bit.ly/2NafovP.)*

The prevalence of some patient injuries changed over the 10-year study period. "While the injuries of adverse medication reaction and death remained steady, the other major injuries demonstrated increases over the studied years," the study authors wrote. "Emotional distress and infections showed slight increases as the years proceeded. However, nerve damage and punctures/perforations rose at a steeper rate, with puncture/perforation having the most pronounced rise in major injuries."

The severity of claims also showed variation through the 10 years. The low-severity category remained steady, but medium-severity claims decreased from 56% in the 2008-2013 period to 48% in the 2014-2018 period.

"This drop was manifested in the expanded percentage of high-severity claims during the 2014 to 2018 period, 41% of the claims, compared to 35% during the interval from 2008 to 2013, including a rise in deaths from 16% to 21% during 2014 to 2018," the authors wrote.

Poor Communication a Problem

The most surprising finding in the study was the ongoing communication problem between physicians and patients, says study co-author **Michelle Swift**, RN, JD, CPHRM, senior patient safety risk manager with The Doctors Company. With insufficient informed consent as a top contributing factor in 90% of pain management claims, there clearly is a need for improved communication with patients and family members.

"The importance of informed consent cannot be overlooked. With that, we also look at health literacy as a factor to consider with these patients," Swift says. "This lack of adequate informed consent occurred frequently among the paid claims."

Educate Physicians on Communication

The 90% figure suggests the consent process is ineffective, she says. Either it is not happening at all, or perhaps the physician is just giving the patient a form to sign without truly explaining the potential risks and benefits. It also is possible the physician is making a good-faith effort to communicate but the patient does not understand.

If the physician is trying to communicate effectively but the patient does not understand, there could be a language barrier, or the information might be provided in a way that is too complicated for the patient to understand. "This happens in all settings, but more so in pain and the other high-level specialties that involve a lot of technical terms and procedures that maybe the patients have a hard time understanding," Swift explains. "We know that the information must be at a fifth-grade level to be understood by most patients. There's really a disconnect there. For us, that was surprising because I would think the top issue would be something more like technical or clinical judgment, which were still present in the claims

EXECUTIVE SUMMARY

A study of closed claims related to pain management shows the most common injuries. COVID-19 has brought new pain management risks.

- Insufficient consent was a factor in 90% of claims.
- Adverse reaction to medications was a common claim.
- The spinal cord was the area most often involved.

study, but this popped out as the surprise for 90% of the claims."

Swift says the solution will involve reminding physicians the informed consent process is more than just handing a patient a form. It should be an actual discussion and a time for teaching with models and illustrations, for instance, and it should be well documented. It also is important to allow the patient to acknowledge understanding. The physician should be confident the patient understands the information and is not just nodding yes to be compliant.

Swift notes pain patients may find it especially hard to focus and participate in informed consent. "When you're in pain, you don't always have the ability to hear information and focus on what is coming at you. It takes a lot of repetition in your communication, engaging in that discussion, and involving the family," she says.

Timeouts Necessary for Pain Procedures

Swift says a good risk reduction tactic in pain management would be to ensure physician practices are following the timeout procedure in which the entire team pauses immediately before beginning the procedure to confirm crucial information such as the patient's identity, surgery location, and the planned procedure. Although required as part of the Universal Protocol by The Joint Commission and other accrediting bodies, Swift says timeouts may not be routine at some physician practices performing pain procedures.

"Timeouts are pretty well recognized and followed at most hospitals and surgery centers, but pain practices that do a lot of procedures may not implement that timeout checklist within their organization," Swift says. "Many of these physicians have in-office facilities, and that checklist should include correct site, review of medications the patient is currently taking, the correct identification, and having the patient participate in that timeout verification as much as possible."

A separate anesthesia provider can be helpful, controlling the level of sedation so the patient can respond as needed during the timeout checklist and possibly during the procedure.

"The implementation of a checklist and a timeout for pain procedures is something I really advocate for, and I'm just not seeing it put into play," Swift says.

COVID-19 Adds More Risks

COVID-19 has affected pain management, says **Christopher Malinky**, MD, chief medical officer of Interventional Pain Management in Colorado Springs, CO. Malinky contributed to the closed claims study.

If patient is infected, the procedure is delayed for two weeks until he or she is asymptomatic, Malinky says. For patients who test positive for long periods, the consensus has been to wait for 14 days, and if the patient is asymptomatic, then it is safe to proceed.

More complex procedures, such as spinal cord stimulation and intrathecal pumps, also can lead to delays depending on the policy of the ambulatory surgery center and anesthesia group, Malinky explains. Delays can lead to a wide range of issues, including increased narcotic consumption.

"As a physician, I am worried about patients who use opioids and the potential for adverse events if they become infected with COVID without realizing it, or have a fast decline. This sort of respiratory compromise combined with narcotics definitely increases the risk of respiratory issues and is very difficult to deal with or prevent," he explains. "Patients in skilled nursing facilities where breakouts have occurred can be very difficult to adequately evaluate. My practice has not had those patients be seen in office as we want to prevent further spread to our staff or other patients."

Trying to see those patients via telehealth can be challenging, especially if they are not tech savvy. "Other at-risk patients have also been seen via telehealth. As a provider, you cannot examine the patient, and it is hard to get any feel or sense of what is going on with the patient if there is a problem," Malinky says. "Body language, patient behavior, and face-to-face interaction does provide some valuable information when treating patients, and theses variables are almost absent on telehealth visits."

COVID-19 Patients at Greater Risk

Patients who have been ill with COVID-19 and required hospitalizations often are more anxious, as a healthcare office tends to bring memories and fears back to the patient, Malinky says. This can lead to larger doses or more patients than normal receiving sedation when procedures/injections are performed.

