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Lack of 'reasonable diligence' defeats late nonparty fault notice

By Todd C. Berg, Esq.

Dr. Jennifer Battiste and the Caledonia, Mich., clinic she works for learned a hard lesson about filing a late notice of nonparty fault.

Because they did not exercise "reasonable diligence" to discover a nonparty doctor they say was at fault, Battiste and her fellow medical-malpractice defendants will be barred from asking the jury to assess that doctor's fault and, thus, his liability should the medical-malpractice lawsuit against them go to trial.

"The percentage of fault that otherwise would have been shifted to the nonparty doctor will have to be shared among Battiste and the other defendants," said Spring Lake attorney Elliot B. Grysen, representing the plaintiff.

"There will be no place on the verdict form for the nonparty doctor's name."

That's the effect of the Michigan Court of Appeals ruling in *Snyder v. Advantage Health Physicians, et al.*

The "defendants failed to establish that the facts underlying their notice of nonparty fault against [the nonparty doctor] could not, with reasonable diligence, have been known earlier," said the *Snyder* court in a unanimous per curiam decision.

Pointing fingers may still be allowed, but ruling stops jury from apportioning fault to nonparty.

Photo illustration by Vasko Miokovic/iStockphoto.com

The judges said the defendants should have undertaken an "independent investigation" into a potential defense that, in the court's opinion, could have been gleaned from the allegations in the plaintiff's notice of intent (NOI) to sue.

Although the nonparty doctor was identified in the NOI, he was not named as a defendant in the plaintiff's lawsuit.

The Nov. 18 opinion, which reversed the lower court's order allowing the defendants to file a notice of nonparty fault and remanded the case for further proceedings, was signed by Judges Kurtis T. Wilder, Henry William Saad and Michael R. Smolenski.

"The defendants didn't conduct the investigation they should have," Grysen said.

They were in the best position to know what the doctors did and didn't

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Specialists disagree about NOI drafting guidepost

By Todd C. Berg, Esq.

Despite two Michigan Supreme Court cases and a recent published opinion from the Michigan Court of Appeals, medical-malpractice specialists still don't see eye-to-eye about whom notices of intent to sue (NOI) should be drafted for.

The options include writing the NOI for the "casual observer" or lay person, which is the standard the courts have adopted; writing for the courts; simply satisfying the NOI statute's specific requirements; and, to be safe, throwing everything into the NOI.

Detroit attorney Ramona C. Howard of McKeen & Associates P.C. has resigned herself to the first approach.

"You must act as though you are writing to a lay person," she said.

Howard represents the plaintiff in *Miller v. Malik, et al.*, in which the Court of Appeals recently held her client's NOI was insufficient because it didn't state how the doctor "proximately caused" the plaintiff's decedent's deep vein thrombosis, pulmonary embolism or death.

"[C]ausation is not obvious to a casual observer," the *Miller* majority said.

Howard disputed the court's conclusion and said she'll be moving for reconsideration and applying for leave to the Supreme Court, if necessary.

"Any first-year medical student worth his or her salt" would have known the proximate cause her NOI was alleging, she said.

Nevertheless, Howard said, the lesson from *Miller*, and the Supreme Court cases that laid the foundation for *Miller*, is clear.

Even though the NOI goes to a doctor, she said, the lawyer who

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HIPAA didn't do away with ex parte interviews

Federal law changed Michigan law, but still allows one-on-one meetings between defense counsel and plaintiff's doctors

By Todd C. Berg, Esq.

The Michigan Court of Appeals has held that, even though the Health Insurance Portability and Accountability Act of 1996 (HIPAA) erected new procedural hurdles, medical-malpractice defense attorneys still may do ex parte interviews with plaintiffs' treating physicians.

In *Holman v. Rasak*, a unanimous panel rejected the trial court's conclusion that HIPAA doesn't authorize such one-on-one meetings.

HIPAA permits an ex parte interview between a defense attorney and a plaintiff's treating physician, as long as a qualified protective order as defined by federal HIPAA regulations is "first put in place," the court said.

The judges said HIPAA modified, rather than overhauled, Michigan law on ex parte interviews.

They're still permissible, said the court, but there are more conditions that litigants must contend with.

HIPAA, according to the court, is a federal law that "regulates the retention, use, and transfer of patient information by health care providers."

Judges Kathleen Jansen, Peter D. O'Connell and Donald S. Owens signed the Nov. 18 per curiam published opinion that reversed the trial court's denial of the defendant's request for a qualified protective order allowing an ex parte interview.

Specialists say the *Holman* decision will affect more than just medical-malpractice cases.

It "impacts any area of personal injury litigation that involves treating physicians," said Berkley attorney Jules B. Olsman, chair of the State Bar of Michigan's Negligence Section and president of Olsman Mueller, P.C.

Flint attorney Robert H.S. Schaffer, who is president of the Michigan Defense Trial Counsel, agreed.

Holman will come into play "where protected health care information is at issue," he said.

Despite the breadth of the ruling's application, Olsman said, it won't cause a significant change in how litigation occurs.

He described *Holman* as settling a point of contention among the bench and bar.

"Since the enactment of HIPAA, there has been a disagreement among the trial courts with regards to the impact of HIPAA and the permissibility of these ex parte meetings," Olsman said. "*Holman* now recognizes that such meetings are not contrary to HIPAA if a qualified protective order is issued."

He said the importance of the order can't be overstated.

"*Holman* does not provide defense counsel with an unfettered right to these meetings," Olsman said. "They still need to show a need sufficient to warrant the granting

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Putting a price on attendant care

COA questions whether agency rates should be the measure of reasonable compensation for family-provided services

By Todd C. Berg, Esq.

No-fault plaintiffs' lawyers may be about to lose an important weapon in their trial arsenals.

No longer will they be able to argue that a family member's compensation for providing in-home attendant care services should be determined by having judges and juries consider the rates that health care agencies charge for comparable services.

Instead, they'll be forced to base their compensation arguments on the rates that health care agencies pay their employees who actually provide the services.

That would be a setback for plaintiffs' lawyers because the agency rates are higher than the amounts agencies pay their employees.

Yet, that may be the future of no-fault attendant-care litigation if the ideas recently espoused by a Michigan Court of Appeals panel come to fruition.

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"Agency employees who have invested in training and education deserve to have their services valued at a higher rate than unlicensed providers."
— Detroit attorney James G. Gross

"If juries are going to be limited to considering only what an agency pays its [employees,] then it's only fair that the juries be made aware of everything the agencies pay ..."
— Bloomfield Hills lawyer Nicholas S. Andrews

"The defense bar has had major problems with using agency rates to justify higher hourly rates for compensating family members who provide in-home attendant care services."
— Detroit attorney Daniel S. Saylor

"If we're no longer going to look at what agencies charge, but instead we're going to look at what they pay, then we must look at everything the agencies pay."
— Southfield attorney Wayne J. Miller

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The 2009 Medicare Physician Fee Schedule

Medicare's Anti-Markup Rule and IDTF Enrollment Requirements for Mobile Imaging

By Adrienne Dresevic, Esq. and Carey F. Kalmowitz, Esq.

In recent years, diagnostic-imaging services have been intensively scrutinized by the federal government.

Significant recent federal regulatory changes included in the 2009 Medicare Final Physician Fee Schedule (2009 MFPFS) affect diagnostic-imaging arrangements.

Industry stakeholders should anticipate, and be attentive to, future regulatory changes. The Centers for Medicare and Medicaid Services (CMS) is expected to continue to focus on areas, such as diagnostic imaging, which it believes are vulnerable to patient and program abuse, and which are among the fastest-growing set of services paid for under Medicare Part B physician fee schedule.

Medicare's Anti-Markup Rule — CMS finalizes two alternatives

On Oct. 30, CMS released the 2009 MFPFS. In the 2009 MFPFS, with respect to the application of the anti-markup rule to the provision of certain diagnostic-testing services, effective January 1, 2009, CMS adopted two alternative tests for determining the applicability of the anti-markup rule.

Specifically, the following principles determine the applicability of the anti-markup rule:

• **Alternative 1** — "Substantially All Test." Arrangements should first be analyzed under this alternative. If the performing physician — i.e., the physician who supervises the technical component ("TC"), or performs the professional component ("PC"), or both — performs substantially all (at least 75 percent) of his or her professional services for the billing physician or other supplier, the services will not be subject the anti-markup rule payment limitations. If the "substantially all" services requirement is not satisfied, an analysis under Alternative 2 may be applied.

• **Alternative 2** — "Site of Service Test." TCs conducted and supervised in, and PCs performed in, the "office of the billing physician," which includes the "same building," by an employee or independent contractor physician avoid the anti-markup payment limitation.

