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Hospitals are limiting pre-term inductions to reduce birth risks

Strict rules require permission for early delivery before 39 weeks

Hospitals are beginning to crack down on the use of oxytocin and induced delivery before 39 weeks gestation in an effort to reduce the high risks of birth trauma and liability. Strict policies on when induced labor is allowed can be effective, say some risk managers and clinicians, but enforcing the rule with obstetricians is no easy task.

Clinicians always have had the option of inducing labor early when necessary, but the practice has become far too common and often is done for the wrong reasons, says **Kathy Connolly**, RN, MSEd, CPHRM, assistant vice president of risk management at the insurance management unit of Premier, an alliance of 1,500 nonprofit hospitals based in San Diego. In response to concerns of too-common use of induction, the nonprofit Institute for Healthcare Improvement (IHI) launched a program in 2005 with Premier and Ascension Health in St. Louis that is designed to reduce those numbers. The program called "Idealized Design of Perinatal Care" includes steps for deciding whether induction is appropriate and another set of guidelines for managing a birth that is not progressing.

EXECUTIVE SUMMARY

Health care providers are restricting the use of induced labor for early delivery in an effort to reduce childbirth risks and the associated costs. Some hospitals require obstetricians to prove a clinical need for induction and obtain special permission.

- Early induction is associated with higher childbirth risk.
- Many obstetricians will induce early labor for convenience when it is not clinically necessary.
- Risk managers may have some difficulty getting obstetricians to comply with new rules.

None of the criteria in the IHI program are new, Connolly says. In fact, they are all based on previously published criteria from clinical groups such as the American College of Obstetricians and Gynecologists (ACOG). The point of the IHI program is to encourage more judicious use of induction and a better adherence to professional guidelines. A goal of the IHI program is for a participating hospital to reduce the rate of birth trauma to 3.3 incidents per live birth, much lower than the national average of 6.34. The results for various hospitals vary, but IHI reports that some have reduced the rate to less than one per live birth. **(Editor's note: For more on the IHI program, go to www.premierinc.com and enter "Idealized Design of Perinatal Care" in the search box.)**

A concerted effort to reduce elective inductions can yield big results, but it won't be an easy task, says **Janie Wilson**, MS, RN, operations director for the Women and Newborns Clinical Program at Salt Lake City-based Intermountain Healthcare, which operates hospitals in Utah and Colorado. Intermountain delivers about 30,000 babies a year and about half of all babies delivered in Utah.

Intermountain started restricting the use of elective inductions in 1999, when 27% of all deliveries in the system were induced before 39 weeks. While far too high, Wilson says Intermountain's 27% rate was not even the highest in Colorado. Other providers in that state reported to Intermountain that their induced deliveries accounted for more than 30% of all births.

Now the rate at Intermountain is only 5%. Wilson says Intermountain cracked down on elective inductions when it became clear that babies were suffering from the too liberal use of this option. **(See p. 112 for more on the motivations behind induced delivery.)** "We had babies coming to the neonatal intensive care for no reason other than we were medically inducing them early, sometimes as early as 36 weeks," she says. "We decided that was just bad practice, and it didn't comply with the clinical guidelines from ACOG."

To change the status quo, Intermountain organized meetings with obstetricians and the labor and delivery staff in 1999 and 2000. When everyone went over the rates of induced delivery and looked at the ACOG guidelines, there was quick agreement that something was amiss. The suggestion that Intermountain forbid delivery before 39 weeks without a solid clinical reason was greeted with praise. "They said it would sort of take the monkey off their back if we just made a rule," Wilson explains. "They wouldn't have to argue about it or try to convince someone that early induction was wrong if they could just point to the rule and say they didn't have a choice."

In addition, Intermountain officials printed brochures to educate patients about the risks of early induction in an effort to relieve some of the pressure on clinicians from patients eager to deliver. But the rate of inductions really started to fall in 2001 when Intermountain programmed its best practice guidelines into its labor and delivery charting system.

"We took the ACOG criteria and programmed that into our system, so that if you try to schedule an elective delivery without meeting that criteria, an alert pops up on the screen that says the patient

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Injury and liability risk high without induction

The risks from early induction are known to be high, and risk managers don't need any more risk from the obstetrics unit than they already have. The American College of Obstetricians and Gynecologists (ACOG) reports that obstetricians and gynecologists have an average of 2.6 claims filed against them during their career. Of these, 61% are obstetrics-related cases.

The most recent data (2004) from the National Practitioner Data Bank notes that obstetrics-related cases generated 8.1% of all physician malpractice payment reports and had the highest median ($300,000) and the highest mean ($503,564) payment amounts. They also took the longest amount of time to resolve, with a mean delay between incident and payment of 6.01 years. For comparison, the mean delay for anesthesia-related cases was 4.09 years. ■

does not meet the criteria and a delivery cannot be scheduled," Wilson says. "The physician has to go to a regional supervisor to ask for permission, and the supervisor usually says no. We make exceptions for some unusual family situations, but they are few and far between."

Document the reasons for induction

Premier followed a similar path and began implementing the IHI guidelines in February 2005. Ten hospitals introduced the guidelines for obstetric care, and each was required to have a obstetrician champion who would be the leader in teaching the guidelines and encouraging compliance. The key part of the program is that obstetrical teams are discouraged from inducing labor before 39 weeks.

"We weren't dictating that you can't induce before then, but we said that if you induced you should have good documentation of the reasons in the medical record," Connolly says. "Our experience with claims was that the reason was not always documented well, and that made our defense difficult if we had a bad outcome and a claim."