In theory, this can raise the risk of complications from IV sedation, such as aspiration, hypoxia, or nausea/vomiting. Patients have been more anxious about the future than in

previous years, and are exhibiting more depression and anxiety.

"This can be from illness, family deaths, lack of social interaction, loss of job/income, or lack of any enjoyable activities and exercise," Malinky explains. "Primary care providers have not been able to deal with this large increase in depression and anxiety, so patients have been self-treating or simply worsening as a result."

Malinky notes an increase in abnormal urinalysis results for illicit drugs in his practice in 2020. The combination of drugs is dangerous, but also requires consideration of dismissing that patient from the clinic for breaking his or her narcotic contract.

In addition, depression and anxiety can worsen pain (or give a patient the sense of worsening pain) and can lead to repetitive requests for escalated narcotic doses. This can be dangerous; does not address the real, underlying problem; and places stress on medical providers, Malinky says.

"Having a discussion with patients in which you decline to prescribe more opioids is stressful, time-consuming, and frustrating for providers. It also requires a lot of energy to have these discussions repeatedly and not relent to their demands," he says. "This, in addition to constant cleaning/sterilization, mask-wearing, and increased vigilance can lead to provider and staff burnout. This is becoming more of a problem as the pandemic continues with little hope for a quick resolution."

Naloxone Necessary for Some Patients

Swift says that because of the drug use risks exacerbated by COVID-19, it is important for physicians to make naloxone available to the patients and families of patients who are at high risk for an overdose.

"Having naloxone at home with those patients is critical, and even more so now with COVID-19," she says. "Patients having procedures may be on steroids or anticoagulants post-COVID treatment, so a pain physician really needs to focus on the COVID considerations with pain management, whereas previously that wasn't really a consideration. It needs to be part of the treatment plan."

Burnout and staff shortages can lead to less thorough care, missed details, and a decline of patient-provider relationships, Malinky says. The increase in patient depression and anxiety has been significant, and was not really considered early in the pandemic.

Malinky says he expects many of these issues will continue for the foreseeable future. The emergence of new strains and the lack of detailed medical knowledge about COVID-19 and all its potential health effects creates an atmosphere of ambiguity and confusion. These factors can create more risk.

"I think it will be important for all providers to continue to educate themselves about COVID and its effects. Professional societies have been updating policies continuously to help educate their members," he says. "Physicians will need to stay up to date with the changing nature of the virus. Simply ignoring or procrastinating this type of learning will lead to more mistakes, higher liability, and a longer pandemic." ■

SOURCES

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Biden Administration Expected to Expand Enforcement; Pandemic Grants Targeted

The enforcement of white-collar crime laws in the healthcare sector is likely to expand under the Biden administration, particularly regarding fraud associated with the billions of dollars in grants Congress allocated to hospitals and other health providers for pandemic relief.

Healthcare organizations should plan now for increased scrutiny, says **John Kihlberg**, senior director for engagement and client management with H5 in San Francisco. The Coronavirus Aid, Relief, and Economic Security (CARES) Act funds are likely to be supplemented by additional money from Congress — and it comes with a lot of strings attached.

"A lot of different offices were created along with the CARES Act to audit and investigate how that money was used. Fraud is going to be a big issue when that much

money is pushed into the system," Kihlberg says. "The government is likely to use the False Claims Act to look into those areas. If you look at the False Claims Act over the past 10 years, it's been multibillion-dollar recoveries that the government has obtained. In each of those years, $2 billion of that has been healthcare-focused."

Past targets have included hot issues such as opioids and upcoding. Now, Kihlberg says fraud related to COVID-19 will take center stage. Recipients of those funds might face many more compliance obligations than they expected, and much closer oversight.

"When this help was initially announced, it was 'no strings attached.' That's really never the case," he says. "You do have to document how that money was used and have controls around how you've audited that, so that when the government comes and asks about that, you have a good story."

Similar advice relates to the relaxation of some rules regarding telehealth and licensing during the pandemic, Kihlberg says. Although the government made it easier to accommodate those needs during the crisis, investigators may one day want to see justification for those actions, and that providers did not take advantage of those relaxed rules.

Documentation of actions and reasoning will go a long way toward preventing problems in those areas, he says. For instance, if a facility changed its telehealth requirements, document why this was necessary and the understanding at that time of how the changing government regulations made this possible.

Frontline healthcare workers have been pushed to extremes during the epidemic, but administrative staff also have been asked to do more, says **Jeffrey Grobart**, associate director for professional services at H5 in Chicago. Risk managers should not assume that administrative operations have proceeded normally and that all compliance issues have been addressed.

"Obviously, frontline workers were burdened with an overwhelming crush of demands and needs, but I think that was passed on to the back office folks as well, in terms of keeping track of things and being able to duly record all of the transactions and information that must be accounted for," Grobart says. "That includes the normal metrics that hospitals are accustomed to tracking, and the new and novel things that came into play. People are working at home where it is harder to put into the typical controls you might use. Layer on to that an influx of new challenges, and you create a prime scenario for lost information."

Self-audits are more challenging under those circumstances, Grobart says, but government regulators will expect the same level of compliance.

"There is a greater risk when you partner that with an administration that is already showing signs of returning to business as usual after four years of slowly dismantling many aspects of government oversight across many organizations," he says. "The level of scrutiny from regulators is going to inevitably increase in many industries. It is important for healthcare groups to take stock of what they've done over the past year from a financial perspective and every other compliance perspective you can conceive of." ■

SOURCES

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$12.5 Million False Claims Act Settlement Shows Government Loss Not Required

A False Claims Act (FCA) lawsuit involving alleged kickbacks for placing drugs on formularies has been settled for $12.5 million. The case is instructive because it shows the FCA can apply even when the government has not lost money from the alleged violations.