These alternative tests measure whether a performing or supervising physician "shares a practice" with the billing physician or other supplier. A physician is no longer required to exclusively work for one physician practice; rather, a physician need only "share a practice" with a physician or physician organization. This change aligns certain provisions of the Stark group practice definition with the anti-markup provisions.

Additionally, the 2009 MFPFS provides that a billing physician or other supplier satisfies Alternative 1 if he or she has a reasonable belief, at the time he or she submits a claim, that either: (1) the performing physician furnished substantially all of his or her professional services through the billing physician or other supplier for the period of 12 months prior to and including the month in which the service was performed; or (2) the performing physician is expected to furnish substantially all of his or her professional services through the billing physician or other supplier during the following 12 months (including the month the service is performed).

With respect to Alternative 2, CMS aligns the location test with the Stark Law "same building" test by clarifying that a physician or other supplier may have more than one "office of the billing physician or other supplier."

Such space is one in which the ordering physician or ordering supplier regularly furnishes patient care (and with respect to physician organizations or group practices, the space in which the ordering physician performs substantially the full range of patient care services that the ordering physician provides generally).

Additionally, CMS requires the physician supervising the TC to be an owner, employee, or independent contractor of the billing physician or other supplier. With respect to the PC, the performing physician must be an employee or independent contractor of the billing physician or supplier.

As a practical matter, the final anti-markup provisions permit the use of shared space imaging arrangements between physicians that occur in the "same building."

Nevertheless, CMS notes that centralized building locations raise concerns for over-utilization and are not permitted for the provision of diagnostic tests. CMS further cautions that despite its flexibility, it has concerns with the present use of the In-Office Ancillary Services Exception (IOAS) under Stark and may issue future changes.

Of particular significance for those physicians providing imaging services in reliance on Alternative 2, the TC must be both conducted and supervised in the "office of the billing physician or other supplier" ("the Same Office Requirement").

While Stark Law generally applies the Medicare coverage and payment regulations governing supervision of tests ("Medicare Coverage Requirements"), providers seeking to rely on Alternative 2 must meet the Same Office Requirement. This is due to CMS's belief that the Same Office Requirement is necessary to minimize the potential for overutilization and program abuse.

Arrangements that fall within the ambit of the anti-markup provisions are subject to restrictive payment limitations, such that payment to the billing entity will be limited to the lowest of the following: (1) the performing physician's or other supplier's net charge to the billing entity; (2) the billing entity's actual charge; or (3) the fee schedule amount for the test that would be allowed if the performing physician or supplier billed directly.

Significantly, the net charge amount must be determined without reference to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.

Therefore, the billing physician, or other supplier may only recover costs for the salary and benefits it paid to the performing supplier of the TC or PC. As a result, billing physicians or other suppliers who implicate the anti-markup rule will likely receive reimbursement that fails to even cover the costs of providing the services.

Below are two examples of the final anti-markup provisions and their application to common imaging services arrangements:

Group Practice Independent Radiologist Arrangement: A physician in a multi-specialty group practice orders an X-ray, and the part-time technician employee performs the X-ray in the group's office.

The ordering physician works exclusively for the multi-specialty group and supervises the test in the group's office. A radiologist, who is an independent contractor with the multi-specialty group practice, performs the PC of the test in the group's office and reassigns his right to payment to the group.

The radiologist provides professional services to several groups and hospitals in the area. He or she performs approximately 20 percent of those professional services for the multi-specialty group practice.

The anti-markup rule does not apply to the group's billing of the TC because the supervising physician (i.e., the performing physician) "shares a practice" with the billing group insofar as he or she performs at least 75 percent of his professional services for the group.

With respect to the PC of the test, the independent contractor (i.e., the performing physician) does not perform substantially all of his or her professional services to the group (he or she performs approximately 20 percent). Thus, an analysis under Alternative 2 applies. Under the "site of service" test, the anti-markup rule does not apply because the performing radiologist provided the interpretation on-site in the group's office.

Independent Diagnostic Testing Facility (IDTF) Arrangement: A physician orders a diagnostic test from an IDTF. The IDTF bills globally for the test (TC and PC). The anti-markup rule does not apply because the IDTF did not order the test; rather, it was ordered by an outside physician.

IDTF performance standards for mobile imaging providers

In the 2009 MFPFS, CMS finalized its earlier proposal by requiring mobile IDTFs to enroll and bill Medicare directly for the provision of TC services.

However, CMS does not require mobile testing entities to bill directly for their services when such services are furnished "under arrangements" with hospitals. This final rule prohibits many common arrangements in which mobile entities lease diagnostic testing equipment and technicians to physicians who conduct and bill for such tests in their offices.

To summarize, effective January 1, 2009, all mobile entities furnishing diagnostic-testing services must enroll in the Medicare program and bill directly for the services, unless they are billing "under arrangements" with a hospital.

Conclusion

Through a series of regulatory actions, CMS has been targeting diagnostic-imaging arrangements. Diagnostic-imaging providers and suppliers should be attentive to developments with future rulemakings, which may significantly affect the structure of many current imaging arrangements.

As a result, we advise providers to incorporate mechanisms into their current contractual arrangements that will permit these arrangements to adopt a more stringent regulatory framework.

Finally, the regulatory changes discussed in this article probably will not be CMS's final word on diagnostic imaging. Providers should be mindful of this before entering into structures that cannot be unwound or modified.

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Compliance Corner

Health News Briefly

Some doctors may give up vaccines due to cost

ATLANTA (AP)—About one in 10 doctors who vaccinate privately insured children are considering dropping that service largely because they are losing money when they do it, according to a new survey.

A second survey revealed startling differences between what doctors pay for vaccines and what private health insurers reimburse: For example, one in 10 doctors lost money on one recommended infant vaccine, but others made almost $40 per dose on the same shot.

The survey was revealing even to some doctors. "Many physicians really weren't aware and that they were getting reimbursed so little," said Dr. Gary Freed of the University of Michigan, a co-author of both articles published in the December issue of the journal Pediatrics.

The studies are the first to attach numbers to doctors' long-simmering complaints that they are only breaking even — or even losing money — when they give shots.

"It's a pleasure to see a real study to show we're not just making this up," said Dr. Herschel Lessin, a pediatrician in Hopewell Junction, N.Y. who said his practice's spending on vaccines has more than doubled from 2006 to 2007.

Experts say there's no evidence that significant numbers of doctors are quitting the vaccination business yet because of financial concerns.

But health officials are worried. Reimbursement concerns were behind an exodus of doctors from vaccine programs in the 1980s, which contributed to a terrible resurgence of measles in 1989-91 that caused 11,000 hospitalizations and 123 deaths.

This year, U.S. measles cases rose to the highest level in more than a decade, mainly because some parents are opting out of getting their kids vaccinated.

Health officials fear that problem, along with doctor's economic concerns, could set the stage for bigger outbreaks in the future.

"This is a very important wake-up call," said Dr. Lance Rodewald of the U.S. Centers for Disease Control and Prevention, referring to the two new studies.

State's medical pot law in effect amid questions

DETROIT (AP) — Medical marijuana became legal in Michigan this fall, but smoking a joint could still get a patient arrested because the regulations needed to protect them won't be ready for months.

The law approved by voters in November allows patients with cancer, HIV, AIDS, glaucoma and other diseases to use marijuana to relieve their symptoms on a doctor's recommendation.

Qualifying patients can register with the state and receive ID cards allowing them to legally acquire, possess, grow, transport and use a limited amount — no more than 2.5 ounces (717 grams) and 12 plants — of marijuana. They also can designate a primary caregiver to receive similar protection.

But those cards won't be issued until the Department of Community Health introduces guidelines addressing how applications will be handled, what fees will be charged and other issues. The rules must be finalized by April 4.

Until then, anyone possessing marijuana — even patients who could later qualify for the program — can be arrested and prosecuted, though the law allows patients to use a medical-justification defense at trial.

A medical-marijuana program nearly identical to Michigan's was implemented without major incident in Rhode Island in 2006, said Charles Alexandre, who oversees the program as chief of health professions regulation in Rhode Island's Department of Health. That state also had a period where the law went into effect before the regulations were in place, and patients simply had to wait until the rules were in order.

"It's been very quiet," Alexandre said.

Michigan is the 13th U.S. state to allow medicinal use of marijuana, though the state's law doesn't address how patients can obtain it. It's illegal to sell marijuana, even to registered patients. That's also the case in several other states.

Police in Michigan say they want guidance on the issue, and some experts said the Legislature may have to intervene if that or any other aspect of the program becomes a problem.

Brain-injured troops face some long-term risks

WASHINGTON (AP) — Many of the thousands of U.S. troops who suffered traumatic brain injuries in Iraq and Afghanistan are at risk of long-term health problems including depression and Alzheimer's-like dementia, but it's impossible to predict how high those risks are, researchers say.

