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INSIDE

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Outside Counsel Can Be the Right Choice, but Know When

Outside counsel can be an important resource for hospitals and health systems, but knowing when it is right to bring in someone can be difficult. If you move too quickly to call in an outside law firm, you may waste budgeted resources while casting doubts on the abilities of the risk manager and in-house counsel.

But holding on to legal matters that should be handled by outside counsel can have even worse consequences.

Regardless of the size of the legal department, there will always be times when it is appropriate to bring in outside counsel, says **Brent L. Henry**, JD, an attorney with the Mintz law firm in Boston. Prior to joining the firm, he was vice president and general counsel of Partners HealthCare, the largest hospital network in New England, overseeing the legal, internal audit, corporate compliance, and business ethics departments for the organization.

> REGARDLESS OF THE SIZE OF THE LEGAL DEPARTMENT, THERE WILL ALWAYS BE TIMES WHEN IT IS APPROPRIATE TO BRING IN OUTSIDE COUNSEL.

Determining when to bring in outside counsel depends on several factors, including the nature and magnitude of the problem, the level of in-house expertise, client expectations, turnaround time, level of sensitivity, and budget, Henry says. When an organization decides to keep a matter in-house, there still are considerations that need to be kept in mind, such as assembling the appropriate team to handle the matter and maintaining the client's confidence.

When engaging outside counsel, the hospital or health system must consider

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reputation, cost, quality, expertise in the area, track record with similar matters, and staffing patterns, Henry says.

"Make sure you understand the problem and its implications. When an issue arises that you feel might have to be sent out, take the time to think through the problem and its implications for your client before the decision is made," Henry says. "In addition to the individual business unit/clinical department where the problem originated, this might involve a discussion with your colleagues in public affairs, internal audit, finance, compliance, regulatory affairs, and human resources."

Issues to Consider

Henry suggests considering the following issues when selecting and hiring outside counsel:

• **Magnitude of exposure.** Is the matter a "bet the farm" issue, or is the organization merely seeking a second opinion from outside experts? How big a public relations problem could an adverse outcome create? How confidential should the mere existence of the problem be kept? What are the adverse financial implications? Is there a regulatory precedent to consider? Might the resolution of the matter result in employment terminations?

• **Client expectations.** Managing client expectations is key to long-term survival. First, make sure that you and client colleagues agree on what the goal should be as you seek to resolve the problem. If the goal has to be adjusted once more information comes to light, do not hesitate to initiate that discussion. Never promise more than you can deliver. Avoid predicting outcomes when you can; if pressed, better to state them in terms of percentages rather than absolutes. If it becomes clear that your client has unrealistic expectations, going outside might help increase your chances of success or at least help to reinforce your message to lower expectations.

• **Turnaround time.** What is the time frame within which the matter needs to be resolved? If you are faced with a tight time frame, consider going outside — but be prepared to pay for it. Unless it is a routine matter that inside counsel deals with regularly, if you are under a time crunch, you should not hesitate to find an outside firm that can put a team together to handle the legal analysis, document production, etc., in a timely manner.

EXECUTIVE SUMMARY

Healthcare organizations will need to call on outside legal assistance for some situations, but it is not always obvious when that is the right decision. Many factors should be considered before entrusting a legal issue with a law firm rather than in-house counsel.

- Major lawsuits that could have serious consequences might be appropriate for outside counsel.
- In-house counsel may be inappropriate if they could be called as witnesses in litigation.
- Outside counsel may be best for negotiating with physicians and executives who will be in a position of power.

• **Sensitivity**. This issue cuts two ways. While clients almost always want to keep highly sensitive matters within the organization, they often present unique issues that compel looking to outside counsel for advice. If it is likely that resolution of the matter could lead to litigation, it is important to keep issues of attorney-client privilege in mind. While the safest route to protecting the privilege is to retain outside counsel and have them oversee the information-gathering, there are ways to avoid having to do that depending on how your legal department is structured.

Henry also cautions that you should not be handcuffed by your budget. While most legal departments have outside counsel budgets, it is important not to let a lack of budgeted funds restrict your decision at the outset, he says.

"When faced with a major matter that might be a 'budget buster,' talk with the appropriate people in the business unit or clinical department as well as your executive colleagues to make sure they understand the trade-off between staying within budget and solving the problem in the most effective manner," Henry says. "Most will choose the latter. One way to ease the budget pressure on a major project is to have outside counsel team up with inside staff, both in and outside the legal department. But remember that someone will have to supervise and serve as a liaison with outside counsel."

Evaluate Resources Realistically

Do not underestimate your inside resources, but evaluate them realistically, Henry advises. Depending on the nature of the problem, you should not necessarily be constrained by the size of your legal department, he says. Many matters will involve fact-gathering, document production, and other nonanalytical tasks that can be carried out by colleagues who are not attorneys.

"The key here is selecting an effective team leader and making sure your colleagues serving on the team understand the importance of the project so that they make it a priority. Assembling the right in-house team can help to deliver the results you need without blowing your outside counsel budget," he says. "Keep in mind that at the appropriate point, you may have to integrate outside counsel into the team in order to ensure that you get the benefit of that expert advice in the most cost-efficient manner."

Hospitals retain outside counsel for many different purposes, often in response to a significant event, says **Jeffrey P. Rust**, JD, partner with the Rivkin Radler law firm in Uniondale, NY. These events may include anticipated or pending litigation, a government or payer investigation, a major transaction, or some other legal concern that requires expert or impartial legal advice. These often are specific, stressful events requiring a proactive approach where outside counsel anticipates the client's needs and remains focused on solving the client's problem, he says.

In-house attorneys may not be the best choice to handle some of these matters if they specialize in risk management, or they may have a general practice background with experience in some specialized areas, Rust says.