Connolly says Premier sometimes had a difficult time in court because juries would look at the guidelines from ACOG and other standards that said labor should not be induced before 39 weeks without a good reason, and then they would look to the medical record for the good reason. Too often, there wasn't one, she says. Part of the problem was that the clinical guidelines make reference to a desire on the patient's part to induce early, so some obstetricians have used that as wiggle room to say that early induction for nonclinical reasons still fit the clinical guidelines. It had become common for women to ask for early induction as a matter of convenience, such as avoiding a delivery on a holiday or simply because the woman was tired of being pregnant, Connolly says.

"We discourage that kind of interpretation," Connolly says. "If the patient has preeclampsia and the early induction is necessary for the safety of the mother and child, we're not going to question that clinical judgment. We just hope to see it documented well so that we can explain that reasoning to a jury if there is an unfortunate outcome."

Premier's experience shows that in nearly 90% of childbirths leading to claims, oxytocin was used to start or augment labor.

The program was introduced through educational sessions held with obstetrics staff at each hospital, but Connolly says the different hospital teams were allowed to determine their own methods of compliance. The goals were made clear and then, for instance, each facility's obstetrics team developed its own method for making sure that proper documentation was in the record before any labor induction. Some developed systems that required special stickers to be placed on the chart indicating that certain examinations had been done, and others introduced paperwork for the doctor to fill out.

"However they decided to meet the goals, we

SOURCES

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Induced delivery often for convenience, not care

Risk managers should investigate the rate of induced deliveries in their organizations and determine what is motivating that practice, suggests **Janie Wilson**, MS, RN, operations director for the Women and Newborns Clinical Program at Intermountain Healthcare, based in Salt Lake City. Chances are you will find that women and babies are being put at high risk of complications for no good reason.

Before 2001, many women at Intermountain underwent elective inductions because they and their doctors wanted it, usually not for any good clinical reason, Wilson says. Doctors sometimes chose to induce because they wanted to deliver their patients' babies and they were going out of town that weekend, for instance, and women often pushed for an elective induction for convenience.

"Women want to schedule a birth the way they schedule a manicure," Wilson says. "If grandparents are flying in, they want that baby born while they're in town. You can't underestimate how much patients push for this. It's not just doctors."

Wilson says Intermountain has even had nurses within its own system, who should know better, request a premature delivery for convenience. One even manipulated her doctor into scheduling an induction by complaining of the appropriate symptoms before labor and delivery nurses intervened and convinced her that she was risking her child's health.

"People tell us that it'll be OK because preemies do so well in intensive care these days and they'll be fine in the long run," Wilson says. "It's a strange result of how much better our preemie care is that now some people don't take it seriously. That fact is that delivering before 39 weeks is still very risky and not something you should do without a good reason." ■

let them do it in a way that conformed to their existing processes rather than forcing them to adopt a totally new process," Connolly says. "That helped with getting the buy-in. It was a gradual thing, with the physician champion encouraged to get some of his peers to adopt the changes first and then spread it throughout the department."

Premier provided the physician champions with slides and other educational materials to present to their peers. The teams also were required to perform chart audits to gauge compliance, and many teams chose to post the audit reports in the department, which helped encourage interest and better participation.

Premier still is monitoring the results of the effort, and Connolly notes that it can take years to see a reduction in claim costs related to birth trauma. But she says the new guidelines already have produced some positive results, including better communication among obstetrical staff and improved satisfaction among staff.

"Some of the teams report that they're seeing better staff retention, less turnover than they were seeing before," Connolly says. "The reason is that this is a program that encourages better care through a more systematic adherence to the guidelines that everyone knows will help them provide care, and better communication. It's more than just declaring that we don't want to see labor induced before 39 weeks. ■

Physicians still resist full disclosure of errors

Even as the health care system continues to adopt the idea of full disclosure after a medical error, with many leaders touting it as the key to improving patient safety and ethics, new research is confirming something that many risk managers already suspected: Doctors are the least enthusiastic about the idea.

A study from the University of Iowa examined why doctors are reluctant to disclose. The study involved a review of more than 300 previously published papers on factors that hinder or help

EXECUTIVE SUMMARY

Although the health care community as a whole is embracing the idea of full disclosure following medical errors, physicians are not as willing to tell. Risk managers can help physicians fully disclose by understanding how doctors are affected by medical errors.

- Malpractice liability is not the only concern, but it must be addressed.
- Physicians can be personally devastated by an error.
- Don't assume doctors are telling patients the whole truth.

Doctors more likely to tell when patient knows error

Physicians in the United States and Canada generally report that they support disclosing medical errors to patients, but they have widely varying positions on when and how they would tell patients an error had occurred, according to recent work by **Thomas H. Gallagher**, MD, a researcher at the University of Washington School of Medicine in Seattle.[1,2]

In many cases, the physician is likely to disclose the error only if the patient already knows something went wrong.

In a survey of 2,637 physicians from various specialties, the researchers presented the physicians with one of four scenarios involving a medical error. Two of the scenarios were tailored to internal medicine specialists, and two were tailored to surgeons. One of each type of error would be apparent to the patient, and the others would not be apparent to the patient if he or she was not informed.

For instance, the more apparent surgical error involved a sponge left inside a patient's body and the less apparent surgical error involved an internal injury that a surgeon inflicted because of unfamiliarity with a new surgical tool. The physicians answered a series of questions about the scenario they received, including how likely they would be to disclose the error, what information they would convey if they did disclose the error, how serious the error was, and how likely it was to result in a lawsuit.

Eighty-five percent of the physicians agreed that the error they received was serious, and 81% believed the physician was very or extremely responsible for the error. Overall, 65% would definitely disclose the error, 29% would probably disclose, 4% would disclose only if the patient asked and 1% would definitely not disclose. The language the physicians would use also varied widely. Forty-two percent would use the word "error," 56% would mention the adverse event but not the error, 50% would give the patient specific information about what the error was, and 13% would not reveal any details not requested by the patient.