About 22 percent of wounded troops have a brain injury, concluded the prestigious Institute of Medicine — and it urged precise steps for studying how these patients fare years later so that chances to help are not missed.

The Veterans Affairs Department, which requested the report, and the Pentagon already are taking some of the recommended steps. But a new report highlights the urgency.

"I don't think we really knew how big a hole in scientific knowledge there is about blast-induced brain injuries," said Dr. George Rutherford of the University of California, San Francisco, the report's lead researcher.

Traumatic brain injury, or TBI, is a signature injury of the Iraq war. Most aren't penetrating head wounds but damage hidden inside the skull caused by an explosion's pressure wave. It can range from a mild concussion to severe injury. And because symptoms may not be immediately apparent, troops may not seek care.

"If you have a gunshot wound to some specific part of your brain, I can tell you the consequences," Rutherford said. But with blast concussions, it's not even possible to say "if you have six of these, are you six times more likely to have something bad happen to you than if you've had one?"

Returning soldiers have reported headaches, dizziness, memory loss, confusion, irritability, insomnia and depression. The military has said most recover with treatment.

"There's clearly a whole bunch of people who have mild TBI who have no negative outcomes," Rutherford agreed.

But his committee examined decades of studies into mostly civilian injuries and found:

• Moderate-to-severe TBI is linked with later-in-life risks including Alzheimer's-like dementia, Parkinson's-like symptoms, seizures, problems with social functioning and unemployment.

• TBI in general is linked to depression, aggressive behavior and post-concussion symptoms such dizziness and amnesia.

• If mild TBI caused loss of consciousness, a risk of later memory, movement and seizure problems cannot be ruled out.

The report recommends that every soldier exposed to a blast, even a low-intensity one, be screened for TBI — and that everyone get a pre- and post-deployment brain-function test. The military has begun those steps.

Report: New doctors are still too tired for safety

WASHINGTON (AP) — Doctors-in-train ing are still too exhausted, says a new U.S. report that calls on hospitals to let them have a nap.

Regulations that capped the working hours of bleary-eyed young doctors came just five years ago, limiting them to about 80 hours a week.

The prestigious Institute of Medicine recently recommended easing the workload a bit more: Anyone working the maximum 30-hour shift should get an uninterrupted five-hour break for sleep after 16 hours.

At issue is how to balance patient safety with the education of roughly 100,000 medical residents, doctors fresh out of medical school who spend the next three to seven years in on-the-job training for their specialty. The long hours are in some ways a badge of the profession; doctors cannot simply clock out if a patient is in danger.

But sleep deprivation fogs the brain, a problem that can lead to serious medical mistakes. So in 2003, the Accreditation Council for Graduate Medical Education issued the first caps. Before then, residents in some specialties could average 110 hours a week.

The government asked the institute to study the current caps. Violations of current limits are common and residents seldom complain, the committee found. While quality of life has improved, there's still a lot of burnout.

And despite one study that found residents made more errors while working longer shifts, patient safety depends on so many factors that it is impossible to tell yet if the caps helped that problem, the report said.

Economy likely to move up Medicare's insolvency

WASHINGTON (AP) — Federal health officials estimate that the struggling economy will speed up by one to three years the exhaustion of the Medicare trust fund covering hospital and nursing home care.

Trustees for the Social Security and Medicare programs warned last March that the trust fund for Medicare Part A would become insolvent in 2019. But the chief actuary for Medicare recently said the economy will likely generate less revenue through payroll taxes than the trustees had projected.

Once the trust fund is exhausted, the federal government will continue to pay for hospital care and other services, but it initially would only have enough money coming in to cover 78 percent of estimated costs.

Trustees issue a once-a-year report on the financial conditions for Social Security and Medicare. In the fall, the trustees get an update that tells them what's happening versus what their latest projection indicated. In the latest update, Medicare's top actuary braced the trustees for a deterioration in Medicare's finances.

"Right now, we know that we're in the start of the recession. We don't yet know how severe it might be," Richard Foster, chief actuary for the Centers for Medicare and Medicaid Services, said in an interview. "We did a very, very rough estimate suggesting that because of the recession, the exhaustion date might advance anywhere from one to three years."

That estimate would place the exhaustion of the Part A trust fund somewhere between 2016 and 2018.

Foster said that higher unemployment as well as smaller wage increases are behind the projected drop in revenue for Medicare Part A. Services covered through the Part A trust fund include inpatient hospital care, nursing home care, hospice and home health.

Health and Human Services Secretary Mike Leavitt said that Foster's update reinforced his concern that too many people view Medicare's finances as one that is in the distant future.

"We're not talking about some future president. We may be talking about this one," Leavitt said, referring to President-elect Barack Obama."

Over the past year, Leavitt has frequently talked about Medicare drifting toward a financial disaster. He said Congress will be forced to take action by raising taxes, cutting benefits to seniors or reducing payment rates for health care providers. But those changes can be less severe the sooner that Congress acts.

"The more you anticipate the problem, the better chance you have of averting disaster," he said. "That's why the trustees here are frantically trying to get people's attention to say you have to start now."

Medicare insurers' profits top expectations

WASHINGTON — Health insurance companies that serve the elderly and disabled in Medicare are realizing significantly higher profits than they anticipated, resulting in the companies getting $1.3 billion more than projected, congressional auditors say.

Under a program called Medicare Advantage, the federal government pays insurers for delivering Medicare benefits. The insurance companies' payments are based, in part, on their anticipated revenues and expenses. If the companies had been more accurate, they could have spent much of that $1.3 billion on enhanced health benefits or lower monthly premiums, and they still would have maintained their expected profit margin, the Government Accountability Office said in a report.

The GAO studied the Medicare Advantage program for 2006, the most recent year for which figures were available.

Rep. Pete Stark, D-Calif., who requested the analysis, said the government spends more on beneficiaries when they're in Medicare Advantage than if they're in traditional Medicare, about 13 percent more on average.

"This puts to bed this idea the plans are offering tremendous extra benefits with the overpayments," said Stark, a frequent critic of the program. "The overpayments are going to profits."

Stark, chairman of the House Ways and Means health subcommittee, said he will push for legislation that would lower the government's payments to insurers, an idea that President-elect Barack Obama backed on the campaign trail. But supporters of the Medicare Advantage program said participants are happy with their benefits, and they note that millions have enrolled in the program in recent years as a result.

Any attempts to scale back payments to private insurers would lead to benefit cuts or higher premiums for seniors in those plans, supporters of the program contend. About three-quarters of Medicare's 45 million beneficiaries are still enrolled in traditional Medicare, in which the government pays health care providers a set fee for particular services.

The GAO said that Medicare Advantage insurers generated $50 billion in revenue during 2006. On average, plans earned profits of 6.6 percent and they had projected to the federal government that they would earn profits of 4.1 percent.

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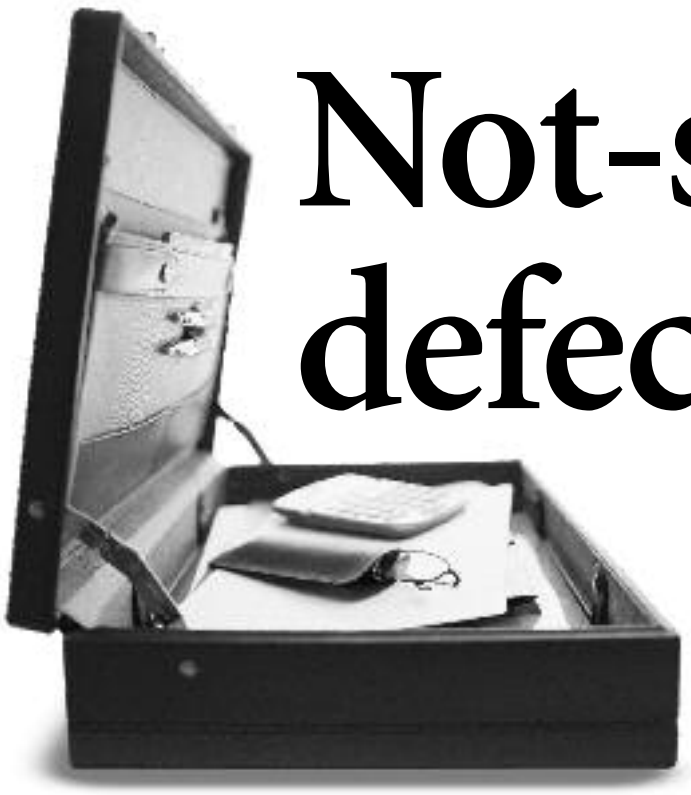


Not-so-fatal defect

Under pending House bill, med-mal plaintiffs would have opportunity to amend faulty NOIs

Legislative Preview: Medical-Malpractice

By Todd C. Berg, Esq.