"For instance, negotiating a complex commercial lease or an acquisition or merger with another hospital or system may require outside counsel experienced in such matters," Rust says. "Although most in-house attorneys have a wealth of experience, at times it makes sense to bring in the experts."

Impartiality Can Drive Decision

Another instance where it is important to bring in outside counsel is when dealing with a serious matter requiring an appearance of impartiality, Rust notes. There are times when in-house counsel's participation in an actual or threatened litigation or investigation could be problematic because the in-house counsel could be called as a witness, he says.

"There is often a fine line between whether in-house counsel has been providing business advice as opposed to legal advice, leading to challenges of privilege," Rust says. "Outside counsel should always be engaged if in-house attorneys played a part in the conduct being investigated."

In-house counsel also may not want to take a lead role in negotiations with high-ranking physicians or hospital executives, Rust says. Bringing in outside counsel allows the in-house attorneys to avoid negotiating on behalf of the hospital with individuals that may be in a power position post-negotiation, he explains.

"Employment agreements with high-ranking persons are often heavily negotiated and may involve complex compliance and regulatory issues as they apply to healthcare providers and not-for-profit hospitals," he says. "In-house counsel may be better served allowing outside counsel to handle these difficult negotiations so as to retain a positive working relationship with hospital leadership and to avoid any appearance of bias."

Establish Expectations, Communication With Outside Counsel

A hospital is best served when in-house counsel works closely with outside counsel, notes **Jeffrey P. Rust**, JD, partner with the Rivkin Radler law firm in Uniondale, NY.

In-house counsel can provide background information and assistance, as they are the most knowledgeable about the hospital's structure, policies and procedures, culture, and personalities.

Rust advises following these tenets of effective legal project management:

1. Define the scope of the matter and set clear goals to measure success.
2. Agree on a budget, understanding that unforeseen events may require adjustment to the matter's scope and budget.
3. Select the right legal team of both in-house and outside attorneys and legal assistants, each with the right level of knowledge and experience.
4. Assign specific tasks with due dates to each team member.
5. Communicate with the team through use of a secure shared site or other secure technology and scheduled status conferences.
6. Track all work against the budget regularly.
7. Analyze results with outside counsel after the matter concludes.

The reporting relationship also is important, says **David S. Sokolow**, JD, partner with the law firm of Fox Rothschild in Philadelphia.

"It is important to figure out who the outside lawyer reports to, who is hiring me, who is authorizing payment on my bills, who I'm supposed to send deliverables to. In many cases this will be the in-house counsel, but it also could be the CEO, the compliance officer, the board," Sokolow says. "There also is the political issue of how this relates to what in-house counsel is doing and how much I should keep in-house counsel in the loop. There is no one answer that works for every organization, and I have to understand that up front so that I don't exacerbate any existing issues."

Access to other hospital departments also can be an issue, says **Rodney K. Adams**, JD, a healthcare attorney with the law firm of LeClairRyan in Richmond, VA.

"Some hospitals want us to go through in-house counsel for everything, like a records request. So we have to ask their counsel, who will then go to the department and make the request, then pass the records on to us," Adams says. "Others will give us direct access, and that's most efficient. When in-house counsel wants to stay so much in the loop that we're not allowed to talk with other staff, that can get onerous sometimes." ■

In some situations, it may be necessary to bring in outside counsel due to the limited number of attorneys, nonattorney support staff, and technical staff in an in-house legal department, Rust says. The legal department's resources may be fully engaged in other matters, necessitating the assignment of overflow work to outside counsel.

Also, if the hospital is planning a potential transaction or litigation that requires a substantial due diligence review or other investigation, in-house counsel may not have enough qualified support staff to properly manage the investigation in a time-effective manner, Rust says. Outside counsel can draw from resources throughout the firm to focus on the matter and produce results more quickly and effectively than can in-house counsel acting alone, he says.

Special Expertise May Be Needed

Karl Thallner, JD, partner with the Reed Smith law firm in Philadelphia, frequently works with hospitals and notes that in-house counsel are under pressure to keep their budgets under control, so they do not use an outside firm lightly. Hospitals only approach him after carefully determining that either they are not properly qualified for a particular matter or there is a strategic reason to have an outsider lead the effort, he says.

For instance, this may be the case when a broader perspective is needed to assess risks on an unusual proposed activity or arrangement, he says. Or, when in-house counsel is not experienced in situations such as an FDA dispute or a complex Stark Law issue.

The perceived credibility and

independence of an outside firm also may be helpful in dealing with a third party, he says. Attorney privilege and the need to protect work product from discovery also may be good reasons, he says.

"In-house counsel is usually given the authority to decide when and how to select the outside counsel. So you usually have a collaborative relationship rather than an adversarial relationship in which in-house counsel feels threatened or pushed aside," Thallner says. "I can imagine in an organization where the in-house counsel isn't given that authority and the decision is made by the CEO or someone else, that could create some friction or tension that is not good for the organization. If the in-house lawyers think of the outside lawyers as a competitive threat and don't respect them, that could be problematic."

Serving Different Masters

Another attorney who works as outside counsel for hospitals is **David S. Sokolow**, JD, partner with the law firm of Fox Rothschild in Philadelphia. He finds that subject matter expertise is the most common reason hospitals call on him or other outside counsel.

For example, a high-stakes fraud and abuse investigation might require an attorney experienced in such matters rather than having otherwise qualified in-house counsel learn as they go, he says.

The need for impartiality also is a common reason, he says.

"There often is a perception of greater impartiality when the attorney is an outside person. Sometimes that is helpful when you're dealing with the government or another third party that knows the firm," Sokolow says. "It can give a different air to the discussions rather than the government talking to an employee of the hospital, even though those employees may have ethical obligations as lawyers. That appearance that you serve two different masters — your employer and your legal ethics — can make people wonder if they're getting the whole story."