The whistleblower filed a lawsuit in 2014 alleging Roche Diabetes and Roche Diagnostics paid Humana and Humana Pharmacies kickbacks for putting Roche's diabetes testing products on their Medicare Advantage formularies. The lawsuit claimed the plaintiff, an employee of Roche Diagnostics, was fired when he objected to the fraud.

Sanford Heisler Sharp, the New York City law firm representing the plaintiff, announced the settlement. The whistleblower will receive a 29% share of the settlement, totaling $3.6 million.

The plaintiff claimed the defendants violated the Anti-Kickback Statute and FCA, submitting false

claims to the Medicare Advantage program and defrauding taxpayers.

According to the whistleblower, Humana and Roche established a kickback relationship in which debt forgiveness was traded for access to government-funded Medicare business. "Specifically, Relator alleged that Roche forgave millions of dollars owed by Humana in exchange for Humana purchasing Roche diabetes testing supplies and favoring Roche diabetes testing supplies over competitors' products in Humana's Medicare Advantage plans," the law firm explained in the settlement announcement. *(More information is available at: https://bit.ly/2NbzztE.)*

The plaintiff alleged the plan worked this way: Roche Diagnostics first overpaid Humana $45 million in drug rebates. When that overpayment was discovered, Roche Diagnostics offered to accept a refund of only $27.5 million, with Humana keeping the rest. But Humana negotiated to keep more and eventually retained $34 million of the $45 million overpayment. Humana used access to its formulary as leverage, according to the lawsuit.

The case illustrates how the government does not have to lose money for the FCA to apply, says **Inayat Ali Hemani**, JD, partner with Sanford Heisler Sharp.

"In addition to establishing liability for false claims submitted to the government, the False Claims Act creates liability for false claims submitted to entities that receive government funds even if the claims do not result in the government paying an increased amount," he explains. "Medicare Advantage organizations and entities accused of fraud in the Medicare Advantage system have routinely argued that their conduct does not harm the government because the government pays Medicare Advantage organizations a fixed capitated rate for insuring individuals."

This settlement demonstrates Medicare Advantage organizations, pharmaceutical manufacturers, and other entities can be pursued for engaging in fraud in the Medicare Advantage system, and the capitated payment system does not provide a get-out-of-jail-free card, Hemani says. As the Medicare Advantage program continues to grow, rooting out fraud in the program remains a priority for the government, and Hemani expects to see more cases brought in this area.

"The relator in this case alleged that Roche paid a kickback to Humana by agreeing to partially forgive Humana's obligation to repay Roche money," he says. "The case sends a signal that where healthcare entities are discussing the repayment of amounts owed, they run a risk under the Anti-Kickback Statute and False Claims Act if they agree to a reduction in the amount owed in exchange for referrals of government-funded healthcare business." ■

SOURCE

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Finger-Pointing in Nurse Charting Is Opportunity for Plaintiff

By Stacey Kusterbeck

When experts review ED charts for plaintiff attorneys, nursing notes almost always are an area of focus. "The nursing notes are often the documentation that 'fills in the blanks' not covered by the physician reports," says **Andrew P. Garlisi**, MD, MPH, MBA, VAQSF, EMS medical director at Cleveland-based University Hospitals EMS Training & Disaster Preparedness Institute.

Sometimes, nursing notes seem intent on pointing out what emergency physicians (EPs) did wrong.

"This creates the opportunity for finger-pointing, a dream come true for the plaintiff attorney," Garlisi says. Some examples of this kind of problematic charting:

- "Patient became hypotensive. Physician advised, but did not immediately examine the patient."
- "Doctor informed of chest pain at 15:24."
- "Physician informed of patient's increased agitation."

"If the physician does not have a matching notation, specifically timed, addressing the nursing concern, it leaves an opening for the plaintiff in the event of an adverse outcome," Garlisi cautions. The reverse also is true. Garlisi has seen EPs document these passive-aggressive items:

- "Antibiotics ordered for patient with septic shock at 14:00, but were not administered by nurse until 16:25."
- "Patient was ordered to be on continuous cardiorespiratory monitoring. However, when I entered the room, the patient

was not on the monitor and was unresponsive."

• "I ordered vital signs every 15 minutes, but vitals were not performed for over one hour, and the patient was found to be profoundly hypotensive."

Generally, a unified defense is recognized as the best approach for all defendants in ED malpractice claims, but finger-pointing notes make it difficult. Garlisi suggests EPs and ED nurses meet briefly before each shift to discuss the importance of teamwork, not only regarding patient care but also documentation.

"Combined physician-nurse staff meetings are actually not common," Garlisi observes. "This makes pitfalls in patient care and documentation more likely to occur."

ED nurses are more likely to be employed by the hospital than EPs, who often are independent contractors. This can create different chains of command.

"If emergency directors and administrators do not see eye to eye with nursing directors and administrators, combined meetings are not likely to occur," Garlisi cautions.

As a result, many ED nurses and EPs have no idea about the liability implications of using charts to air grievances. "They may not be aware of the potential risk management complications that could ensue," Garlisi offers.

Typically, juries do not want to assess large damages against nurses, according to **Michael M. Wilson**, MD, JD, a Washington, DC-based healthcare attorney. "But when they make criticisms in the chart against the other healthcare providers, it will most likely come back to prevent the institution from mounting a successful defense," Wilson warns. These are some common examples:

• **The ED nurse documents findings that contradict the EP's findings.** One malpractice claim alleged a delay in diagnosing and treating Stevens-Johnson syndrome, a rare but serious disorder. The EP did not document a rash, but the ED nurse did. The plaintiff attorney raised this question: Why would an ED nurse document a rash that did not exist?