If state Rep. Mark Meadows' bill becomes law, then wrongful-death medical-malpractice plaintiffs who find themselves in the same situation as Nancy Miller might not have their cases thrown out of court.

In *Miller v. Malik, et al.*, the Michigan Court of Appeals held that Nancy Miller's insufficiently specific notice of intent to sue (NOI) didn't toll the statute of limitations and, thus, the wrongful-death medical-malpractice lawsuit she had filed should be dismissed as untimely.

Under Meadows' House Bill 6277 an insufficient NOI would not necessarily doom a plaintiff's case.

According to Meadows' proposed amendment, after a trial court rules an NOI does not comply with the requirements of the statute, MCL 600.2912b, the court "shall allow" the plaintiff 14 days to correct the defect.

A revised NOI would relate back to the date the original NOI was filed and tolling of the statute of limitations would be triggered by the filing of the NOI.

Additionally, HB 6277 would require defendants to object to NOI defects within 28 days of being served with the complaint, otherwise all objections would be deemed waived.

Current law prohibits revisions to the NOI that relate back to the time of filing. Also, under the current law, tolling is triggered only by NOIs that are "in compliance" with the NOI statute, and there is no time limit for objecting to the form or content of a plaintiff's NOI.

Meadows, an East Lansing Democrat, said he got the impression from the insurance companies' representatives who appeared at a September hearing of the House Judiciary Committee that they recognized there were some problems that needed to be addressed with the medical-malpractice reform statutes, of which the NOI statute was one.

David Finkbeiner, Senior Vice President of Advocacy for the Michigan Health & Hospital Association, however, said, in written materials submitted to the Judiciary Committee, that MHA didn't favor any changes to the NOI statute.

The "bill weakens ... the 'notice of intent' requirement," he wrote. "The MHA is not aware of any evidence that the current notices of intent provisions are preventing legitimate cases from moving forward."

Meadows wasn't certain when a vote on his bill would occur, but said he's optimistic it will be taken up during the lame duck session after the November election, but before the first of the year.

Detroit attorney Ramona C. Howard of McKeen & Associates P.C., who represents Nancy Miller, said she favors not conditioning tolling on the NOI's being "in compliance" with the statute.

Not only would more medical-malpractice cases actually get trials on the merits, she said, but courts would likely see a drop in pre-trial, summary disposition litigation

"In fact," she said, "should this be adopted, I would bet that suddenly, NOIs would be perceived to be substantially more clear, and challenges to them would essentially cease."

Troy attorney John J. Ramar of Ramar & Paradiso PC, who represents a *Miller* defendant, said he thought HB 6277's proposed tolling provision was "reasonable since it forces opposing counsel to timely challenge."

And, Bloomfield Hills attorney Julie McCann O'Connor of O'Connor De Grazia Tamm & O'Connor PC, who represents another *Miller* defendant, said the bill's "practical effect would be to preserve virtually all cases, even if the initial notice is non-compliant."

Ramar, however, said the 28-day time frame for objecting to the NOI was unrealistic.

It's "too little time," Ramar said, because defense counsel often isn't even assigned to the case until a week or more after the complaint was served on the defendant.

Detroit attorney Linda M. Garbarino of Tanoury Corbet Shaw Nauts & Essad PLLC, who also represents a *Miller* defendant, said that, even though she wasn't familiar with HB 6277, "legislation which simply allows a claimant to amend the notice after suit is filed, without dismissal, is unwise and essentially renders the pre-suit notice statute meaningless."

It undermines the incentive for settlement discussions, which is the NOI statute's purpose, she said.

And, it impairs the defendant's ability to "secure proper expert review" because the defendant won't know "the basis for the plaintiff's allegations," Garbarino said.

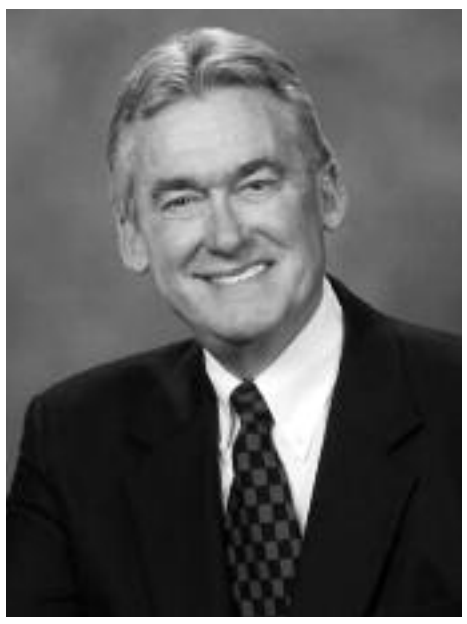
That the plaintiff's allegations in the NOI may not be the same allegations she endeavors to prove at trial is a point the Michigan Supreme Court has acknowledged.

In *Roberts v. Mecosta County General Hospital, et al. (Roberts II)* and in *Boodt v. Borgess Medical Center, et al.*, the Michigan Supreme Court said a plaintiff must make a good faith effort to include in her NOI the information required by the statute, but the plaintiff "is not required ultimately to prove that her statements are 'correct' in the legal sense."

Because the notice "is provided at the earliest stage of a medical-malpractice proceeding," it is "reasonably anticipatable" the plaintiff's allegations "may prove to be 'inaccurate' or erroneous following formal discovery," the *Roberts* court said.

As such, the justices said, the plaintiff "is not required to craft her notice with omniscience."

If you would like to comment on this story, please contact Todd C. Berg at (248) 865-3113 or todd.berg@ mi.lawyersweekly.com.



The "bill weakens ... the 'notice of intent' requirement. The MHA is not aware of any evidence that the current notices of intent provisions are preventing legitimate cases from moving forward."

— Rep. Mark Meadows

"[L]egislation which simply allows a claimant to amend the notice after suit is filed, without dismissal, is unwise and essentially renders the pre-suit notice statute meaningless."

— Detroit attorney Linda M. Garbarino

NOI

Continued from page 1

drafts the NOI can't assume the reader "understands medical terms or has any understanding of basic principles of medicine, human anatomy and physiology and chemistry."

In *Miller*, William Miller died of a pulmonary embolism caused by a deep vein thrombosis that occurred after he had undergone a cervical diskectomy.

Nancy Miller, personal representative of William Miller's estate, served William Miller's doctors and the hospital with notice of her intent to sue, then filed a wrongful-death medical-malpractice lawsuit.

The defendants moved successfully for summary disposition alleging Miller's "proximate cause" statement in her NOI was insufficient and thus, her lawsuit should be dismissed as untimely because the statute of limitations had run.

Miller had alleged: "Had the standard of care been complied with in a timely and appropriate manner, William Miller's deep vein thrombosis would have been avoided and/or timely diagnosed and treated, thereby avoiding his demise from pulmonary embolism."

Miller appealed, but the Court of Appeals affirmed the trial court.

To reach its conclusion in *Miller*, the Court of Appeals' two-judge majority relied on the Supreme Court's 2004 and 2008 interpretations of the NOI statute in *Roberts v. Mecosta County General Hospital, et al. (Roberts II)* and *Boodt v. Borgess Medical Center, et al.*

In both cases, the Supreme Court struck NOIs because they didn't state with sufficient specificity how the alleged negligence "proximately caused" the plaintiffs' injuries.

And, in *Roberts*, the court coined the "obvious to a casual observer" standard for pleading specificity, albeit in reference to the NOI statute's standard of practice or care requirement.

While acknowledging the case law, Southfield attorney Robert B. Sickels of Sommers Schwartz P.C. said that, in practice, the "casual observer" standard may be a little off the mark.

Instead, he said, NOI drafters should be playing to the entities that ultimately will be deciding their NOIs' fates and, consequently, the fates of their clients' lawsuits: the courts.

The "connection between the failure to diagnose and treat common medical conditions and the claimed injury ... must be painstakingly articulated," Sickels said, "not for the benefit of the recipient of the NOI, who surely knows, but for the benefit of the court, solely and exclusively."

Bloomfield Hills attorney Julie McCann O'Connor of O'Connor De Grazia Tamm & O'Connor PC, who represents one of the defendants in *Miller*, disagreed.

She said drafters would be better off gauging the specificity of their NOI allegations on the "specific requirements of the NOI statute," rather than on what a "casual observer" or the courts might understand.

For example, McCann O'Connor said, when the issue is the statute's "proximate cause" requirement, practitioners should zero in on the Legislature's use of the word "manner."

"This seems to suggest that the parties must set forth a chain of causation, going step-by-step from the breach [of the standard of practice or care], and describing the medical consequences of the act or omission which eventually led to the injury," she said.

Detroit attorney Linda M. Garbarino of Tanoury Corbet Shaw Nauts & Essad PLLC, who also represents a *Miller* defendant, said practitioners should think of the "manner" language as establishing a "but for" standard for "proximate cause."