Sokolow notes that in-house counsel often wear different hats, acting as business advisor in addition to legal representative. That can blur the lines when it comes time to handle a negotiation or litigation. There is a greater ability to preserve attorney-client privilege with outside counsel who is clearly providing a legal service and nothing else, he says.

"Sometimes, the issue involves the actions of senior management, maybe even the legal or compliance office, and allegations that they failed to detect something or take action. That will be a time when you want to avoid the appearance of some kind of conflict or taint with people investigating the conduct of their own colleagues," Sokolow says.

The outside firm also may have greater access to technology and other resources that are beyond the reach of the hospital, Sokolow says. *(See the story on page 4 for more on how to best work with outside counsel.)*

Hospitals also may leverage the independence of the outside counsel when difficult decisions or changes must be made, he says.

"Sometimes it's helpful for inside counsel to go back to managers, especially if it's a compliance issue, and say they consulted this impartial, well-regarded outside counsel and here's their advice," Sokolow explains. "Outside counsel can give political cover to in-house counsel to get the results they need. It's harder to ignore the advice of outside counsel, whereas you might think in-house counsel is being overly cautious or giving you business advice and not legal advice."

The use of outside counsel might be downplayed when a medical center is involved in a controversial matter, says **Rodney K. Adams**, JD, a healthcare attorney with the law firm of LeClairRyan in Richmond, VA. He was called on to represent a hospital that was embroiled in litigation over discontinuation of life support for a brain-dead child.

The medical center wanted Adams to handle the litigation because he was more qualified than its in-house counsel, but he was not the public face of the hospital's legal team. An in-house attorney acted as the public voice for the hospital regarding the litigation.

"They didn't want it to look like the hospital was ganging up on the family by calling in an outside firm," Adams says. "The situation was already so delicate that they wanted to avoid any impression that they were throwing their weight around and the family was at a disadvantage." ■

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FTC Investigations Could Bring Unwanted Scrutiny to Hospitals

Hospitals may face scrutiny from the Federal Trade Commission (FTC) as it investigates anti-competitive behavior in healthcare and should assess their level of risk.

U.S. Senator Chuck Grassley recently asked the FTC to investigate hospital contracts and determine whether they violate antitrust laws by secretly prohibiting insurers from working with smaller, less expensive competitors. An FTC investigation into such anti-competitive behavior could lead to antitrust lawsuits, so it is important for hospitals to assess and fully understand their exposure before government inspectors come knocking, says **Robert H. Iseman**, JD, partner with the Rivkin Radler law firm in Albany, NY.

Hospitals and health systems that are regarded as "must-have" participants in health insurance plans face substantial antitrust risk, Iseman says. "Must-have" status means that, within the particular market, there is no reasonable substitute for the healthcare services they offer and insurers must have the hospital or health system in order to market a financially viable health insurance product, he explains.

The term "must-have" is sometimes used synonymously with the term "market power," and any health system that possesses market power is at heightened risk for antitrust enforcement depending on the nature of their actions and business decisions in the marketplace, Iseman says.

"Hospitals or health systems that use their must-have status to coerce insurers into accepting contract provisions that damage competition and increase costs face significant antitrust risk and liability," Iseman says. "This is especially so because of Senator Grassley's request that the FTC investigate anti-steering provisions, thus bringing such matters into sharp focus for public debate and attention by regulatory enforcement agencies."

Anti-Steering Provisions Cited

Iseman notes that there is heightened focus on anti-steering provisions because of two pending cases. On Nov. 15, 2018, it was announced that the Justice Department's prosecution of the Atrium case in North Carolina is in the process of being settled based on Atrium's agreement to discontinue the anti-steering provisions in its payor contracts. A similar case is pending in California against the Sutter Health System. The Justice Department alleged that anti-steering provisions prevented payers from directing patients to different plans or lower-cost providers.

"This public activity says to me that must-have providers who have negotiated anti-steering provisions in their contracts with third-party payers through market coercion need to buckle their seatbelts," Iseman says.

The risk could be high for health systems that are the product of recent mergers, he says. Since the passage of the Affordable Care Act, there has been substantial merger activity in healthcare — and the result, in some markets, has been the creation of new must-have systems. In some cases, the newly merged entity is virtually the only acute care provider in the market.

"There is already substantial skepticism about whether hospital mergers are in the public interest, and many believe that the mergers have increased prices. A recently merged entity that has used its must-have status to require third-party payers to include anti-steering provisions is at risk of not only having the anti-steering provisions attacked, but also having its merger reviewed and reconsidered by antitrust enforcement agencies."

Factors to Consider

To assess how much a hospital or health system is at risk, Iseman says the risk manager should take these three steps:

EXECUTIVE SUMMARY

The Federal Trade Commission is investigating whether hospitals and health systems violated antitrust laws through contracts with payors. Assess your risk before the government investigates.

- The hospital or health system's "must-have" status in the region is key.
- Email and other communications could indicate intent and knowledge of the effect on other hospitals.
- Smaller healthcare providers could sue if a government investigation finds anti-competitive behavior.

• Assess whether the organization is a must-have provider based on whether competitors provide a reasonable substitute for their services and whether a financially viable health insurance plan can be marketed without them.

• Determine whether anti-steering provisions or other potentially anticompetitive terms have been added to the hospital's contracts with third-party payers and, if so, whether they have a business rationale for why such contract terms are necessary to protect legitimate interests and are not anticompetitive.

• Consider relationships with third-party payers in their area, as well as with major employers and others who may be aggrieved by the hospital's conduct.