The documentation created major credibility issues during litigation. "It made it inadvisable to try the case," Wilson explains. "The malpractice claim was settled by the institution that employed the ED physician and operated the ED."

• **An ED nurse is upset about the EP's actions.** One malpractice case hinged on the ED nurse's documentation of "multiple calls made to the on-call obstetrician, which went unanswered for a two-hour period."

The neonate was subsequently delivered through an emergency cesarean procedure. The baby sustained severe brain injury. "That case had to be settled for seven figures," Wilson recalls.

• **Experienced nurses are unhappy with the performance of less-experienced residents.** Some ED nurses intentionally flag the resident's perceived mistakes. That can create major legal issues — and not just for the resident, but also for the institution and everyone involved in the case. "Once the healthcare providers start blaming each other, the case frequently becomes nondefensible," Wilson says.

That is because healthcare providers have far greater credibility than any of the hired experts on either side. "Once the ED nurses start telling the jury that, for example, the resident made medical mistakes that caused injury to the plaintiff, it damages the credibility of defense counsel, their experts, and other ED providers who will all be testifying that nothing was done wrong," Wilson explains.

Unfortunately, some ED nurses view inflammatory charting as a way to protect patients from unsafe care. Ideally, there is a chain of command through which nurses can discuss what they see as inappropriate treatment decisions or incompetence. "They could report concerns without repercussions, instead of taking matters into their own hands and putting negative comments in the chart," Wilson says. ■

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **When is objective falsity required for a False Claims Act claim, according to Olivia R. King, JD?**

   a. It depends on the federal circuit court.
   b. When the alleged fraud involves more than $50 million.
   c. It depends on the nature of the claim.
   d. When the claim alleges fraud by an individual.

2. **What would be the effect of proposed changes to the Anti-Kickback Statute and Stark Law, according to Gretchen Heinze Townshend, JD?**

   a. More flexibility to comply without self-disclosure for inadvertent errors.
   b. Less flexibility to comply without self-disclosure for inadvertent errors.
   c. Greater risk of criminal prosecution for inadvertent errors.
   d. Less risk of criminal prosecution for inadvertent errors.

3. **In the pain management closed claim study from The Doctors Company, what percentage of claims involved insufficient informed consent as a top contributor?**

   a. 20%
   b. 40%
   c. 60%
   d. 90%

4. **What is a key lesson in the False Claims Act case settled for $12.5 million, according to Inayat Ali Hemani, JD?**

   a. Formularies may be influenced by funds from suppliers if the policy is uniform.
   b. Formularies may not be influenced by funds from suppliers if the source of the funding is known.
   c. The government must be overcharged for the False Claims Act to apply.
   d. The government need not be overcharged for the False Claims Act to apply.

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

Court of Appeals Reverses Doctor's Trial Court Win in Botched Spinal Surgery Case

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News: A court of appeals reversed a directed verdict in favor of an orthopedic surgeon who botched a spinal fusion surgery, causing the plaintiff permanent nerve damage and decreased mobility. The trial court had found in favor of the defendant physician, holding the plaintiff's expert did not provide adequate testimony as to the applicable standard of care. The court of appeals reversed the decision, finding that although the plaintiff's expert did not provide a clear definition of the standard of care, he did demonstrate sufficient familiarity with the standard to opine in the case. In fact, the court noted the expert had extensive experience as a neurosurgeon and adequately testified as to what he believed the proper course of treatment would have been for the patient. Further, the expert identified several breaches in the patient's care, and noted the defendant physician failed to perform a bone density test before deciding if a spinal fusion would be the best option for his patient.

THE COURT NOTED THE EXPERT HAD EXTENSIVE EXPERIENCE AS A NEUROSURGEON AND ADEQUATELY TESTIFIED AS TO WHAT HE BELIEVED THE PROPER COURSE OF TREATMENT WOULD HAVE BEEN FOR THE PATIENT.

Background: In April 2014, a physician performed spinal fusion of the lumbar vertebrae, a procedure in which adjacent vertebrae are fixated and fastened together. This procedure can be performed by placing a bone graft and reinforcing the graft with screws, rods, or bone marrow. Depending on the patient's condition, a surgeon will select the most appropriate method of fastening the graft.

In this case, defendant physician used screws. Specifically, a pedicle screw was inserted in the ala of her sacrum, and the screw had pulled out completely. In fact, the plaintiff's expert testified the surgeon had already broken off the pedicle before placing it in the ala of the sacrum. According to the expert, this already constituted a breach in the standard of care because the physician had adamaged the patient's anatomy. The expert also opined that although the difference between the pedicle and the sacral ala is minimal in terms of thickness, there is a significant anatomical difference whereby the sacral ala is a slightly movable joint in relation to the mechanics of the pelvis. The slight but measurable mobility of the joint still would result in unstable fixation. Thus, the surgeon should have used a different method to reinforce the bone graft.

Later, the patient underwent a second operation, known as a revision procedure, to address certain complications that occurred during the first surgery. After the revision procedure, the patient suffered from foot drop, a condition in which a person cannot lift the front part of their foot, causing it to drag, and in severe cases, requiring a brace to maintain the foot in its normal position. The patient also continued

to experience pain in her lower back, effectively rendering the surgeries a failure.

In August 2017, the plaintiff filed a complaint against defendant physician, alleging he had departed from the standard of care in performing the surgery. The medical review panel that examined the patient's hospital records and evaluated the physician's conduct found the physician had not violated the standard of care. However, the plaintiff's medical expert — a surgeon who had performed more than 12,000 spine procedures, including 150 spine fusions — testified that he disagreed with the panel's conclusions. In particular, the expert noted the patient's history of osteoarthritis and osteoporosis, among other conditions, and noted the surgeon failed to perform a bone density test before deciding whether to proceed with the surgery. Nevertheless, the trial court found the plaintiff's expert failed to adequately define the proper standard of care, and returned a verdict in favor of defendants. On appeal, the court reviewed the expert's testimony and reversed the lower court's decision.