"[I]nclusion of the word 'manner' requires a description showing that 'but for' the health care provider's actions or inactions, the plaintiff's injury would not have occurred," she said.

McCann O'Connor said "manner" is "defined as a 'way of doing, being done or happening.'"

And *Black's Law Dictionary (6th Ed.)* defines "manner" as a "way, mode, method of doing anything ..."

According to MCL 600.2912b(4)(e), before medical-malpractice plaintiffs can sue, they must serve the doctors they intend to sue with notice, and the notice must state the "manner" in which the doctor's alleged malpractice proximately caused the plaintiff's injury.

Whether one focuses on the "casual observer," the courts or the statute, Troy attorney John J. Ramar of Ramar & Paradiso PC, who represents a *Miller* defendant, said the message from *Roberts*, *Boodt* and *Miller* is unmistakable.

The statute's "manner/proximate cause" requirement must be stated with "painstaking specificity in order to survive a challenge and withstand appellate scrutiny," he said.

Since *Roberts*, *Boodt* and *Miller* all fail to "define the 'minimal criteria,' and until the appellate court offers guidance on what is minimal sufficiency," Ramar said practitioners should err on the side of caution and throw in the kitchen sink.

"More is best," he said.

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The "connection between the failure to diagnose and treat common medical conditions and the claimed injury ... must be painstakingly articulated, not for the benefit of the recipient of the NOI, who surely knows, but for the benefit of the court, solely and exclusively."

— Southfield attorney Robert B. Sickels

Michigan's e-health overhaul:
Regulating use of the Internet in medical practice

Health Care Technology

By Maro E. Bush, Esq.

Maro E. Bush is an associate with Frank, Haron, Weiner and Navarro PLC. Her practice focuses on federal False Claims Act/qui tam litigation and the representation of physicians, health care professionals, home health agencies and other health care entities in a variety of areas relating to health law and regulations. Contact her at (248) 952-0400 or mbush@fhwnlaw.com.

E-health is a rapidly expanding health care delivery model with the potential to enhance accessibility to health care and save health providers and patients both money and time.

The use of such technologies as the Internet, e-mail and physician-sponsored Web sites provides physicians with unique opportunities to help and treat their patients.

However, health care providers must use caution when balancing the efficiency and cost benefits of e-health against the possible legal implications, such as the risk of a compromised physician-patient relationship or diminished patient privacy.

Defining e-health

Although there are varying definitions of e-health, it is helpful to begin thinking of it as the intersection of health care and technology.

E-health can encompass everything from passive Web sites disseminating medical information to wirelessly controlled Educated Doctor Guided Assisting Robots (EDGARs) capable of transmitting the virtual presence of a doctor, nurse or other consultant who might be thousands of miles away.

Using the Internet, teleconferencing and computerized medical records is just a fraction of the technology that is beginning to define the concept of e-health and modern health care.

There is often confusion over the appropriate terms to use when discussing e-health, possibly because of the interdisciplinary nature of the field.

E-health is an umbrella term used to encompass all practices related to the technologically facilitated delivery of health care. Telehealth refers to health monitoring at a distance, while telemedicine, the delivery of health care at a distance, is a subset of telehealth.

Cybermedicine, a more specific area of telemedicine, describes situations in which patients and health care providers communicate via electronic mail. Cybermedicine also encompasses e-prescribing, the use of automated data-entry systems to generate prescriptions electronically rather than on paper.

Successful e-health ventures

In 1995, the U.S. Department of Defense implemented the first wave of telemedicine technology to provide U.S. armed forces overseas with comprehensive telemedicine services.

Using a dedicated video link, doctors at a central hospital were able to share time-sensitive health information with a primary-care doctor thousands of miles away.

In that manner, military men and women were able to receive telemental, telepathology, and teledermatology health care services. Because of its capability, telemedicine has been said to provide "good medicine in bad places."

More recently, the U.S. Department of Veterans Affairs implemented the largest telehealth patient-monitoring system in the country.

More than 30,000 veterans are connected to their health care providers though telehealth devices that use modem technology to transmit data directly to the patient's electronic health records at the VA Medical Center.

The program has saved valuable hospital resources by reducing emergency room visits, unscheduled clinic appointments and in-patient hospital stays. The monitoring is expected to expand to 90,000 veterans in 2009.

In addition, the VA has launched an $18 million pilot program to address the growing population of Iraq war veterans suffering from post-traumatic stress disorder.

In Michigan, health care providers have been implementing aspects of e-health in their practices for over a decade.

One of the first large-scale efforts of that kind was the 2005 collaboration among Detroit's Henry Ford Health System, Health Alliance Plan and Medseek.

More than 300 primary care physicians, 577,000 patients and 24 medical centers participated in an e-prescribing program, which in the first year alone helped physicians avoid an estimated 6,500 allergic reactions in patients and saved more than $3.1 million in pharmacy costs by increasing generic drug use.

Another program involving virtual e-visit consultations between patients and their health care providers enabled more than 100,000 patients to obtain lab results, view health information, renew prescriptions and schedule follow up medical visits online.

Both programs demonstrate the potential to increase patient safety and satisfaction and greatly improve the quality of health care.

Potential legal pitfalls

While e-health can benefit both patients and physicians, it also raises a variety of legal issues for providers, including: preserving the integrity of the physician-patient relationship; the best mechanisms for securing confidentiality of private health information; and the importance of maintaining the duty of care a physician owes patients.

Michigan has been proactive in addressing e-health concerns. In 2005, the director of the Bureau of Health Professions of the Michigan Department of Community Health assembled a work group to examine the issues associated with the delivery of health care through the use of various technologies.

Specifically, the group reviewed e-health technologies, current federal and Michigan laws affecting the use of technology in health care, and the related positions and regulations of other states.

The result was the 2008 Report and Recommendations of the E-health Workgroup (available on the Michigan Department of Community Health Web site).

In June, the director gave approval for the Bureau of Health Professions to implement the major recommendations of the group's report. The three major recommendations include:

- Establishing a special purpose license for out-of-state physicians delivering health care to Michigan patients via e-health technology;
- Adopting the Federation of State Medical Boards' Model Guidelines for the Appropriate Use of the Internet in Medical Practice; and
- Drafting legislation to establish the National Association of Board of Pharmacy's Verified Internet Pharmacy Practice Standards (VIPPS) to protect Michigan citizens against unlawful Internet prescribing.

The Federation of State Medical Boards' Model Guidelines for the Use of the Internet in Medical Practice regulates the use of electronic mail and Web sites by physicians in medical practice.

The guidelines require doctors to conduct a documented, in-person patient evaluation, including history and physical exam, before providing treatment via the Internet and-or issuing electronic prescriptions.

In other words, treatment based solely on a questionnaire does not constitute an acceptable standard of care. Electronic treatment and consultation, including issuing of prescriptions via the Internet, are held to the same standard of appropriate practice as those in traditional face-to-face settings.

In addition, the guidelines encourage physicians to maintain written policies and procedures for the use of patient-physician electronic mail. Such policies and procedures should address: privacy; health-care personnel (in addition to the physician) who will process messages; hours of operation; types of transactions that will be permitted electronically; required patient information to be included in the communication; archives and retrievals; and quality-oversight mechanisms.

Sufficient security measures, such as firewalls, encryption and password protection must also be in place to assure the confidentiality and integrity of protected health information.

A written agreement documenting a patient's informed consent for the use of patient-physician electronic mail should be discussed with and signed by the patient. The medical record should both include the patient's informed consent and document all other patient-related electronic communications.

Physician medical practice sites are also regulated by the Federation of State Medical Boards' "Model Guidelines for the Use of the Internet in Medical Practice."

Physician medical practice sites are defined as Internet sites to which access is limited to licensed physicians, associated medical personnel and patients. A physician medical practice site is interactive and therefore qualifies as a practice location.

The Web page should clearly disclose the owner of the site, the specific services provided and the physician's contact information, licensure and qualifications. The site also should include the fees for online consultations and services, and how payment is to be made.

If the physician has a financial interest in any information, products or services advertised on the site, he or she must disclose that financial interest.

The site must disclose its appropriate uses and limitations, the estimated response times for patient e-mails, to whom patient health information may be disclosed, and the rights of patients with regard to patient health information.

In addition, a physician medical practice site should provide patients with a clear mechanism to access, supplement and amend patient-provided personal health information. It also should allow patients to provide feedback regarding the site and the quality of information and services.

The site must also contain information on how a patient can issue a complaint both to the physician operating the site and to the applicable state medical boards.

Finally, the advertising or promotion of goods or products from which the physician receives direct remuneration, benefits, or incentives is prohibited on a physician's medical practice site.

Michigan's newly adopted e-health regulations should be strictly adhered to in order to ensure compliance in this developing field.