Surgeons more likely to disclose

Specialty and the nature of the error affected how likely the physicians were to disclose the error. Surgeons were more likely than other physicians to say they would definitely disclose the error (81% vs. 54%) but also reported that they would disclose less information. Thirty-five percent of surgeons and 61% of other physicians said they would disclose specific details about the error.

Those who received the more apparent errors were more likely to say they would disclose them than those who received the less apparent errors (81% vs. 50%) and would also disclose more information about them. Fifty-one percent of those who received the more apparent errors would use the word "error," vs. 32% of the other group.

"Some dimensions of errors might justify disclosing less information, such as if the error caused only trivial harm," the authors wrote. "However, physicians agreed that all the scenarios represented serious errors. Basing disclosure decisions on whether the patient was aware of the error is not ethically defensible or consistent with standards such as those from the Joint Commission on Accreditation of Health Care Organizations."

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2. Gallagher TH, Waterman AD, Garbutt, JM, et al. Choosing your words carefully: How physicians would disclose harmful medical errors to patients. *Arch Intern Med* 2006; 166:1,585-1,593. ■

doctors' disclosure of mistakes.[1] The research suggests doctors are profoundly disturbed by their involvement with a medical error and their distress can hinder any efforts at disclosure, says **Lauris Kaldjian**, MD, PhD, associate professor of internal medicine at the University of Iowa Roy J. and Lucille A. Carver College of Medicine and director of the college's program in biomedical ethics and medical humanities.

"The physician's focus should always be on the patient, but at the moment of a medical error, we also must consider the professional who was involved in that error," Kaldjian says. Often an error is not directly an individual person's fault, but a system-based problem, he says. "Yet disclosing errors can be a very individual issue because sometimes only one person knows about it and, as a result, disclosure becomes an individual responsibility."

Not just malpractice concerns

Another researcher points out that, contrary to some assumptions, malpractice concerns are

not always the reason a physician is reluctant to disclose.

Thomas H. Gallagher, MD, a researcher at the University of Washington School of Medicine in Seattle, recently surveyed physicians in the United States and Canada to gauge their attitudes regarding the disclosure of medical errors.[2,3] In Gallagher's research, physicians' estimates of how likely they were to be sued did not affect whether they supported disclosing errors to patients. The medical profession should consider whether the culture of medicine itself represents a more important barrier than the malpractice environment to the disclosure of harmful medical errors to patients, Gallagher says. **(For more on Gallagher's research, see p. 113.)**

Kaldjian agrees and says he advises risk managers to consider the emotional impact on a physician who is involved with an error. "One comment from the focus groups clearly showed how emotionally traumatic errors are for physician, by referring to that 'sinking feeling' when a doctor realizes that an effort to help someone has actually harmed them," Kaldjian says. "Whatever else you say about medical errors, we need to remember that it's really difficult terrain."

Too often, he says, risk managers and other hospital leaders focus exclusively on the potential malpractice liability and assume that that also is the main concern of the doctor. While a looming lawsuit is certainly on the physician's mind, he or she is likely to be more concerned about failing the patient, Kaldjian says.

The best thing a risk manager can do is to acknowledge that concern up front, he says. "Don't go in with the attitude that the physician is only concerned about money and lawsuits," Kaldjian says. "Let the doctor know that you appreciate what a terrifically difficult time this is."

Feedback is essential

The research also showed that some physicians are frustrated with reporting systems set up by hospitals to encourage error reporting because there is little or no feedback. Some doctors said they felt like they were "sending a message into a black hole." Kaldjian says this frustration can make them less likely to take time out of a busy schedule to report an error.

The solution to that problem is plenty of feedback, he says. Let the doctors know they have been heard and that you appreciate their input. **(See p. 115 for more advice on helping doctors disclose.)**

Some doctors said the bottom line in terms of positive motivation to report an error was the desire to be straightforward with patients, but some also noted that talking about errors "doesn't earn you points" with patients. The culture of competition in medicine can discourage doctors from being straightforward about mistakes, even among colleagues, they reported.

Kaldjian also explains that physicians can sometimes feel like they are left holding the bag when, in actuality, the system failed. And they can feel that no one understands their unique concerns when it comes to disclosure. He suggests that risk managers can improve disclosure by acknowledging those problems.

"I, as an MD, would want the risk manager to come to me and acknowledge that there are barriers and challenges to disclosure that no one else involved in this error faces," he says. "The emotions, the anxiety, the risk to professional reputation, all these negatives need to be acknowledged before you start pushing me to disclose. Empathize, in detail, and you can really disarm a lot of the negatives that stand in the way of a physician and full disclosure."

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3. Gallagher TH, Waterman AD, Garbutt JM, et al.

SOURCES

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Choosing your words carefully: How physicians would disclose harmful medical errors to patients. *Arch Intern Med* 2006; 166:1,585-1,593. ■

How you can encourage doctors to disclose errors

To encourage physicians to fully disclose errors, health care risk managers must understand that the adverse event can place the doctor in what feels like an untenable situation, says **John Banja**, PhD, assistant director for health sciences and clinical ethics at Emory University in Atlanta and an expert on applying ethical principles in risk management.

"Disclosing an adverse event puts the physician an extreme dilemma of duty vs. inclination," he explains. "He or she says, 'My duty requires me to do this,' but the inclination is to protect yourself, and every physician will fear that disclosing puts you and your career at risk."

The following suggestions were offered by Banja and **Lauris Kaldjian**, MD, PhD, associate professor of internal medicine in the University of Iowa Roy J. and Lucille A. Carver College of Medicine and director of the college's program in biomedical ethics and medical humanities:

• **Don't assume that the doctor looks at the situation in the same way you do.** Risk managers and other involved parties may see the incident as just another adverse event — unfortunate yes, but something to handle just as you handle all the others. But for the physician involved, the incident may be personally devastating, Banja says. It is not just a work issue that can be addressed and forgotten.