What this means to you: When reviewing the expert's testimony, the court of appeals focused on whether the plaintiff's expert provided an adequate definition of standard of care. In the disputed remark, the expert stated "there is no such thing as standard of care except what the individual doctor thinks it is." Further, defendant's counsel noted that during the expert's deposition, he stated 40% to 50% of spinal surgeries result in negative outcomes, and that a negative outcome in and of itself does not necessarily indicate bad medicine. These statements were used by the defendant to question the expert's testimony and conclusion that defendant physician breached the applicable standard of care.

The court of appeals began its review by analyzing the expert's credentials and his ability to provide expert testimony. The court found the physician's educational background and years of practice as a spinal surgeon, paired with his extensive experience performing spinal procedures and fusions, qualified him as a reputable expert. Regarding the doctor's statement on the applicable standard of care, the court considered the context and other remarks made by the physician. Although the expert repeatedly opined that no written standard of care exists and the term is somewhat arbitrary, he did provide a detailed description of the mistakes made during the procedure and the proper course of action the defendant should have taken. Specifically, the expert noted the patient's chart and medical records lacked information, and the presurgery workup was "sparse." Most notably, the surgeon did not order a bone density test for the patient, who took vitamin D2 as a bone supplement. This should have raised a red flag and induced the physician to verify if the patient had osteoporosis.

Further, the expert held the choice of performing a spinal fusion was controversial in and of itself. An alternative procedure, a decompressive laminectomy, would have been preferable. The expert criticized defendant's choice to perform the surgery using pedicle screws. In fact, the witness stated the surgeon should have performed a bone graft without hardware, using bone marrow to strengthen the graft.

After a thorough review of the trial records, the court of appeals found the doctor's testimony was sufficient in establishing the applicable standard of care and the breach thereof. In fact, although the physician's remarks were "imprecise," they did show sufficient familiarity with the applicable standard. The appeals court especially relied on the expert's statement that a "prudent surgeon" would have performed a bone density test and that a decompressive laminectomy would have been the proper procedure given the patient's condition and background. In addition, the expert established with sufficient certainty the injuries plaintiff sustained were caused by nerve damage from the surgery. Thus, the court of appeals found the trial court erred in granting defendant's directed verdict and reversed the decision, remanding the case to the lower court.

Although the plaintiff's expert provided some controversial comments on the standard of care, it is likely that, if given his well-established expertise, a proper analysis and explanation of his testimony will, at the very least, increase the plaintiff's odds of obtaining a favorable verdict. There always is a standard of care, especially for relatively common procedures. The standard may not exist in written form. Instead, it is considered to be what a reasonable physician would do in similar circumstances within the same community. Assuming the patient is older than age 55 years and female, osteoporosis must be considered. Orthopedic hardware, and screws in particular, occasionally do either break and remain irretrievable, or damage bone and surrounding tissue. They can even cause allergic reactions due to the metals. It could be deemed more reasonable to use hardware if other alternative treatments were contraindicated. ■

REFERENCE

- Decided Dec. 18, 2020, Court of Appeals of Indiana, Case No. 20A-CT-571.

North Carolina Supreme Court Rejects Loss of Chance Doctrine

News: The Supreme Court of North Carolina rejected the loss of chance doctrine for medical malpractice cases in a lawsuit involving a patient who suffered from a stroke and was not diagnosed for more than six hours after reaching the hospital.

The complaint alleged the physician's failure to diagnose the stroke, even after a CT scan was performed and the patient's symptoms persisted, deprived the patient of the possibility to receive a time-sensitive treatment, which may have increased her chances of a positive outcome with no or little permanent damage. The plaintiff's argument, known as loss of chance, allows a plaintiff to be compensated for losing the possibility of a more favorable outcome. However, the supreme court rejected this argument, ruling the 50% threshold for proximate causation in medical malpractice cases also should be applied to a loss of chance claim, and the decision to lower such threshold should belong to state lawmakers.

Background: In late August 2014, the patient complained to her husband that her left arm and leg felt heavy and weak, and thought she might be having a stroke. Because the patient's speech also appeared to be slurred, her family rushed her to a nearby hospital. She immediately told doctors about her symptoms, which had started approximately an hour earlier. A CT scan was performed, and the patient's primary care physician was contacted about an hour and a half later. The hospital physician erroneously communicated the patient showed "no neurological deficits." Her symptoms persisted through the night. The next morning, at approximately 6:00 a.m., hospital staff noted the patient was exhibiting left facial droop, slightly slurred speech, and left arm drift. An hour later, plaintiff's primary care physician arrived and immediately noted the patient's neurological signs. The physician ordered a neurological consult and admitted patient to the hospital.

PLAINTIFF ASSERTED THE ADMINISTRATION OF TPA WOULD HAVE INCREASED HER OPPORTUNITY OF A BETTER OUTCOME, AND THE UNTIMELY DIAGNOSIS CAUSED HER TO LOSE THE OPPORTUNITY FOR A BETTER OUTCOME.

After the consult, the neurologist advised the patient's primary care physician that her opportunity to benefit from alteplase, a tissue plasminogen activator (tPA), had passed. In her complaint, the patient alleged that due to the failure to timely diagnose her stroke, she had suffered increased losses and harm, including permanent injuries. Further, plaintiff asserted had she been timely diagnosed, she could have benefited from tPA. This failure to timely diagnose resulted in plaintiff losing an opportunity to an improved neurological outcome. Namely, plaintiff asserted the administration of tPA would have increased her opportunity of a better outcome, and the untimely diagnosis caused her to lose the opportunity for a better outcome.