Health care providers must use caution when implementing e-health technology in their practice, and may ultimately benefit from consulting with an attorney to help navigate the waters of e-health in Michigan.

That way, health care providers can ensure that they, and their patients, receive all the benefits of e-health while avoiding any legal pitfalls.

Get ready — Recovery Audit Contractors are coming to Michigan

Medicare providers and suppliers nationwide soon can expect to see increased scrutiny of Medicare claims.

The Centers for Medicare and Medicaid Services (CMS, or Medicare) Recovery Audit Contractor (RAC) program has been made permanent and is now expanding nationwide.

Medicare providers and suppliers in Michigan, who will be some of the first to go through RAC audits and claim denials under this permanent program, need guidance on and explanations of the RAC program.

Medicare Update

By Andrew B. Wachler, Esq., Abby Pendleton, Esq., and Jessica L. Gustafson, Esq.

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Recovery Audit Contractors

Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) required the Secretary of the Department of Health and Human Services (HHS) to conduct a three-year demonstration program to determine whether the use of RACs would be a cost-effective way to identify and correct improper Medicare payments.

The RAC demonstration program began in 2005 in the three states with the highest Medicare expenditures: California, Florida and New York. In 2007, the program expanded to include Arizona, South Carolina and Massachusetts.

The RACs were private companies tasked to identify and recoup Medicare overpayments and to identify underpayments. They were paid a contingency fee based upon the principal amount collected from and/or returned to the provider or supplier.

The RAC demonstration program concluded March 27 this year. The demonstration proved highly "cost-effective" from the point of view of CMS.

Throughout the three-year demonstration program, the RACs identified and collected more than $1.03 billion in improper payments. CMS estimates that the program cost approximately 20 cents for each dollar returned to the Medicare Trust Funds.

Section 302 of the Tax Relief and Health Care Act of 2006 made the RAC program permanent and required its expansion nationwide by no later than 2010, but CMS already is expanding the program nationally.

According to its most-recently published "Expansion Schedule," CMS planned to expand to 19 states, including Michigan, by Oct. 1 of this year, four more states by March 1, 2009, and the remaining states by Aug. 1, 2009, or later.

On Oct. 6, CMS announced the RAC vendors for the permanent program and identified the initial states for which each will be responsible. The RAC vendor assigned to Michigan is CGI Technologies and Solutions, Inc. of Fairfax, Va.

Before the RACs begin auditing in the permanent program, they will have outreach meetings to meet with representatives from CMS and with providers and suppliers.

In Michigan, this outreach was to take place on Nov. 6, with a presentation to the Michigan Health and Hospital Association. However, due to protests initiated by two companies that unsuccessfully bid to become RACs for the permanent program, all RAC activity (including outreach meetings) has been delayed, possibly until February 2009.

However, soon after decisions are rendered on the protests and the outreach meetings are completed, Michigan Medicare providers and suppliers can expect to receive requests for medical records and/or overpayment demand letters from the RACs.

The RAC review process

Although the RACs are tasked to identify all types of improper payments (i.e., underpayments and overpayments), it is the process of identifying and recouping alleged overpayments that is of particular significance to Medicare providers.

RACs are permitted to attempt to identify improper payments resulting from incorrect payments, non-covered services (including services denied as not medically necessary), incorrectly coded services (including DRG miscoding), and duplicate services.

RACs are prohibited from selecting claims at random to review. Instead, RACs use proprietary "data analysis techniques" to determine claims likely to contain overpayments, a process known as "targeted review."

RACs engage in two types of claim reviews to identify improper payments, automated review and complex review.

An automated review is a review of claims data without a review of the records supporting the claim. A complex review is a review of medical or other records, and is used in situations in which there is a high probability (but not a certainty) that a claim includes an overpayment.

In summary, the RAC complex-review process is as follows:

- The RAC will either visit the provider's location to view and/or copy medical records necessary for its review; or request that the provider mail, fax, or otherwise securely transmit the records to the RAC. During the RAC demonstration program, some providers felt burdened by the volume of records requests received from the RACs. To address this concern, CMS has imposed limits on the number of records RACs may request per 45-day period in the RAC permanent program.

Despite such limits, providers still may find it challenging to timely respond to the volume of records requests received.

Significantly, however, if a RAC does not receive requested medical records within 45 days, it is authorized to render an overpayment determination with respect to the underlying claim.

If the provider or supplier appeals such a denial, Medicare is not required to reopen the claim and consider the appeal.

Thus, providers failing to timely respond to RACs' medical records requests could lose appeal rights with respect to these claims.

- Once the requested medical records are received, the RAC will review the claim. In conducting reviews, RACs are required to comply with National Coverage Decisions (NCDs), Coverage Provisions in Interpretive Manuals, national coverage and coding articles, Local Coverage Decisions (LCDs), and local coverage and coding articles in their respective jurisdictions.
- Generally, a RAC must complete complex reviews within 60 days from receipt of the requested medical records. Following its review, the RAC will issue a letter to the provider setting forth the findings for each claim and notifying the provider of its appeal rights.

Alleged overpayments identified by RACs may be appealed through the uniform Medicare appeals process.

RAC planning and compliance

Although providers and suppliers cannot stop RAC audits from happening, they can enact systems for tracking record requests and timely responding, implement appropriate compliance programs, and make efforts to understand available audit defenses.

Specifically, Medicare providers and suppliers should enact systems to address the following:

- Responding to record requests within the required timeframes;
- Internally monitoring protocols to better identify and monitor areas that may be subject to review;
- Implementing compliance efforts, including, but not limited to, documentation and coding education; and
- Properly working up appeals to challenge denials in the appeals process.

Although it cannot be predicted with certainty the areas that will be subject to review during the permanent RAC program, the Office of Inspector General (OIG) publishes an annual Work Plan document that sets forth projects the OIG plans to address during the upcoming fiscal year, including areas of planned audit activity.

In addition, reviewing the types of denials made during the RAC demonstration program is a helpful tool for Medicare providers and suppliers to identify potential target areas for the RACs operating in the permanent program.

During the RAC demonstration program:

- The vast majority (85 percent) of claim denials involved inpatient hospital claims;
- Six percent of claim denials involved inpatient rehabilitation facility (IRF) services;
- Four percent of claim denials involved outpatient hospitals;
- The remaining denials involved the claims of physicians, skilled nursing facilities, durable medical equipment suppliers and ambulance, laboratory or other providers.

Medicare providers and suppliers can expect similar audit activity during the RAC permanent program. In addition, on Oct. 6, CMS announced its plan to focus its upcoming review activities on home health agencies (which were exempt from the RAC demonstration program) and durable medical equipment suppliers in Michigan specifically.

Of the denials made by RACs during the demonstration program:

- 35 percent of the improper payments identified were the result of incorrect coding;
- 40 percent were denied because the claims did not meet Medicare's medical necessity criteria;
- 8 percent were denied for the reason, "no/insufficient documentation," meaning the RAC requested the information, but the entity did not respond timely or completely; and
- 17 percent were denied for "other" reasons, including that claims were paid based upon outdated fee schedules, duplicate claims, etc.

Medicare providers and suppliers are advised to adopt and implement compliance policies and procedures to address these and other areas of Medicare scrutiny now, before the RACs begin auditing in the permanent program.

Strategies for successfully appealing claim denials

If a Medicare provider or supplier receives a claim denial, or a finding of overpayment is made as a result of a RAC review, this denial will be subject to the uniform Medicare Part A and Part B appeals process. The five-stage appeals process is as follows:

- Redetermination
- Reconsideration
- Administrative Law Judge (ALJ) hearing
- Medicare Appeals Council (MAC) review
- Federal district court review

Medicare providers and suppliers subject to RAC or other Medicare audits and claim denials should understand that many strategies can be employed in the appeals process to effectuate successful results. These strategies involve effectively advocating the merits of the underlying claim and employing legal defenses.

When advocating the merits of a claim, it is useful to draft a position paper outlining the factual and legal arguments in support of payment for a disputed claim.

Other strategies that can prove successful include the use of medical summaries, illustrations, and color-coded charts or graphs depicting the claims at issue. Such presentations should be user-friendly for the decision maker.

Additionally, in most cases, it is advantageous to engage the services of a qualified expert, particularly when an audit or claim denial involves issues of medical necessity.

In addition to advocating the merits of a claim through various techniques, providers and suppliers should be aware that certain legal defenses are available. A qualified health care attorney can assist Medicare providers and suppliers in navigating the Medicare appeals process and successfully applying appropriate legal defenses.

Michigan Medicare providers and suppliers should prepare now for increased Medicare scrutiny as the RAC program expands into Michigan. Providers and suppliers should act now to evaluate their compliance with Medicare policies and guidelines.

Should a Medicare provider or supplier be subject to a RAC or other Medicare audit, effective strategies are available that can be successfully employed in the appeals process to challenge denied claims.