But here is an important point: Iseman says any such assessment should be conducted under the guidance of counsel and made subject to the attorney-client privilege.

"At-risk hospitals and healthcare systems should be carefully monitoring the settlement of the Atrium case and the progress of the Sutter case and reviewing and strengthening their rationale for why the anti-steering provisions are reasonable and necessary from a business perspective and not violations of the antitrust laws," Iseman says.

"It is possible that all of the interest and publicity surrounding this topic will result in payers approaching must-have providers with requests for contract amendments. Obviously, that would be an extremely sensitive and important event, and any contact from payers should immediately be referred to hospital counsel."

Iseman notes that must-have providers tend to be large, sophisticated business organizations with access to knowledgeable antitrust counsel. Because the behavior of must-have providers in third-party payer negotiations always is a matter of concern, he suspects that many health systems had the anti-steering provisions reviewed by their antitrust counsel and perhaps have attorney-client privileged opinion letters on the point.

> "THIS PUBLIC ACTIVITY SAYS TO ME THAT MUST-HAVE PROVIDERS WHO HAVE NEGOTIATED ANTI-STEERING PROVISIONS IN THEIR CONTRACTS WITH THIRD-PARTY PAYERS THROUGH MARKET COERCION NEED TO BUCKLE THEIR SEATBELTS."

"They should be reviewing any such letters and advice to assess whether they have followed the guidance of counsel and, if not, how their behavior in the marketplace should change," Iseman says.

Look for Intent in Communications

Reviewing the contracts themselves may not be enough, says **John Kihlberg**, senior director for engagement and client management with H5, a data management consulting company in San Francisco. The bigger question is the hospital's policy and strategy at the time it negotiated those contracts, he says.

"There will be a question of what the company's intent was. For that, you need to turn to the email communications that were happening at the time of the negotiations," Kihlberg says. "The communications in question would involve those people who have approval over the contracts and probably people in various regions that are actually out on the front lines making the deals."

In the Atrium case, for instance, the investigation revealed communications in which health system leaders bragged about having more than 50% of the market share in the region. Investigators also will be looking at deals with payers that did not go through, seeking evidence that they were shut out by another provider with a larger market share.

"If there was intent and knowledge on your part that it had the effect of restraining competition, that becomes a problem. Other smaller hospital chains, not just the government, can file suit," Kihlberg says. "There could be additional litigation that's spurred by the government investigation. Any company that might be the target of that litigation should asses their risk now."

States Also May Investigate

Grassley's call for an FTC investigation is only one avenue by which government enforcers and private plaintiffs are attacking the contracting practices of large integrated healthcare delivery networks, notes **Robert G. Kidwell**, JD, an attorney with the Mintz law firm in Washington, DC.

"Hospitals and provider networks with high market shares in local payer markets face a real possibility that their contracting practices will face enhanced scrutiny — less likely by the federal government save for the biggest players nationwide but more likely by state attorneys general and by their smaller competitors as private antitrust plaintiffs," Kidwell says. "If nothing else, payers may begin to push back on some of these types of provisions during contract negotiations using antitrust concerns as an excuse."

The providers most at risk are those with both high market shares and few competitive alternatives for payors and contract terms that tend to steer patients toward more costly care rather than toward lower-cost care, he says.

There is a danger in assuming that investigators will not find fault with a hospital's contracts just because they have not been questioned in the past, Kidwell says.

"Providers tend to be conservative. Many providers will stick with what works for them today until it stops working for them," Kidwell says. "But the tide is clearly flowing toward steering care to appropriate lower-cost care rather than to higher-cost care. Most hospitals know that they are eventually going to need to address cost of care in a serious way. Many have already embraced change and begun to innovate; many others have not." ■

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Pediatric Safety Still Threatened by Electronic Health Records

Years after the widespread adoption of electronic health records (EHRs), pediatric patients still are at risk from software systems that do not properly account for the needs of younger patients.

One of the most recent reports came from **Raj Ratwani**, PhD, scientific director and senior research scientist with the National Center for Human Factors in Healthcare at the Medstar Institute for Innovation in Washington, DC. He and his colleagues studied the effect of EHRs on pediatric safety, analyzing 9,000 patient safety reports.

They found the most common usability challenges were associated with system feedback and the visual display, and the most common medication error was improper dosing. Of the 9,000 reports, 36% had a usability issue that contributed to the medication event and 18.8% of those incidents might have resulted in patient harm. *(An abstract of the report is available online at: https://bit.ly/2zL28o6.)*

"There's an association between the usability of electronic health records and patient harm events. We focused exclusively on pediatric populations and found that where there were EHR-related medication errors, those can reach the patient," Ratwani says. "There is building evidence that we have to be aware of EHR usability challenges and how they can affect the patient. In pediatric patients, that is particularly alarming given that they are not as resilient as adults to overcome some of these challenges."

EXECUTIVE SUMMARY

Pediatric patients are at risk from electronic health records (EHRs) that do not adequately factor in their needs. Medication dosing is the biggest threat.

- The usability of an EHR affects patient safety.
- Frontline staff may realize the risk more than administrators.
- Efforts to optimize an EHR present an opportunity to address the risk.

Don't Underestimate Impact

Frontline EHR users are aware that the systems pose risks to pediatric patients, he says. Their vigilance and the redundant safety checks built into the healthcare delivery system prevent many instances of potential harm from reaching the patient, Ratwani says.

"From a risk management perspective, there may not be an awareness of how much impact

an EHR can have. I think one of the reasons is that when there is an adverse event or near miss, rarely do we look back at the IT system to see how that might have contributed," he says. "Many people don't take that system perspective on how the error might have occurred. Instead, they focus on processes and look to blame the individual, when they could be looking for poorly designed technology that contributed to the error."