• **Remind them that, deep down, they want do to the right thing.** "Tap into how they felt when they were leaving medical school, that idealism and enthusiasm for providing the best care to the patient," Kaldjian says. "Point out that making an error doesn't negate that. They can still do the right thing by informing the patient properly."

• **Pretend for a moment that there is no risk of a malpractice lawsuit.** When you stop focusing so much on that concern, you can see that there still are plenty of other issues still troubling the physician, Kaldjian says.

• **Offer continuing education for physicians that shows the true relationship between disclosure and malpractice liability.** Many physicians assume that disclosing an error increases the chance of being sued, but the research has proven otherwise, Banja notes.

• **Acknowledge that the physician probably is worried about being reported to the National Practitioner Data Bank.** This is a major concern for most physicians, who may fear this even more than being sued, Banja says. Explore the realities of whether this incident is a reportable, and whether the way it is handled after the fact has any effect on it being reported. ■

SOURCE

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Outside counsel must know what you need from them

(Editor's note: This is the second of a two-part series on how to get the most from your relationship with inside and outside counsel. Last month's article discussed how to work best with your in-house counsel. This month's Healthcare Risk Management *will explore how to best work with outside counsel.)*

Working with outside counsel can be very different than working with your corporate colleague, and a few tips can help you get the most from that relationship. Keep the costs of outside counsel in mind but don't make it the primary consideration, attorneys and risk managers say.

It can be a challenge to balance a desire to save money on legal expenses with the need to obtain good representation, says **Stacy Gulick**, JD, an attorney with the law firm of Garfunkel Wild in Great Neck, NY, and a former hospital risk manager. Don't be afraid to consult legal counsel when drawing up policies and procedures, for instance, she says. Preparing solid policies and procedures can help avoid many problems and make incidents far easier to defend, Gulick notes.

James M. Stewart, JD, a partner with the law firm of Stewart & Stimmel in Dallas, also warns

EXECUTIVE SUMMARY

Working well with outside counsel requires a good rapport and an awareness of the costs involved. Be careful not to focus exclusively on cutting legal expenses.

- A good relationship with one attorney at the firm is ideal.
- Try to choose an attorney with whom you feel comfortable working.
- Expect on-site visits to investigate incidents.

that it can be a mistake to focus too much on hourly rates and other cost concerns.

"Risk managers clearly have an obligation to achieve the best possible result in the most cost effective manner; however, the way to control this is not to simply select the lowest-priced firm," Stewart says. Quality counts, he emphasizes. "Effective lawyers get cases dismissed earlier and have stronger cases going into trial or mediation, which leads to lower monies spent."

A good relationship with one attorney in the law firm is important, Gulick notes. Develop a rapport with that one person, even if he or she can't satisfy all your legal needs. When you need a referral to another person in the firm or even elsewhere, it will be more productive for your close contact to make the connection than for you to do it yourself, she explains.

Also, using a discreet number of firms is more efficient, Stewart says. The firms begin to know the processes, policies, and other areas and do not have to reinvent the wheel each time there is a new lawsuit.

Gulick reminds risk managers that the billing structure will be different when working with outside counsel who handle malpractice cases and a firm handling any other legal concerns. For medical malpractice cases, the attorneys usually will be paid directly by the insurer and the risk manager won't receive a bill. For other issues, the attorney probably will bill you every time you pick up the phone with a question. That fee should not discourage necessary interaction, Gulick says, but keep in mind that frequent chats are not free.

"It's unfortunate that sometimes the billing structure dictates how you interact with people," she says. "But at the same time, you have to remember that you can be too cheap up front, and it will cost you in the end."

Gulick notes that risk managers should not be cowed by outside counsel. While counsel will be the expert on the legal system, risk managers have their own areas of expertise and shouldn't

Outside counsel should visit where incident occurred

Risk managers should expect more than telephone conversations with outside counsel. In most cases, counsel should visit your facility to investigate first hand, says **Tony Corleto**, JD, founder of Corleto & Associates, an insurance defense law firm based in Danbury, CT, and White Plains, NY.

Corleto notes that visiting the actual physical location where events take place provides counsel with the most in-depth understanding of how an alleged incident might have happened. For example, he cites a case recently handled by his firm in which a physical therapy center was sued for malpractice. The patient claimed that he had been abandoned during treatment on a continuous passive motion machine. At the time, he was being treated for a dislocated shoulder and was claiming that he suffered another dislocation as the result an alleged improper treatment.

The client provided all treatment records, but there was much more needed: records for the last prior event and meeting with the physical therapist who did the treatment and all staff members who were in the area at the time of the alleged event. The firm needed to investigate and validate or refute the patients claims that he "screamed for help." To best set up the defense, the firm needed to see, photograph, and map the physical location, to coordinate witness testimony at trial.

Digging still deeper, the firm needed to see the actual machine involved, which had been put into storage. They had to track all manuals and operating instructions and training materials, even going back to the manufacturer when they could not get some of the information at the facility. They needed to see if there been any product recalls, for instance, and whether any retrofits had not been done. Every detail had to be covered to find out if there was any validity to the claim, Corleto explains. "The attorney must conduct a thorough forensic investigation to find out exactly what did and did not happen," he explains.

In this case, the plaintiff refused any kind of settlement, Corleto says. "The case went to trial, and the conclusion was a good defense verdict, with minimal damages awarded," he says. ■

SOURCES

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be shy about contributing, Gulick says. "The risk managers who deal best with outside counsel are the ones who are very well educated about their own jobs," she says. "This should be a partnership in which you work to each other's strengths, so the more you are skilled as a risk manager, the more you can get out of your work with outside counsel."