Verdicts & Settlements

VERDICTS FOR DOCTORS

Lost opportunity to survive not proven in case

Plaintiff's expert doesn't offer specific, quantifiable percentage for med-mal

Therel B. Kuzma, the plaintiff's decedent, was a 70-year-old woman referred to defendant John D. Koziarski, M.D, for repair of a recurrent incisional hernia. She had a history of diabetes, COPD, chronic anemia and smoking, and a surgical history that included arterial grafting, triple bypass, appendectomy, hysterectomy and oophorectomy. Kuzma also had myelodysplastic syndrome, a bone marrow disorder that inhibited her ability to create white blood cells.

After consultation and explanation of the treatment options and their risks, Kuzma chose the laparoscopic approach. The surgery was performed Oct. 3, 2000, and she was discharged later that day in stable condition.

Two days later, Kuzma returned with complaints of nausea, vomiting and increased pain. An exploratory laparoscopy was performed, which revealed an 8 mm hole in the small bowel. The laparoscopy was converted to open surgery, and the bowel was repaired.

Kuzma's condition improved briefly but then continued to deteriorate. On Oct. 20, 2000, she was transferred to Borgess Hospital where further surgery was performed, but Kuzma died nine days later.

The plaintiff's complaint alleged a single theory: Koziarski should have performed an open surgical procedure, rather than laparoscopic, to repair the hernia. Plaintiff's expert agreed that a bowel perforation is a known complication, and there were no claims of negligence with respect to the laparoscopic repair. The expert also argued that given the surgical history of the decedent, Koziarski should have anticipated that a bowel perforation could prove fatal.

However, plaintiff's expert testified at deposition that the risk of bowel perforation was essentially the same for an open procedure versus a closed one (about 5 percent), yet plaintiff's counsel took the position that the decedent had a 100 percent chance to survive if a puncture happened and the procedure was done open, and no chance of survival if done closed.

The defense replied that one cannot skip past the complication when making the calculation; without the puncture, the decedent had a 100 percent chance to survive if it was done laparoscopically. Plaintiff's expert agreed that the chance of a puncture laparoscopically was small.

The judge reviewed the law on record and concluded that it was not enough for the plaintiff's expert to testify that it is probable the patient would have lived had the procedure been open. He noted that the cases all referenced a specific, quantifiable percentage to be utilized in calculating the lost opportunity. In his trial testimony, the plaintiff's expert did not include sufficient testimony to satisfy MCL 600.2912a(2), which provided that the plaintiff cannot recover for a loss of opportunity to survive unless the opportunity was greater than 50 percent.

Type of action: Medical malpractice, wrongful death
Type of injuries: Death
Name of case: *Estate of Therel B. Kuzma v. John D. Koziarski, M.D., et al.*
Court/Case no./Date: Calhoun County Circuit Court; 03-1783-NH; Aug. 21, 2008
Tried before: Jury
Name of judge: James C. Kingsley
Verdict amount: No cause of action
Most helpful experts: David E. Scheeres, M.D., Grand Rapids; Daniel K. Borreson, M.D., Grand Rapids; Stanley Sherman, M.D., West Bloomfield Township
Insurance carrier: American Physicians Assurance Corporation
Attorney for plaintiff: Withheld
Attorney for defendant: Brian W. Whitelaw, John R. LaParl

Surgeries, including coccyx removal, argued

Cause of rectal mass, fistula too uncertain, defense contends

Plaintiff Michael Olson, then 45 years old, was working for the State of Michigan as a deputy warden. In 1995, Dr. Mark I. Menning performed surgery on Olson to treat a rectal abscess and rectal fistula.


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On April 1, 2004, he returned to Menning complaining of flattening stools. He was diagnosed with hemorrhoids. On May 4, 2006, Olson returned, describing his situation as severe constipation and "noodlelike" stools.

A mass was diagnosed, and after various diagnostic tests, Menning performed surgery on June 4, 2006, using the posterior approach to remove the mass. It required the removal of the coccyx, the triangular bone at the lower end of the vertebral column.

Subsequently, Olson developed a fistula that required two additional surgeries and approximately one year to heal.

Olson argued that Menning failed to remove the fistula tract during the 1995 procedure. Knowing the tract existed, Menning should have suspected an abscess in 2004 and then again in 2006, the plaintiff argued. Further, in 2006, a simple abscess draining, and not the posterior approach, should have been performed.

The defense argued that the correct approach was used, given the uncertainty of the cause of the mass. Also, the defense contended, the 2006 fistula developed subsequently because of the mass that was diagnosed in 2006, and was not the one that was present in 1995.

The jury agreed, and came up with a no cause of action verdict.

Type of action: Medical malpractice
Type of injuries: Unneeded surgery resulting in removal of coccyx, two additional surgeries, residual pain and numbness for surgical site
Name of case: *Olson, et al., v. Menning, et al.*
Court/Case no./Date: Ingham County Circuit Court; 06-1514-NH; Oct. 14, 2008
Tried before: Jury
Name of judge: Joyce A. Draganchuk
Demand: $2.15 million
Verdict amount: No cause of action
Most helpful experts: Robert K. Cleary, M.D., Ypsilanti; Daniel K. Borreson, M.D., Grand Rapids
Insurance carrier: American Physicians
Attorney for plaintiff: Withheld
Attorney for defendant: Michael W. Stephenson

VERDICTS AGAINST DOCTORS

Slow to diagnose woman's bowel perforation

Septic shock, renal and respiratory failure follow elective hysterectomy

Plaintiff Evangeline Hall underwent an elective hysterectomy at Oaklawn Hospital in Marshall. The surgery was performed by gynecologist Neysa Bartlett, D.O. Post-operatively, Hall suffered continual deterioration with abdominal distention, severe pain, extreme bandemia and progressive hypovolemia. All of her problems, however, were written off by the attending health care providers as "post-op ileus."

On the second post-op day, Bartlett ordered four different cathartic medications, but they only made Hall's conditions worse. Indications of renal failure and hypovolemia were detected, and although Bartlett was contacted at least 14 times by Oakland nurses, no significant changes in Hall's management occurred beside continued administration of bowel stimulants.

Bartlett finally suspected a bowel injury on the third post-op day and told Hall she may have to go back into surgery. However, a general surgery consult was requested, with the general surgeon diagnosing Hall's condition as simply post-op ileus. Within hours, Hall deteriorated into respiratory and renal failure and septic shock. A second surgeon promptly diagnosed an "abdominal catastrophe" and took Hall back to surgery. A bowel perforation was found and 2 liters of waste were removed.

Hall remained in respiratory failure and suffered a prolonged course on a ventilator that eventually required a tracheostomy. Her abdomen remained split open and had to heal via secondary intention, leaving her with massive disfigurement. Multiple follow-up operations were required for complete reconstruction of her abdominal wall. Hall attempted to return to work on three separate occasions and ultimately went on long-term disability.

The defendants maintained that bowel perforations were a recognized risk of hysterectomy; that Hall's condition was consistent with a post-op ileus, not intra-abdominal sepsis from perforation; that the cathartics used were appropriate and did not affect Hall's condition; that once intra-abdominal sepsis started, it couldn't be stopped; and that the nurses continually reported Hall's condition to her attending doctors and no chain of command was necessary.

However, defense experts could not agree on the mechanism of the injury to the bowel, as some said it stemmed from electrocautery and others said it was due to cutting or impingement.

After a five-week trial, the jury reached a $3.535 million verdict for Hall, finding Bartlett 85 percent liable for medical malpractice and Oaklawn 15 percent liable for nursing negligence. Application of damage caps reduced the verdict to $1.276 million.

Type of action: Medical malpractice
Type of injuries: Bowel perforation leading to septic shock, respiratory/renal failure, ventilator dependence, disfigurement, disability
Name of case: *Hall v. Bartlett, et al.*
Court/Case no./Date: Calhoun County Circuit Court; 06-2001-NH; Oct. 6, 2008
Tried before: Jury
Name of judge: James C. Kingsley
Verdict amount: $1,276,519.22
Most helpful experts: Arnold Sperling, M.D., Boston; Brendan Carroll, M.D., Los Angeles; Patricia Waldron, R.N., Eureka, Calif.; Grace McCallum, R.N., Detroit
Attorney for plaintiff: Stephen Goethel
Attorney for defendant: Withheld

SETTLEMENTS

Conflicting due dates at issue in med-mal case

Mother's non-compliancy wasn't all completely to blame, plaintiffs argue

The plaintiff-mother, who was pregnant for the first time, was treated prenatally at a family practice prenatal clinic. She was a non-compliant patient and did not attend her first prenatal visit until 21 weeks' gestation.