This type of claim, known as loss of chance, is recognized in certain jurisdictions and allows a plaintiff to recover for the loss of a more favorable medical outcome. In general, some limitations on recovery may exist, including demonstrating the plaintiff's loss of the chance of a better outcome was greater than or equal to 50%, had a certain course of treatment been followed. However, the Supreme Court of North Carolina refused to accept this argument, stating that whether a theoretical loss of chance could be claimed in a medical malpractice suit was a question for the legislature to decide.

What this means to you: The loss of chance doctrine can be a strong tool for plaintiffs to recover damages when a physician's failure to follow a certain course of treatment resulted in the patient losing the opportunity of a better outcome. It is important to consult with qualified legal counsel in the local jurisdiction to ascertain whether it applies, and with what potential nuances.

In general, such claims can increase the damages awarded in a medical malpractice case because not only can the plaintiff recover for the injuries suffered, but he or she also is compensated for a missed opportunity of suffering a less severe injury. However, the main issue reviewed by the court was whether

the state of North Carolina would recognize this doctrine and apply it in the present case.

In reviewing the decision of the court of appeals, the Supreme Court of North Carolina first analyzed the effect on stroke patient of administering tPA within three hours of the onset of symptoms. First, the court looked at a medical study the plaintiff's medical expert relied on during trial. According to the study, stroke patients who were given a placebo in place of tPA had a 20% to 26% chance of a good neurological outcome (i.e., either recovering completely or almost completely). By contrast, patients who received tPA within three hours had a 39% chance of a good neurological outcome. In other words, tPA only changed a stroke patient's favorable outcome odds by approximately 13%. Further, patients who received the drug also presented a 6.4% chance of experiencing more adverse effects. However, the plaintiff's expert argued that in the current case, the patient would have had a 35% to 39% chance of a better outcome had tPA been administered.

Next, the court examined the proximate causation standard in medical negligence cases. Based on this standard, a breach is considered to have caused a certain injury if it is likely the injury would not have occurred without the breach. In practice, this translates to a 50% or greater chance the injury would not have occurred without the claimed breach. Based on this standard, the court opined that even if the theory of loss of chance were to be applied, it would only be applicable if the plaintiff could demonstrate the alleged conduct caused a loss of opportunity of at least 50% to obtain a more favorable outcome. Thus, in the present matter, the plaintiff's expert should have demonstrated that with the administration of tPA within three hours, the patient would have had at least a 50% chance of experiencing a more favorable outcome. However, this was not the case.

Further, the evidence relating to tPA would not have supported such an opinion. The court found that awarding damages for loss of chance in this scenario would violate the general standard of proximate causation, which must remain unaltered for medical malpractice cases. Plaintiff also argued that under a loss of chance theory, the proximate cause standard should be lowered because a 15% or 30% chance of an improved outcome is measurable and represents a compensable injury, which should remain separate from a traditional malpractice claim. The court rejected this argument and held the decision to lower the proximate causation standard was up to the state legislature. Nonetheless, the loss of chance doctrine will remain an important concept to remember when analyzing medical malpractice cases, especially in those jurisdictions where it has been held to apply.

Finally, note tPA only is useful for ischemic strokes. Its efficacy is determined by how quickly the patient can get to a facility that provides it, and the healthcare providers determine it is the appropriate course of treatment. A CT scan is the fastest way to visualize a hemorrhagic stroke — in which tPA is contraindicated — but the CT scan often will not show evidence of an early infarction. The MRI is more diagnostic, but not immediately. This is one reason many hospitals have become stroke centers. They can activate a stroke team, similar to a Code Blue or Rapid Response team. But it is up to the physicians and nurses caring for the patient to carefully and precisely assess the patient's symptoms for signs of stroke and stroke progression. This includes neurological assessments every 15 minutes. A hemorrhagic stroke is accompanied frequently by extreme headaches as blood leaks into the intracranial space and increases pressure on the brain. An experienced neurologist can review the data and make the appropriate diagnosis. If a neurologist is unavailable, a patient should be transferred to a stroke facility or, at the very least, to a neurology service elsewhere. Time is critical to minimize the damage in either type of stroke. ■

REFERENCE

- Decided Dec. 18, 2020, Supreme Court of North Carolina, Case No. 241PA19.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

Lessons Learned from Overturned $4.3 Million HIPAA Penalty

A covered entity's victory over proposed penalties from the Department of Health and Human Services (HHS) was good news for those responsible for HIPAA compliance, showing that good faith efforts and a willingness to fight the allegations can pay off.

In January, the 5th U.S. Circuit Court of Appeals overturned the $4.3 million civil monetary penalty (CMP) imposed by HHS on The University of Texas M.D. Anderson Cancer Center.[1] That decision is a "game changer," says **Erin Dunlap**, JD, an attorney with Coppersmith Brockelman in Phoenix.

"While the decision is limited in its precedential authority, I think it will impact how HIPAA-covered entities and business associates view HIPAA's encryption rule, evaluate a loss of protected health information [PHI], and engage with HHS in determining settlement amounts, particularly if the alleged violations relate to a loss of PHI," Dunlap says.

HHS' Office for Civil Rights (OCR) imposed a CMP on M.D. Anderson in June 2018 after a lengthy investigation into three data breaches reported by the hospital in 2013 and 2014.[2] The breaches involved the loss or theft of an unencrypted laptop containing the PHI of 29,021 individuals and two unencrypted USB drives containing the PHI of 5,862 individuals.

OCR concluded M.D. Anderson failed to implement encryption or adopt an alternative and equivalent method to limit access to electronic PHI (ePHI) stored on electronic devices and to prohibit unauthorized disclosures of ePHI.