Pediatric patients are especially vulnerable to dosing errors, and any EHR system that does not provide adequate safeguards against those errors is problematic, says **Robert Hanscom**, JD, vice president of business analytics with Coverys, a medical malpractice insurer based in Boston.

"Any time you have scenarios in which specific information is put in and then calculations made on that data, those are fraught with risk. Errors can occur with any patient population, but we have seen that the risk is greater with pediatrics whether you are using an EHR or not, and a poorly designed EHR only increases that risk," he says.

"Back when these things were done manually, we had terrible errors with pediatric patients suffering great harm. EHRs have helped reduce those kinds of errors, but at the same time EHRs have not been designed to cure all ills. Other vulnerabilities have emerged."

Many EHRs are simply not designed with the pediatric patient in mind, particularly with regard to dosing, says **Ruben Nazario**, MD, clinical editor and strategist with Zynx Health, a company in Los Angeles that provides EHR support. He previously worked full-time as a pediatric ED physician, and still works part-time in that role.

"I see that almost every day with EHRs that are not optimized for pediatric patients. They may have some kind of basic safeguards with formularies that specify some medications are more appropriate for adults, and there may be some alerting to maximum dosing," Nazario says. "But there are still a lot of issues with alerts in terms of usability and when in the work process they provide that information."

Pediatric safety issues should be assessed and addressed when a hospital or health system is in the process of optimizing the system or changing the EHR product, he says.

"There is a great opportunity now that most providers are through the implementation phase and looking to optimize their EHR systems," he says.

Hospital leaders are beginning to address the issue more directly and effectively, says **Sean Morris**, sales director with Digitech Systems, a software company in Greenwood Village, CO.

"Five years ago, the picture was different, but we've seen in recent years that a lot of hospital leaders have become more techno-savvy. That may be because we have folks who are a little younger coming up into leadership roles, and it may be that people established in those roles are learning that they need to be better at staying on top of those issues," Morris says. "We're seeing a transition in those organizations where they are bringing in groups who understand what components need to work together and individuals who understand the need to address disparity of information across different resources." ■

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Emergency Preparedness Pays Off When Water Supply Lost

A Utah health system confirmed the value of emergency preparedness when it was faced with a severe water shortage after a wildfire. The affected hospital got through the crisis with relatively little effect on patient care because it had planned for the most likely emergencies in the region and pooled resources with facilities in a five-county area.

The events began on a Saturday morning when flash flood waters ran over the site of the recent Brian Head fire in Utah. The large volume of water running over the scorched earth overwhelmed and contaminated the spring water collection boxes that feed into the Panguitch, UT, culinary water system.

The city of 1,800 declared a "No Water Use" order for culinary water, which meant the water could not be used at all. Even boiling the water would not render it safe.

The 14-bed Intermountain Garfield Memorial Hospital, part of the Intermountain Healthcare system, relied on the city's water supply. Once word of the water use order was received at the health system, its emergency preparedness team implemented its water disruption emergency response plan for the affected hospital.

Hospital Coalition Reacts

Because the duration of the water loss could not be predicted, the health system needed water filtration systems for the hospital in addition to shipping bottled water. Intermountain contacted the Southwest Utah Healthcare Preparedness Coalition, which includes healthcare representatives from five southwest Utah counties. Of the six participating hospitals, three are part of the Intermountain system.

The coalition plans for a wide range of crises and coordinates response efforts among the hospitals, says **Steve Ikuta**, BS, MEP, emergency management southern area manager for Intermountain Healthcare, based in Salt Lake City.

"Over the last eight years, we've been meeting on a regular basis to create those external partnerships, getting to know each other's resources and what we have to loan or borrow during an incident such as this," Ikuta says. "When I heard it was a 'No Water Use' order, I knew the coalition's water filtration systems would be needed."

Anticipating this kind of emergency, the coalition had used federal grant funds to purchase low- and high-density water filtration systems — models that can filter 60 gallons per hour and larger models that can process 720 gallons per hour. Because Garfield is a critical access hospital with a long-term care unit and an attached clinic, the coalition asked for both sizes from the hospitals that host them.

The coalition delivered the units to Intermountain Garfield Memorial, and they were operational by 3 p.m. of the day the water crisis began.

Water Supplied by Filters

By 3 p.m. Saturday afternoon, the filtration systems were fully hooked up, filtering water through a four-stage process. The hospital used the filtered water for drinking, handwashing, bathing, and food service operations.

"The health department was there, and we had water samples tested for chloroform and *E. coli* before we cleared it for use in the hospital, even though the manufacturer says the four-stage filtration system makes it safe to consume," Ikuta says. "We took that extra step because we knew we had enough bottled water on hand to get by for 24 hours while we were waiting for the test to come back clean from the health department."

To supplement the bottled water cached at Garfield Memorial, the Intermountain health system sent 150 one-gallon containers of water purchased from a local grocery store. Dixie Regional Medical Center in St. George, UT, the Intermountain

EXECUTIVE SUMMARY

A hospital system's experience with a severe water outage shows the value of emergency preparedness. The event was manageable because the system had carefully planned for such a crisis.

- Plan for the most common emergencies in any region.
- Work with local hospitals to share resources and coordinate a response.
- Practice how employees will respond to water shortages.

hospital where Ikuta works, sent two pallets of 16.9 oz. bottles of drinking water — 2,880 bottles — which it stockpiled in its own emergency preparedness cache.

"We didn't know if this would be a protracted incident or something that would end quickly," Ikuta says. "It ended up going six days."

Bottled water was used for drinking. Intermountain also delivered food service items including disposable plates, cups, bowls, and cutlery; dishwashers were not usable without the plumbed water supply.

A sister facility about 100 miles away, Intermountain Sevier Valley Hospital, supplied the hospital with clean linens.