There does come a point at which your outside counsel should take the helm, Gulick says. They have more resources available and more skills in certain areas, so be prepared to let outside counsel take over when appropriate. When outside regulators become involved, for instance, it is time to let outside counsel take the lead.

Choose someone you can work with

Linda Stimmel, JD, Stewart's partner and cofounder of the firm in Dallas, makes another point that often goes overlooked when choosing outside counsel.

"We would advise risk managers to actually like the attorneys they chose as outside counsel," she says. "That leads to more communication and effective communication because they think alike." Along with liking your attorneys, you must trust them, she says. "It will be very harmful when a risk manager second-guesses everything provided by an attorney," Stimmel says. "That is the surest way to increase legal fees needlessly as the attorney will feel the distrust and probably 'overdo' everything."

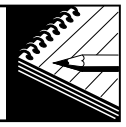
When working with outside counsel, the most important things that risk managers should keep in mind are good, ongoing communication, access to personnel, and access to records, says **Tony Corleto**, JD, founder of Corleto & Associates, an insurance defense law firm based in Danbury, CT, and White Plains, NY.

Getting attorneys in touch with the people who are involved in the situation in a timely manner is extremely important, Corleto explains. Outside counsel needs to have access to people who were directly and indirectly involved. Risk managers at health care facilities can best help by reviewing the records to identify everyone potentially involved directly or as a witness and by making sure that the involved personnel know there is a legal issue that may require their time and effort.

Records also are critical, and Corleto says patient and treatment records are just the start. If a piece of equipment or a product is involved in a case, for instance, every document, from user manuals to training notebooks and safety meeting logs, will be needed.

Be prepared for the attorney to conduct a thorough investigation. In fact, you should insist on it, in order to properly defend against any claims. **(See p. 116 for more on outside counsel investigating the incident on site.)** "The rule of thumb is that every hour in the courtroom requires 10 hours of preparation, investigation, and discovery," Corleto explains. "A visit to the site of the treatment or alleged injury is almost always necessary." ■

GUEST COLUMN



New health services bring new risks to consider

By **Leila Narvid**, JD
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Evolving notions of health and wellness have introduced a plethora of new services to patients, many of which have less to do with medical necessity than with cosmetic appearance. Today, patients can receive a spa service, a

EXECUTIVE SUMMARY

Health care organizations are launching more nontraditional services such as medi-spas and eye surgery clinics, but the financial benefits may come with potential liability. Risk managers should consider the dangers of such offerings and plan accordingly.

- Several states have "corporate practice of medicine" statutes that will dictate risks and limitations.
- Statutory penalties for corporate practice of medicine violations can be severe.
- Medical professionals can lose their licenses and employers can be prosecuted for participating in illegal activity related to these services.

nutrition consultation, and a full-body MRI scan all in a day's work.

However, the regulations that govern health care practices have yet to promulgate provisions that specifically relate to the operation of clinics that offer "spa-medicine" services and elective, nontherapeutic procedures. This article looks at the unique problems encountered by these types of clinics and legal pitfalls for health care risk managers to avoid.

Patients are presented with a variety of options: "medi-spas" that provide cosmetic services in luxurious surroundings, in conjunction with medical care from plastic surgeons or dermatologists; vision therapy clinics that only perform LASIK eye surgery; and centers that perform full-body CT or MRI scans. These clinics are staffed by licensed physicians and nonlicensed employees, such as cosmeticians, plastic surgery counselors, and holistic medicine practitioners. Often, a nonphysician is the first point of contact for a patient. For example, plastic surgery counselors guide patients through the decision-making process and show them before-and-after photographs to "sell" them on the procedure, and optometrists perform initial consultations and refer patients to LASIK specialists.

The patient may not even see the physician until the day of the procedure. The relationships between physicians and nonlicensed persons can create what seems like a sensible opportunity for incentive pay programs wherein, in exchange for referrals, the nonlicensed person receives a commission from the physician. This can be a tremendous liability risk for the physicians and the participating health care organizations. Risk managers must be aware of this potential for significant civil and criminal violations.

Beware 'corporate practice of medicine'

Though the arrangements can be problematic in all states, the risk is higher in California, Colorado, Illinois, New York, and Texas, which have statutes that limit the ability of physicians to be employed by nonphysician entities or to split fees with nonphysicians. These are known as "corporate practice of medicine states." **(See p. 119 for more on the corporate practice of medicine doctrine.)**

Health care providers involved in such arrangements can face tremendous liability, but does this mean that physicians should not award bonuses or commissions to any nonlicensed staff members? Not necessarily. The key rule, however, is that incentive programs should not be linked to referrals or business-generated. For example, practice managers should not be paid based upon a percentage of total profits. Health care risk managers should recommend performance-based incentive programs, in which eligibility is based on monthly evaluations using criteria such as quality of work and patient care. Bonus programs that are based on a percentage of net income are illegal.

To the extent that nonlicensed staff members cause patients to be referred to the clinic for physician services, the fees paid to the physician for performing these services should remain constant. For example, the physician should not receive less compensation for Botox injections he or she performs because someone other than the physician was responsible for getting the patient in the door.

Must not influence doctor's judgment

What types of conduct are construed as exerting influence or control over a physician's professional judgment? In corporate practice of medicine states, the following types of decisions should be made by physicians only and would constitute the unlicensed practice of medicine if performed by a nonphysician:

- determining what diagnostic tests are necessary for a particular condition;
- determining what kinds of procedures should be performed;
- determining the need for referrals to another physician/specialist;

• determining how many patients a physician must see in a given period of time.