OCR also found that M.D. Anderson had "reasonable cause" to know it was in violation of the HIPAA rules, Dunlap says. OCR imposed penalties in the amount of $1.3 million for the of lack of encryption and $3 million ($1.5 million per year) for the impermissible disclosures of ePHI.

M.D. Anderson unsuccessfully sought two levels of administrative review, including with an administrative law judge (ALJ) who sustained the imposition of the CMP.[3] M.D. Anderson then petitioned the 5th Circuit to review the ALJ's ruling.

HHS Acted Arbitrarily

The important part of the decision is found in the 5th Circuit's reasoning. The justices ruled HHS acted arbitrarily and its decision was capricious and contrary to law for four independent reasons.

First, the court found M.D. Anderson had implemented a mechanism to encrypt ePHI, as required by the HIPAA Security Rule,[4] and OCR failed to show M.D. Anderson had not done enough to secure the ePHI of its patients. The court explained M.D. Anderson required employees to acknowledge in writing that portable devices storing ePHI must be encrypted, furnished employees with IronKey devices to encrypt portable devices, and trained employees how to use them. The center implemented a mechanism to encrypt emails and various other mechanisms for file-level encryption.

"According to the 5th Circuit, those steps were sufficient to establish a mechanism, even if three employees failed to encrypt ePHI. The court basically took the position that the encryption specification was not a strict liability rule, and perfection, or 'bulletproof protection,' was not the standard," Dunlap says. "This is helpful for HIPAA-covered entities and business associates trying to prove they took appropriate steps to comply with the

encryption rule, or other HIPAA requirements, even if they could have done more."

Second, the court ruled the definition of "disclosure" under the HIPAA rules requires "an affirmative act of disclosure" rather than "a passive loss of information." To be a disclosure, someone outside the covered entity would need to access the ePHI. "This interpretation turns OCR's longstanding position and prior guidance on the loss of PHI on its head. OCR has always taken the position that the loss of PHI is an impermissible disclosure," Dunlap explains.

In fact, in OCR's breach reporting form, "loss" is listed as one of the options. But apparently the 5th Circuit does not agree with that interpretation, accusing HHS of trying to "transmogrify" the regulation. "I imagine some HIPAA-covered entities and business associates will point to the 5th Circuit's interpretation of 'disclosure' when evaluating whether there was an 'unauthorized disclosure' of PHI under HIPAA's breach notification rule," Dunlap says.

Inconsistent Decisions

Third, the court ruled OCR's decision to fine some covered entities for loss of PHI incidents and not others was inconsistent. The court noted that under bedrock principles of administrative law, agencies like OCR must "treat like cases alike."

"OCR has always taken the position that it will evaluate each case on its individual facts," Dunlap says. "But, in light of this decision, I imagine a more comparative standard will come into play in OCR investigations and settlement discussions moving forward." Fourth, justices determined OCR's calculations of penalties were wrong. Under the "reasonable cause" penalty tier, which is the second tier under HIPAA's three-tiered penalty structure, the maximum fine for violations of an identical provision during a calendar year may not exceed $100,000. Before this decision, OCR had acknowledged it misinterpreted the statutory caps and published a notice that it would exercise its enforcement discretion to follow the $100,000 cap.

"While I don't think OCR will exceed the statutory caps moving forward, I think this decision may prompt HIPAA-covered entities and business associates to push back on OCR's penalty calculations and hefty settlement offers," Dunlap says.

Refused to Interpret

The 5th Circuit criticized the ALJ who initially heard the case and the HHS Departmental Appeals Board, notes **Arielle T. Miliambro**, JD, partner with Frier Levitt in Pine Brook, NJ. The court ruled both "steadfastly refused to interpret the statutes at all."

Miliambro notes the 5th Circuit interpreted the HIPAA Security Rule narrowly. The text of the regulation states a covered entity must "implement a mechanism to encrypt and decrypt" ePHI. Moreover, encryption is an addressable standard rather than a required one.

"The court found that while M.D. Anderson implemented various mechanisms to encrypt information in accordance with the requirements of HIPAA, certain employees did not use those mechanisms," Miliambro says. "The court held that the regulation does not require that all [ePHI] be encrypted. Instead, the court reasoned, a mechanism must be in place to do so. In the court's view, M.D. Anderson undisputedly had a mechanism, even if it could've or should've had a better one."

Regarding whether loss of control of ePHI, such as through the misplacement of laptops or USB drives, constitutes a disclosure, Miliambro says the 5th Circuit adopted a largely textualist approach to interpreting the regulation. It held the government did not establish that a "disclosure" of PHI was made because the government could not show anybody outside the covered entity received the information on the lost devices.

"The court's interpretation of 'disclosure' is narrow and, in the case of lost devices or records, serves to place a nearly insurmountable burden on HHS, establishing that someone outside of the covered entity actually received the information contained within," Miliambro says. "This rationale has potentially significant ramifications."

The 5th Circuit decision shows HHS does not have the final word when imposing penalties, according to **Richard Sheinis**, JD, partner with Hall Booth Smith in Charlotte, NC.

Sheinis says perhaps the best news for providers is the 5th Circuit's clarification of the disclosure rule.[5] Losing control of PHI does not necessarily mean the PHI was disclosed. "This will be an important factor for determining if there was a HIPAA breach when a medical provider loses control of PHI, but there is no evidence that it was accessed by an unauthorized person," he says.

Focus on ePHI

Although there is good news in the 5th Circuit ruling, it also shows healthcare providers must pay close attention to ePHI and the changing expectations for protecting it, says **Maria D. Garcia**, JD, partner with

Kozyak Tropin & Throckmorton in Miami.