Hand Hygiene Maintained

The affected hospital placed "Do Not Use" signs on faucets, showers, and other water sources throughout the hospital and even removed all the bedside drinking water containers, replacing them with bottles of water. The hospital's public information department emailed all employees to explain the water restrictions and how to use the bottled water for handwashing.

Garfield Memorial borrowed portable handwashing stations from another hospital to set up throughout clinical areas of the hospital. They consist of a foot pump connected to a hose with a gooseneck end that is zip-tied to an existing faucet, Ikuta explains. The intake hose is put inside a one-gallon drinking water container or a five-gallon container of the filtered water.

"Our caregivers, patients, and visitors were still able to maintain hand hygiene using these systems and soap. They did that for the following six days," he says. "On Monday we were able to provide our long-term care residents with hot water by hooking up the filtrated water supply to a portable propane water heater. The residents were able to take hot water sponge baths, which they loved because by day three they were already using the disposable hand wipes."

Panguitch City lowered the "No Water Use" order to a "Boil Water" order on the second day, but the hospital still could not use the water supply and continued using only bottled and filtered water.

The order was lifted three days later, but before the hospital could restore regular water service, it first had to clean the hospital's water system.

That required calling in an outside company to fully drain water out of pipes, fill them with chlorinated water, allow that to sanitize for several hours, flush out the system, and then test the water at locations in the hospital. That was accomplished within 48 hours.

Planning Pays Off

Ikuta says the entire emergency was handled as well he could hope for, and he attributes that to all the planning and coordination with other hospitals in the area. He strongly encourages hospitals to seek such partnerships.

"Back in 2013, we realized that since we're in an earthquake-prone state, we could lose water, and so we needed these water filtration systems. We all pooled our money and purchased these water filtration systems, and five years later it was here and we got to use it," Ikuta says. "It's like paying your insurance premiums. You invest in it, and if you need it, it's there to get you through this emergency."

Practicing your response also is important, says **Alberto Vazquez**, MHA, FACHE, administrator at Garfield Memorial Hospital in Panguitch, UT. He coordinated the emergency response at the hospital.

"Now that we know it can happen, we practice our response more so that people are even more comfortable with it," Vazquez says. "Practice with the equipment you have, the water filtration systems, the supplies you will use instead of using water. Get familiar with where everything is, and pull it out once in a while to use it and make everyone more confident when you do have a situation that requires it." ■

SOURCES

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CME/CE QUESTIONS

1. **Which of the following is true, according to Brent L. Henry, JD?**
   a. There always will be times when it is appropriate to bring in outside counsel, regardless of the size of the legal department.
   b. Outside legal counsel is not necessary for any large healthcare organization with its own in-house counsel.
   c. Outside counsel will almost always be less expensive than using in-house counsel for a legal matter.
   d. Outside counsel should be used for litigation only, not for negotiations, investigations, or any other purpose.

2. **What does Jeffrey P. Rust, JD, advise regarding the use of outside counsel for matters involving hospital leadership?**
   a. It is not a good idea because it can create the impression that the hospital is adversarial with the leadership.
   b. It may be better to allow outside counsel to handle these negotiations so as to retain a positive working relationship with the leadership.
   c. Most outside counsel will not take on such disputes.
   d. The leadership must approve the use of outside counsel.

3. **Why does John Kihlberg advise reviewing emails related to payer contracts?**
   a. They can reveal the intent of the hospital and any knowledge that it is a "must-have" organization.
   b. They can confirm data cited in the contract.
   c. They can reveal whether smaller organizations were consulted about the impact of the contract.
   d. They can establish what terms were considered and rejected.

4. **How did Intermountain Garfield Memorial Hospital respond to loss of water from the public utility?**
   a. Patients were transferred to other facilities until water was available again.
   b. Bottled water and water filtration systems were brought to the hospital.
   c. Any water for patient use was first boiled to sanitize it.
   d. Hand hygiene was maintained with only alcohol wipes.

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

Improper Medication Leads to Patient's Death, $10 Million Verdict

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News: A 63-year-old man was admitted to a medical center with multiple ailments. A few days later, he developed bradycardia due to hyperkalemia. His physician treated the condition with Kayexalate, which was administered in a suspension solution containing 35.8% sorbitol. The physician did not inform the patient about the risks related to the drug. The patient developed ischemic colitis, which led to his death three days after receiving the drug.

The patient's estate filed suit against the physician and the medical center, alleging that the physician breached the standard of care by treating the patient's condition with Kayexalate without obtaining his informed consent. The jury found in favor of the plaintiff and awarded $10 million in damages, which was reduced to $906,250 by the court.

Background: On March 10, 2013, a 63-year-old man was transported to a nearby hospital. The patient was suffering from hepatitis C, cirrhosis, end-stage liver disease, renal failure, and congestive heart failure and had been complaining of weakness in his arms and legs. Blood tests revealed that the patient was suffering from acute rhabdomylysis, a condition that, if untreated, can cause muscle weakness and pain, elevated potassium levels, and kidney failure.

The next day, the patient was transferred to the intermediate care unit at a larger medical center. His initial bloodwork showed that the rhabdomylysis was worsening, and he was placed on dialysis. Approximately one week after his admission, the patient developed life-threatening bradycardia. The physician diagnosed the patient with hyperkalemia, an elevated level of potassium in the blood that can cause potentially life-threatening cardiac arrhythmia, and ordered emergency treatment.

IN THE DISCHARGE SUMMARY, THE PHYSICIAN ANNOTATED KAYEXALATE USE AS A POSSIBLE CAUSE OF THE PATIENT'S SUSPECTED INTESTINAL ISCHEMIA.