Physicians are just one of many categories of health care providers, and a host of other non-physician providers are developing subprofessions that involve limited licensure and fill an important need in a specialty. With new forms of health care entities developing at tremendous pace, questions regarding the applicability of the corporate practice of medicine doctrine to these new entities continue to arise.

Health care risk managers should closely scrutinize their entities' contractual agreements, to assure that they are not assisting in the corporate practice of medicine.

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Avoid the corporate practice of medicine

By **Leila Narvid**, JD
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Risk managers must assure that the fast changing face of health care does not draw their organizations into the "corporate practice of medicine," which brings significant liability risk.

The corporate practice of medicine doctrine has three primary tenets:

1. A nonlicensed individual or entity cannot employ a physician or any other health care professional to practice medicine.

2. Entities that provide health care services cannot be owned or controlled by nonlicensed persons or corporations.

3. Licensed health care professionals may not divide or share a professional fee with a nonlicensed person or entity.

These tenets all exemplify the principle that medical decision making should be entirely free of layperson and corporate control, and that physicians should be free to exercise professional judgment and remain fully accountable for their actions. Put another way, if a lay entity has a financial interest in a physician's "bottom line" or "profit," then the entity has a direct interest in and ability to control the medical side of the business, such as how many hours the physician will work, what type of procedures will be performed, and what type of medical technology should be used.

For example, in California, actual "medical" control need not be established to show a statutory violation. (See California Business & Professions Code §§650, 2052, and 2400.) Rather, the law recognizes that many business decisions have direct and indirect medical implications and prohibits arrangements that provide for the potential of inappropriate lay control. Similarly, in Maryland, a physician is subject to discipline if the physician "pays or agrees to pay any sum to any person for bringing or referring a patient or accepts or agrees to accept any sum from any person for bringing or referring a patient." [Health Occupations Article, Maryland Code §14-404(a)(15).]

Penalties may be severe

Statutory penalties for corporate practice of medicine can be severe. Medical professionals can lose their licenses, and employers can be prosecuted for furthering the illegal activity. Professional organizations, such as the American Academy of Ophthalmology, have taken the initiative to promulgate ethical guidelines that address fee-splitting and corporate practice of medicine.

The American Academy of Ophthalmology issued voluntary guidelines that urge eye surgeons not to accept referrals from optometrists in exchange for a cut of the professional fee, even if the optometrist will be responsible for handling the patient's postoperative care.

(Editor's note: For the guidelines, go to www.aao.org/aao/member/ethics/employment_referral.cfm.) ■

COMING IN FUTURE MONTHS

- Strategy to avoid reports to NPDB Liability from allowing access to patient data
- Reducing falls in the ED requires different tack
- E&O insurance for execs — Worth the cost?

CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and other hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

Answers: 13. C; 14. D; 15. A; 16. B.

CE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

13. According to Janie Wilson, MS, RN, what is a risk manager likely to discover is the reason behind high rates of induced delivery?
A. Overall health is declining among the general population
B. More older women are giving birth.
C. Physicians and patients often push for early induced delivery for convenience, not clinical reasons.
D. Most babies are healthier when delivered before 39 weeks.

14. What does Lauris Kaldjian, MD, PhD, advise risk managers to do when addressing a physician involved in a medical error?
A. Address only malpractice concerns and strictly avoid talking about the physician's emotions.
B. Only ask what the physician plans to do, and do not push for full disclosure.
C. Advise the physician that you can not provide any advice and refer him or her to legal counsel.
D. Acknowledge that there are barriers and challenges to disclosure that no one else involved in this error faces. Empathize with the emotions, the anxiety, and the risk to professional reputation.

15. What advice does Stacy Gulick, JD, offer regarding when to consult outside counsel for assistance in preparing policies and procedures?
A. Don't be afraid to consult legal counsel when drawing up policies and procedures, even if you are trying to save money on legal fees.
B. A good risk manager should never need the assistance of outside counsel for this work.
C. Only certain key polices and procedures require the assistance of outside counsel.
D. Seek the assistance of outside counsel only if you are an inexperienced risk manager.

16. According to Leila Narvid, JD, what is the key rule for avoiding problems with the "corporate practice of medicine" doctrine?
A. Ensure that all medical services are provided by licensed professionals.
B. Incentive programs should not be linked to referrals or business generated. For example, practice managers should not be paid based upon a percentage of total profits.
C. Forbid any deals with doctor-owned health care service providers.
D. Require all medical service providers to sign an agreement that prohibits corporate practice of medicine.

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Hospital settles and physician found liable for failure to obtain informed consent

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News: A 70-year-old patient sought relief for respiratory problems. The woman consulted with various physicians, and she decided to undergo angioplasty and coronary stenting. After experiencing complications, the woman died that afternoon. The patient's estate alleged that there was a lack of informed consent from the patient. After the hospital settled for $25,000, a verdict of $156,000 was awarded against the operating physician.

Background: A woman, age 70, had a history of renal artery stenosis, coronary artery stenosis, high blood pressure, angina, emphysema, and chronic pulmonary disease. After experiencing severe respiratory problems, her primary care physician referred her to an interventional cardiologist, a doctor specializing in surgical procedures such as cardiac catheterization or angioplasty to diagnose and treat heart disease. The cardiologist discussed various possible interventional procedures, including coronary artery angiography, which would enable the doctor to see in detail the woman's coronary arteries as they supplied blood to her heart muscle. The procedure involved putting a tube into the woman's heart via an artery in her extremities and injecting a liquid into the coronary arteries so that they could be seen when viewed with X-rays. If the woman's blood flow was being blocked by the buildup of plaque in the artery wall, the injected contrast dye would show the cardiologist the precise location of the blockage.