"Providers have to be increasingly careful with how they safeguard ePHI to make sure they do not run afoul of any of the HIPAA rules," Garcia says. "The interpretation of the HIPAA Privacy and Security Rules may vary. It is a good idea to make sure you have individuals in your provider organization who can tackle the understanding of those HIPAA rules so that your electronic information is protected as much as possible."

The M.D. Anderson case highlights OCR's focus on ePHI and the difficulty in protecting it.

"It is the best practice now to be cautious and try to find ways to protect electronic health information," Garcia says. "The decision gives us guidance to everyday issues that we may face now, because so many employers carry health information on their person on their cellphones, laptops, or a USB device. Those devices should be encrypted, and it is important that providers work with experts who can analyze their specific situation."

One of the Largest Penalties

The $4.3 million was one of the largest amounts imposed or secured in a voluntary settlement, notes **Amy Leopard**, JD, partner with Bradley in Nashville.

HHS had considered several factors in determining the CMP. First, the center's 2011 security risk analysis indicated downloading ePHI was high risk and that no enterprise-wide encryption solution was in effect for laptop and mobile devices. Second, annual security reports in 2010 and 2011 showed the center had not mitigated the high risks for mobile media with encryption. Third, in 2011, the center reported lost or stolen mobile devices with ePHI to the University of Texas Police Department on 19 separate occasions. Fourth, unencrypted devices were used after the center had actual knowledge that encryption was needed to secure ePHI on mobile devices.

Leopard says the Fifth Circuit reasoned that under the disclosure rule, "disclosure" suggests an affirmative act, and it defied reason for HHS to argue that a covered entity acts to disclose information when someone steals it. The court allowed that HHS may issue a regulation to redefine the word, but not in an administrative adjudication.

The court also ruled that under the HIPAA encryption rule, the center was not required to warrant that ePHI was protected by encryption; rather, the obligation is limited to implementing a mechanism to encrypt ePHI. When HHS imposed the CMPs on M.D. Anderson, many large breaches reported to OCR (those affecting 500 or more individuals) involved the loss or theft of laptops. Since then, hackers have become responsible for many large breaches with their cyberattacks on healthcare systems.

"During the timeframe of these breaches, OCR investigated hundreds of large breaches involving the loss or theft of ePHI, most without penalty. This matter was hotly contested, and the center was willing to take the risk and endure five years of administrative adjudications and litigation to get this result," Leopard says. "HIPAA enforcement actions will continue to be resolved primarily by informal means or settled through resolution agreements. OCR limited the HIPAA CMP amounts in 2019 under its Notice of Enforcement Discretion and has entered many resolution agreements at lower thresholds over the past year."[6]

Safe Harbor Possible

Leopard also notes that on Jan. 5, Congress amended the Health Information Technology for Economic and Clinical Health (HITECH) Act to require OCR to consider whether covered entities and business associates implemented certain recognized security practices regarding cybersecurity during the prior 12 months.[7] If so, those entities may fall within a safe harbor requiring consideration of smaller penalties and mitigation of remedies in resolution agreements.

"These developments provide welcome relief to entities who have implemented robust compliance safeguards but still face imminent and increased cyberthreats," Leopard says. "But this case will influence strategies for dealing with investigations that occur after a large breach. We are going to question allegations of noncompliance with the disclosure rule and make arguments to the effect that the entity did not disclose or 'lose control' of the ePHI when those breaches involve lost or stolen PHI. We will continue to offer OCR mitigating factors and affirmative defenses to ensure any penalty discussions will be fair and consistent with similar violations."

OCR recently released its HIPAA audit findings showing significant gaps in security rule compliance.[8] OCR likely will have to pursue many more cases and continue focusing on security fundamentals until industry findings improve. "We hope to see more entities adopt recognized security practices such as NIST [National Institute of Standards and Technology] to thwart these attacks," Leopard says. "The game plan should be security management of these

cyberthreats by adopting recognized security frameworks and having effective security incident and breach response plans in place should those risks materialize." ■

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OCR Audit Findings Show Where to Focus HIPAA Compliance

Covered entities should take note of some key findings from audits conducted by the OCR in 2016 and 2017. OCR assessed covered entities' and business associates' compliance with selected provisions of HIPAA rules.[1]

OCR found material noncompliance with HIPAA's Notice of Privacy Practices (NPP), along with right of access, breach notification, security risk analysis, and risk management requirements, says **Jennifer L. Urban**, JD, CIPP/US, partner with Foley & Lardner in Milwaukee.

The audit findings were published only recently, even though the noncompliance findings were from a few years ago. They remain relevant to today's HIPAA compliance efforts. "A lot of organizations still struggle with doing risk analyses and building in the vulnerabilities and identified risks into their risk management plans," Urban says. "That's been a focus for many years, and that's where most organizations failed in the audits."

Implementing a good security program with risk analysis, security practices, and risk mitigation can be a safe harbor from penalties. "What's most interesting to me in the findings from the audit is that people aren't doing a very good job with the security analysis and risk mitigation plan, and they really should be focusing their efforts on those pieces," Urban says. "The M.D. Anderson case and some recent legislation show that you can create a safe harbor if you put enough effort into that, even if it doesn't make your HIPAA compliance foolproof."

The audit findings also suggest covered entities should review their NPPs. Urban was surprised to see only 2% of those audited met the full content requirements. Access requirements were another area of concern. "OCR has been focusing a lot on patients being able to access their records. Under some proposed changes to the HIPAA rules, they're focusing on providing broader access in quicker time frames," Urban says. "OCR has had this information from the audits for some time now, and I think that's one reason they have this access initiative now." ■

REFERENCE

1. Department of Health and Human Services, Office for Civil Rights, Health Information Privacy Division. *2016-2017 HIPAA Audits Industry Report*. December 2020. https://bit.ly/36xiEsm

SOURCE

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