The physician ordered a sodium polystyrene sulfonate medication called Kayexalate. Because Kayexalate causes constipation and sometimes fecal impaction, it usually is given in combination with an osmotic laxative such as sorbitol. The physician ordered the Kayexalate to be administered orally, in a suspension solution containing 35.8% sorbitol. However, the physician did not warn the patient of the risks and benefits of Kayexalate prior to its administration.

The patient was admitted to the ICU the next day. He was brought to surgery following several bloody bowel movements and severe abdominal pain. In the discharge summary, the physician annotated Kayexalate use as a possible cause of the patient's suspected intestinal ischemia. The patient never regained consciousness from the surgery and died the following day.

The patient's wife and children filed suit against the

physician and the medical center. Three expert witnesses opined that the patient's ischemic colitis and death were caused by the administration of Kayexalate and that the physician had breached the standard of care by not obtaining the patient's informed consent prior to administration. The physician called four experts who asserted that there was no certain link between Kayexalate and ischemic colitis since medical literature establishes a very rare association — not necessarily a cause — between the drug and the condition.

The jury returned a verdict in favor of the plaintiffs, awarding a total of $10 million in damages. Because of the cap on noneconomic damages (pain and suffering, emotional distress, etc.), the award was reduced to $181,250 for the estate and $90,625 for the widow and each of the seven children, for a total of $906,250. The plaintiffs appealed the reduction, claiming that it violated their constitutional rights under the Equal Protection Clause. The appellate court upheld the reduction.

What this means to you: A classic battle is demonstrated by these circumstances: the battle of the experts. Since medical malpractice cases necessarily involve issues beyond the scope of laymen, experts are almost always critical to the legal process and to a jury's determination. With this advanced knowledge, it is important to evaluate and select appropriate experts and work closely with them throughout litigation.

Working intimately with experts enables physicians to more objectively evaluate the circumstances and to establish and maintain a coherent and consistent narrative. Furthermore, physicians may use their own experts to evaluate the qualifications of and potentially disqualify an opposing party's expert, causing significant and often irreparable damage to the opposition's legal case.

In this case, both parties relied heavily on expert opinions to attempt to prove or disprove the causal link between the course of treatment chosen and the onset of the ischemic colitis that led to the patient's death. During the litigation, the physician filed a motion seeking a Frye-Reed evidentiary hearing to exclude the plaintiff's expert. (Note that federal courts and some state courts follow a different case called *Daubert* as the seminal opinion concerning the validity of expert testimony. Always check with counsel in your state concerning expert issues.) After the trial court denied the hearing, the physician appealed. The appellate court found that the denial caused no prejudice to the physician.

At the trial court level, the physician sought to preclude the family from introducing expert opinion that stated there was a causal link between Kayexalate with sorbitol and ischemic colitis. The physician argued that while it was generally accepted in the medical community that Kayexalate and/or its combination with sorbitol could, in very rare cases, be associated with ischemic colitis, it was not generally accepted that the two drugs could actually cause the condition.

The plaintiffs responded by stating that a Frye-Reed evidentiary hearing was unnecessary because there was a general level of acceptance that Kayexalate with sorbitol could induce intestinal necrosis, as confirmed by the medical literature, FDA black box warnings on the drug, and the medical center guidelines.

The trial court determined that no evidentiary hearing was necessary and that the physician could testify but took a conservative approach and held a one-hour hearing on the matter, allowing both parties to introduce evidence.

While both parties presented expert testimony, the court based its decision on two factors. First, the physician identified ischemic colitis caused by Kayexalate in sorbitol as a likely diagnosis before the patient even entered surgery. This diagnosis was reported in the medical note transferring the patient from the intermediate care unit. The court determined that the physician knew of the risk associated with the drug and suspected his patient's condition to be caused by the drug. The facility's internal guidelines — which were available to all physicians — warned about ischemic colitis as a side effect of Kayexalate.

Informed consent is a frequently occurring issue among medical malpractice cases. All patients in hospitals sign, or have their legal representatives sign, consents for general care and treatment that cover issues such as medications, diagnostic testing, and basic treatments like dressing changes, stitches, and so on.

Kayexalate is a common drug used to treat mild hyperkalemia. It should not be used for very ill patients, and it takes longer to work than other possible treatments. As has been discussed, the physician chose a drug that could potentially harm the patient. But informed consent for prescribing the drug is not required. Even with FDA black box warnings, the physician is not mandated to obtain informed consent.

Adverse drug reactions occur in hospitals and at home frequently. It is the risk any patient assumes when using medications. A nurse administering or a pharmacist providing a drug should explain to the patient what the drug is, why it was prescribed, and what side effects the patient might experience. The

patient may then refuse to take the medication if he or she determines that the risks outweigh the benefits.

If the physician feels there is an extraordinary risk to the patient if it is taken, the physician should address this directly with the patient and offer alternatives. However, there is no universal standard of care requiring a physician to obtain informed consent before prescribing medications. In this case, the mere administration of Kayexalate should never have occurred, with or without informed consent.

Another important issue raised and affirmed in this case is the state's statutory maximum on noneconomic damages. More than half of the states have passed some form of law that limits the amount of noneconomic damages a patient may recover in the case of a medical malpractice verdict. Since noneconomic damages include items such as "pain and suffering," this limitation can dramatically reduce a physician's or medical provider's exposure in the event that liability is found. Patients may still be able to recover unlimited economic damages, including those for past and present medical care which may constitute significant amounts for severely disabled younger patients. Under the Medical Injury Compensation Reform Act, for example, California limits noneconomic damages to $250,000 but permits unlimited economic damages.