After meeting with the patient, the cardiologist sent the woman's medical chart to another interventional cardiologist for a second opinion. The second cardiologist also recommended that a coronary artery angiography be performed. Although he never personally met with the patient, the second cardiologist performed the procedure a few days later. After the angiography, the cardiologist used coronary stenting to artificially keep the woman's arteries open and expanded. Coronary stenting consists of a stainless steel mesh tube with slots that is placed inside an artery to prevent the artery from closing after a procedure such as an angiography. The device comes in various sizes to match the size of the artery. Generally, the stenting is mounted on a balloon catheter in a collapsed state. The balloon is then inflated, which causes the stent to expand and push itself against the inner wall of the coronary artery. The balloon is then removed, which leaves the expanded stent in place. By forming a rigid support and helping to prevent closure of the artery, the stent can reduce the need for coronary bypass surgery.

Unfortunately, the woman died after surgery from complications of the procedure. The primary cause of death was listed as perforation of her circumflex artery.

The family brought suit against the two

cardiologists and the hospital. The plaintiffs claimed that because the second cardiologist never saw the patient prior to operating on her and that the only procedure discussed was angiography, the doctor operated without the patient's informed consent. Both cardiologists claimed that the decedent was fully informed and that these procedures were the only options available to the patient.

Prior to trial, the hospital settled for $25,000. A motion for nonsuit was granted to the first cardiologist, and the issue went to the jury solely on issue of medical battery against the operating cardiologist. A verdict of $156,000 was returned, including economic damages for the hospitalization of $6,000 and noneconomic damages of $150,000.

What this means to you: This scenario raises interesting issues of informed consent when a patient is referred by one physician to another. In this case, it appears that the referring cardiologist, by virtue of the referral, essentially picked the interventional cardiologist for the patient. "Prudence suggests that referring physicians should have some information regarding the credentials, expertise, procedure volume, and patient outcomes of the physicians to whom they refer their patients, particularly in those situations where the patient has little choice or input into the referral selection," notes **Marva West Tan**, RN, ARM, FASHRM, associate director of quality initiative, Health Services Cost Review Commission in Baltimore.

Once the referral is made, Tan notes that some consultant physicians may tend to view the referring physician as their client and may rely on the referring physician to provide to the patient the critical discussion portion of the informed consent process, including information on risks, benefits, and alternatives of treatment associated with the proposed procedure and responses to any of the patient's concerns. In this case, for example, the interventional cardiologist may have reduced the informed consent process to having one of his nonphysician staff obtain the patient's signature on a form prior to undergoing the procedure, with no further discussion between the interventional cardiologist and the patient. Tan recognizes that such practice is problematic: "The referring physician may not have the detailed information or expertise necessary to complete the informed consent or may provide some information to the patient assuming that the interventional cardiologist will perform the detailed informed consent process. Hence, each physician is assuming the other completed the informed consent, but neither actually did."

Tan warns that such an approach to the informed consent process is a setup for patient dissatisfaction and potential claims when complications to the interventional cardiology procedure arise. Because there is typically no prior personal relationship with the consultant physician that might mitigate the patient's or family's dissatisfaction, the formal documented consent process takes front and center stage. "Interventional cardiologists and other physicians who perform interventional procedures based on referrals should not assume that the referring physician has performed the informed consent. They should complete informed consent for their own procedures prior to any patient sedation and should attempt, in the brief pre-procedure time available, to establish personal contact and develop a rapport with the patient," says Tan.

Having determined that the interventional cardiologist should have engaged the informed consent process with the patient in this case, Tan recommends a thorough, well-documented process governed by a written informed consent protocol. It is not clear in this case if a completed informed consent form or a progress note addressing consent was present in the medical record. Generally, such documentation, however brief, does form a basis for a defense to a claim of no consent.

If there was no documented informed consent in the medical record, a preoperative check should have identified that this critical information was missing. The *Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery* developed by the Joint Commission on Accreditation of Healthcare Organizations is a good starting point for such a process. The protocol calls for a preoperative verification process to ensure that all relevant documents and studies are available prior to the start of the procedure. A signed informed consent form is one of the relevant documents that should be available. Tan notes that before the development of the Universal Protocol, a Joint Commission standard recommended that prior to any procedure the patient have a current documented history and physical examination and a pre-anesthesia evaluation, if relevant. Preoperatively, the doctor also would review any required preoperative test results, and the patient would sign an informed consent form. "Typically, it was the responsibility of the nursing or technical staff to check that all

required documents were in the record before the start of the procedure," Tan says.

Once a problem developed in this case as a result of the surgery, it is unclear how information about the untoward outcome and patient death was conveyed to the patient's family. Tan recognizes that each facility is now required by the Joint Commission to have a process to discuss unexpected outcomes with the patient and/or family, and most institutions have been working to develop a transparent process over the past several years. Even prior to this requirement, there were ethical guidelines regarding informing patients and their families of untoward events. "In this case, it may have been helpful for the referring cardiologist and the interventional cardiologist to meet with the family to offer a brief factual description of the event and offer their support without pointing fingers or assigning blame," suggests Tan. The physicians also could have explained their plan to investigate the case more fully and share any additional information with the family.

Finally, Tan emphasizes the emergence of shared decision making in recent years in providing quality health care. Shared decision making overlaps in certain aspects with informed consent in that it concerns the discussion of risks, benefits, and alternatives of specific treatments. However, it generally has a much broader scope, involving such things as discussions between physicians and patients about medications and noninvasive treatments, self-management of chronic illness, end-of-life decisions, and other personal health care preferences. Tan points out that national studies have shown a lack of correlation between cost and quality of care, which elevates the importance of personal preferences where there are alternatives. She also notes that various providers, insurers, and consumer groups are developing tools and videos to educate consumers about treatment options, particularly when there are alternatives available, such as in breast cancer treatment. "Physicians seem more comfortable with the practice of shared decision making, while recognizing that some patients want their physicians to take a leading role in medical decisions," Tan says.