In this case, the statutory maximum reduced the amount of the jury verdict to less than 10% of the total awarded. The plaintiffs appealed this reduction, claiming that the statute violated the Equal Protection Clause of the Fourteenth Amendment by discriminating against the injured and larger families. However, the appellate court upheld the statute and found that it did not create irrational or arbitrary classifications. Similar appeals brought by injured patients seeking to overturn these laws have been unsuccessful in many states.

These types of statutory maximums may be additionally beneficial for physicians and medical care providers by drastically reducing the amounts needed to settle medical malpractice claims out of court. When a patient is aware that the maximum recoverable is significantly less than what a jury would award — even given egregious circumstances — the patient may be willing to forgo the time, effort, and expense of a drawn-out legal battle and instead settle for the statutory maximum. Physicians and medical providers should thus consult with counsel and consider any applicable statutory maximums when evaluating medical malpractice cases. ■

REFERENCE

Decided on Aug. 30, 2018, in the Court of Special Appeals of Maryland; Case Number 238 Md. App. 418, 192 A.3d 847; Trial Court Case Number 24-C-15-003384.

Nonoperating Physician Found Exempt From Liability

News: A female patient underwent two surgeries on her right eye at a medical facility. The surgeries caused her to suffer significant vision loss. Both were performed by a board-certified ophthalmologist formerly employed by that facility. The surgeon who had been treating the patient and recommended the surgical course of treatment was a junior physician and shared an office with a more senior ophthalmologist.

The patient brought suit against the facility and both ophthalmologists. In her claim against the senior physician, who had not performed any of the surgeries but was the more experienced physician in the practice, the patient argued that he should be found liable under both negligence and vicarious liability theories. The senior physician argued that since he was not involved in the treatment and was not required to supervise the treating physician, he owed no duty to the patient. The court agreed with the senior physician and found that he could not be liable.

Background: The patient had been advised by an ophthalmologist to undergo two eye surgeries. Her course of treatment had been exclusively decided by this physician, who was a board-certified ophthalmologist and had been treating her during her time as a patient at a medical facility. As a result of the surgeries, the patient suffered serious injuries that resulted in substantial loss of vision. The patient brought suit against the physician, the medical practice group, and the senior ophthalmologist in the practice, who shared an office with the patient's physician.

The patient alleged that the senior physician had negligently supervised

the junior physician and that the senior physician deviated from the applicable standards by failing to assist the junior physician during the eye surgeries. The patient also argued that the senior physician should be found vicariously liable for the junior physician's actions because his seniority imposed a duty to supervise the younger, less experienced physician who worked in the same practice. The senior physician brought a motion for summary judgment in which he argued that because he had never treated the patient, he did not owe her any duty of care and thus could not be found liable for medical malpractice. The trial court denied the motion, and the senior physician appealed.

On review, the appellate court reversed the trial court's denial and established that the senior physician could not be found liable for the damages caused by the treating physician. The appellate court stated that in order to be found liable, a duty of care between the senior physician and the patient must first be established. Because the senior physician played no role in the patient's treatment and did not have a duty to supervise the treating physician in her treatment of the patient, the court found that the senior physician could not be liable.

What this means to you: This matter provides several insights as to the duty of care in medical malpractice suits, the legal relationships among physicians working within the same practice or at the same facility, the respective burdens of proof, and the roles of expert opinion testimony. While the patient alleged that the senior physician owed a duty of care, the court found no such duty existed as a result of the lack of any connection between the physician and patient.

According to the court, in a medical malpractice claim, the burden to prove that the defendant deviated from the accepted standard of practice and that such deviation proximately caused the injuries sustained lies on the plaintiff. In an attempt to satisfy this burden, the patient offered into evidence expert testimony by an ophthalmologist who stated that the senior physician had failed to supervise the junior physician. Specifically, the expert opined that the senior physician failed to confirm the appropriateness of the junior physician's surgical recommendations to the patient and did not follow up with the patient after her surgeries.

The court recognized that expert testimony is necessary to prove a deviation from the accepted standards of medical care and to establish proximate cause but acknowledged that this question is secondary and inherently linked to the question of whether a general duty of care exists and is owed by the physician.

This foundational question — whether a duty of care exists — is legal and requires no expert opinion, according to the court. Thus, while the expert opinion offered into evidence by the patient would have been considered by the court to resolve the question of whether the senior physician had a duty to supervise for this specific procedure, the lack of evidence showing that he owed the patient a general duty of care mooted that question and led the court to rule in favor of the defendant. In this case, the senior physician submitted into evidence the patient's medical chart which, along with the junior physician's and the patient's deposition testimony, confirmed that the senior physician had no role in the patient's treatment.

Vicarious liability is another important doctrine applicable to medical malpractice cases, and it was unsuccessfully argued for in this case.

Under the theory of vicarious liability, employers may be found responsible for the wrongful acts of their employees when such acts occur within the scope of employment. In this case, the patient attempted to argue that the senior physician was vicariously liable for the junior physician's actions as a result of the two being within the same medical practice. Fortunately for the senior physician, the court found that because the junior physician was a board-certified ophthalmologist, the senior physician had no obligation to supervise the junior physician's work.

This decision confirms existing case law regarding relations among physicians working in the same medical practice group and sets the ground rules for establishing the existence of a duty of care in a medical malpractice case. This appellate court confirmed that physicians who merely work within the same medical practice do not owe patients a general duty of care unless they actively partake in the patients' treatment.

For colleagues, including those who may be more experienced than others, vicarious liability imposes responsibility vertically, based upon the employer-employee relationship, rather than horizontally.

Physicians thus may take solace knowing that mere employment by a medical practice or facility will generally not impose personal liability for the actions of a co-worker, absent direct and active involvement with the circumstances giving rise to liability. ■

REFERENCE

Decided on July 5, 2018, in the Appellate Division of the Supreme Court of the State of New York; Case Number 2017-09841.