Despite the fact that the field of shared decision making seems to be expanding in research and practical applications and despite the best educational efforts of risk managers to emphasize the importance of the discussion portion of the informed consent process, the old problem of physicians tending to think that "informed consent" means "signing a form" persists. Tan suggests that perhaps what is needed is a new term for informed consent, involving the discussion and the documentation, to gain traction with busy physicians in their everyday practices.

Reference

• San Diego County (CA) Superior Court, Case No. GIC780566. ■

Failure to report abuse leads to settlement

News: A newborn baby exhibited signs of child abuse each time he was brought to the doctor during the first seven weeks of his life. His injuries, however, were ignored continually. Ultimately, the boy's wounds and fractures necessitated a trip to the emergency department (ED), at which point the natural parents' rights were terminated. The boy's adoptive parents filed suit against the clinic and the doctors and alleged negligence for failing to notify state officials of the abuse. Although the defendants claimed that they did not know that the injuries should have been reported to the state, the parties settled the lawsuit for $600,000.

Background: Parents of a newborn baby boy brought their son to a local clinic 13 times during the first seven weeks of his life. Each time the boy exhibited injuries, including wounds to his genitalia and head. Despite the obvious signs of physical abuse, the clinic and its doctors ignored the signs of neglect. After seven weeks, the boy finally was taken to the ED for treatment. Doctors determined that the boy's injuries included corneal ulcerations to both eyes, permanent blindness to his right eye, partial blindness to his left eye, permanent brain damage from a cerebral infarct, and multiple acute and healing fractures to 29 ribs and bones in his fingers and feet.

The natural parents' rights soon were terminated, and they were prosecuted for child abuse. The boy's adoptive parents brought suit on behalf of their son against the clinic and its doctors for negligence. They argued that the defendants failed to notify child protective Services, as required by applicable standards of care, when they knew or should have known that such abuse and neglect were ongoing.

They also maintained that the failure to notify authorities was the proximate cause of the serious injuries to their son. The defendants responded that they had no way to know that the injuries should be reported to state officials. Nevertheless, the parties settled for $600,000, with the clinic and two of its doctors each contributing $200,000 to be paid in trust for the boy's benefit.

What this means to you: This scenario provides an alarming example of protocol with which every health care practitioner should be familiar. "It is very difficult to understand how the defendant clinic and its physicians could respond that they did not know that this child's injuries should have been reported to the state's child protective services," says **Cheryl Whiteman**, RN, MSN, HCRM, clinical risk manager for Baycare Health System in Clearwater, FL.

As with other obligations imposed by the law, the clinic and the physicians had a responsibility to understand federal and state statutes governing the reporting of suspected child abuse that were applicable where they were providing health care.

As with other obligations imposed by the law, the clinic and the physicians had a responsibility to understand federal and state statutes governing the reporting of suspected child abuse that were applicable where they were providing health care. If the clinical members of an office setting truly do not know what their legal responsibilities are, Whiteman suggests procuring the services of a risk manager as soon as possible. "Risk managers have a responsibility to be aware of state and federal regulations and statutes involving health care. As the number and complexity of these regulations continues to grow, the risk manager may need the assistance of legal counsel and/or a compliance expert to ensure that the organization and its practitioners are abiding by statute and adhering to the applicable standard of care," she advises.

Unfortunately, the examples of physical abuse presented by this scenario are not unusual. A study of infant physical abuse in Alaska by Gessner, Moore, Hamilton, and Muth — published in the January 2004 issue of *Child Abuse & Neglect* — found that 4.6 out of every 1,000 children born alive are physically abused during their first year, and nearly a quarter of those cases result in the baby's hospitalization and/or death. (Gessner B, Moore M, Hamilton B, et al. The incidence of infant physical abuse in Alaska. *Child Abuse & Neglect* 2004; 28:9-23). And a 2003 report published by *Fight Crime: Invest in Kids*, a nonprofit organization based in Washington, DC, reported that on a typical day, at least five children in this country are killed by abuse or neglect, and two of those five are infants younger than 1 year old. (Fight Crime: Invest in Kids. *New Hope for Preventing Child Abuse and Neglect: Proven Solutions to Save Lives and Prevent Future Crime.* Washington, DC; 2003.)

These numbers may seem surprisingly high given the relatively low publicity given to infant abuse as compared with child abuse relating to older children. But a study by the University of Wales College of Medicine — published in the December 2002 issue of *Child Abuse & Neglect* — found that severe abuse is six times more common in babies than in children from 1 year to 4 years of age, and it is 120 times more common than in 5- to 13-year-olds. (Sibert J, Payne E, Kemp A, et al.

The incidence of severe physical child abuse in Wales, *Child Abuse & Neglect* 2002; 26:267-276.) The study emphasized that infant physical abuse should be of particular concern because brain injuries and fractures are more common and because abuse is more likely to cause severe damage and death. Also of note is that the University of Wales study attributed this high incidence of infant physical abuse, at least in part, to the failure of secondary prevention of child abuse by health professionals. One of the study's conclusions was that the vigilance of health care providers in reporting and preventing abuse and neglect needs to increase.

Whiteman notes in addition to any legal responsibilities required of health care professionals when confronted with evidence of child abuse or neglect, the parties involved also had an ethical responsibility to the child who could not speak for himself or protect himself. "Certainly, we must be vigilant regarding potential child abuse and neglect," she says. "We must also remain mindful of potential abuse and neglect of the elderly and vulnerable adults." In this case, the number of injuries this child sustained was staggering: "Thirteen trips to the clinic in seven weeks should certainly have raised a red flag on numerous occasions," says Whiteman.

Reference

• Texas District Court, Hidalgo County, Case No. C-1552. ■