On this visit, a last menstrual period (LMP) of Feb. 6, 2001, was given, and an estimated due date, or estimated date of confinement (EDC), of Nov. 15, 2001, was documented. Plaintiff-mother then failed to return to the next three visits and also failed to obtain an ultrasound as ordered. She finally returned for prenatal care at approximately 33 weeks. Because of patient non-compliance, her care was transferred to an OB/GYN clinic within the same network.

She then began OB/GYN care and an ultrasound was performed a week after her care was transferred. The third-trimester ultrasound gave an EDC of Dec. 12, 2001, which was different from the first clinic's EDC.

The admitting nurse and OB/GYN who saw the plaintiff-mother claimed information gained directly from the plaintiff-mother regarding her LMP was consistent with the ultrasound's EDC, rather than the EDC recorded at the first clinic. As such, they documented the new EDC of Dec. 12.

Plaintiff continued to treat at the OB/GYN clinic through Dec. 6, 2001. The OB/GYN ordered twice-weekly non-stress testing through delivery because of non-compliance issues. Plaintiff went for the first three non-stress tests, but missed the remaining tests.

On Dec. 12, 2001, the plaintiff presented to the defendant hospital. Plaintiff-minor was delivered within 74 minutes by stat C-section. Upon delivery, he had low Apgar scores, was floppy and blue, and demonstrated no respiratory effort. His heart rate was 20 to 40 beats per minute, but cord blood gases were normal. A follow-up blood gas performed 45 minutes later showed some metabolic acidosis, although the pH was normal.

Plaintiff-minor suffers from cognitive delays and deficits, and cerebral palsy.

The plaintiffs asserted that delivery should have occurred at least a week earlier using the original LMP from the first clinic. The defendants, it was further argued, should not have changed the LMP based on a third-trimester ultrasound and history allegedly given by the plaintiff-mother. It was further argued that the defendants should have ordered serial fetal well-being testing to assure fetal status because of the difference in expected due dates; and the delivery should have occurred more quickly on Dec. 12, 2001, due to fetal distress.

Also, though the plaintiff-mother was admittedly non-compliant, it was argued that the defendants should have had an office tracking system, as recommended by the American College of Obstetricians and Gynecologists (ACOG), for following up with non-compliant patients who miss appointments. The first clinic, the plaintiffs said, had a tracking system.

The defendants' position was that injury occurred during the prenatal period as a result of decreased perfusion of oxygen to the fetus partly because of plaintiff-mother's smoking during the pregnancy. In addition, the defendants claimed plaintiff-minor had a genetic condition called Angelman's syndrome. Therefore, sooner delivery would not have made a difference in the outcome. Also, the normal cord blood gas proved that this was not a birth injury.

Through mediation, the case settled for $975,000.


REITER


SABATINI

Type of action: Medical malpractice, birth trauma
Type of injuries: Brain injury resulting in cerebral palsy, cognitive deficits and delays
Name of case: *Confidential*
Court/Case no./Date: Confidential; confidential; Sept. 25, 2008
Tried before: Mediation
Name of judge: Withheld
Settlement amount: $975,000
Most helpful experts: InFocus Research Group, Shelby Township
Attorney for plaintiff: Jesse M. Reiter, Juliana B. Sabatini
Attorney for defendant: Withheld
Key to winning: Focus group utilization early in discovery

Send A Letter To The Editor

Lawyers Weekly accepts letters on subjects of interest to the Michigan medical community. Letters should be typed. Lawyers Weekly reserves the right to reject any letter submitted for publication and to edit those accepted for publication. Letters should be addressed to: Michigan Medical Law Report, 31440 Northwestern Hwy, Suite 170, Farmington Hills, MI 48334

Criminal background check mandatory now for initial licensure, registration of Michigan health care professionals

A newly enforced law in Michigan requires that all health care professionals undergo criminal background checks as part of their initial application for licensure or registration.

Public Act 26 of 2006, which took effect Oct. 1 this year, requires all new applicants to have their fingerprints taken by the Michigan State Police, who then do a statewide criminal check of the applicant.

The state then must forward the fingerprints to the Federal Bureau of Investigation for a national criminal-history check.

Such a required background check is not unique to the state's health care professionals. For example, the State Bar of Michigan long has required that attorney applicants undergo a similar screening process, and the Michigan "School Safety" law passed in 2005 provides that all potential employees of public or private schools be fingerprinted and undergo a criminal background check prior to hire.

Effective Jan. 1, 2009, all mortgage loan officers, such as people employed by brokers or lenders, also must complete criminal background checks.

Forms for health care professionals are provided by the Michigan Department of Community Health and are available on the state of Michigan Web site.

Licenses are required of the following health professions: audiologist; chiropractor; counselor (defined as the rendering of a service involving the application of clinical counseling principles to achieve social, personal, career and emotional development); dentist, hygienist, dental assistant; EMS personnel; marriage and family therapist; medical doctor; nurse, including registered (RN) and licensed practical (LPN).

Also, licenses are required of: nursing home administrator; occupational therapist and occupational therapist assistant; optometrist; osteopathic physician (DO); pharmacist; physical therapist (note that physical therapy assistants are not required to be licensed by the State, but many insurers require that they complete training courses before their services will be paid for); physician's assistant; podiatrist; psychologist; respiratory care; sanitarian (defined as "an individual who has specialized education and experience in the physical, biological, and sanitary sciences as applied to the educational, investigational and technical duties in the field of environmental health"); social worker; veterinarian or veterinarian technician.

The results of both the statewide check and the national check are included in a report of findings sent to the Michigan Department of Community Health, Bureau of Health Professions.

That report can be used only for the purpose of determining whether any disclosures have a bearing on the qualifications of the applicant for the licensure or registration being sought. For the protection of the applicant, the following restrictions are made part of the law:

- "The report cannot be used for any purpose other than in acting on the application;
- "Members of the state Board considering the application are precluded from disclosing or otherwise sharing the content of the report with any person or entity that is not directly involved in evaluation of the application and the applicant, and;
- "Other than for law enforcement purposes, the report and other information attendant to the making, receiving and evaluation of this report are not subject to and cannot be obtained by any person under the freedom of information (FOIA) laws of the State of Michigan."

It is important to note that the fingerprinting and criminal-background check are only part of the process followed when an initial application for licensure or registration is being considered and evaluated.

By statute, the board may, and is likely to, determine and consider whether there have been any licensing or specialty-certification issues in other states; and, whether, in any health-law field of endeavor, there has ever been any revocation or suspension of license, including the license's current status.

Public Act 26 of 2006, which took effect Oct. 1 this year, requires all new applicants to have their fingerprints taken by the Michigan State Police, who then do a statewide criminal check of the applicant.

Health Care Justice

By J. Laevin Weiner, Esq.

J. Laevin Weiner is a principal at Frank, Haron, Weiner and Navarro, PLC. His practice is concentrated in the areas of business and real estate transactions, financial planning, health law and complex litigation in those areas. Contact him at (248) 952-0400 or jweiner@fhwnlaw.com.

Pending Legislation

Michigan Medical Legislation Report

Following is a list of bills pending in the Michigan Legislature related to health care and health care professionals. Detailed information and analysis on this and other pending legislation can be found at www.michiganlegislature.org.

HOUSE BILLS

• **HB 6419** — Education and Training Requirements for Utilization of Surgical Technologists

"A hospital, freestanding surgical outpatient facility, or any other similar entity that utilizes surgical technologists shall not employ, independently contract with, or grant clinical privileges to an individual as a surgical technologist unless that individual satisfies one of the following:

"(a) Has successfully completed an accredited education program for surgical technologist and holds and maintains the national certification established by the national board of surgical technology and surgical assisting for the surgical technologist.

"(b) Has completed an appropriate training program for surgical technology in the United States Army, Air Force, Marine Corps, or Coast Guard or in the United States public health service.

"[This] does not apply to an individual who is employed by or under contract with the federal government or who, on the effective date of this section, is employed by or under contract with a hospital, freestanding surgical outpatient facility, or other entity and has been employed by or under contract with that entity for not less than 18 months over the course of the three years immediately preceding the effective date of this section."

Sponsor: John Stakoe

Status: Referred to Committee on Health Policy

• **HB 6529** — Requirement for Background Criminal History Check for Emergency Medical Services, and Clarify That It is Not Required for Certain Emergency Medical Students

"A health facility or agency that is a nursing home, county medical care facility, hospice, hospital that provides swing bed services, home for the aged, or home health agency shall not employ, independently contract with, or grant clinical privileges to an individual who regularly has direct access to or provides direct services to patients or residents in the health facility or agency after April 1, 2006, if the individual satisfies 1 or more of the following:

"(a) Has been convicted of a relevant crime described under 42 USC 1320a-7.

"(b) Has been convicted of any of the following felonies, an attempt or conspiracy to commit any of those felonies, or any other state or federal crime that is similar to the felonies described in this subdivision, other than a felony for a relevant crime described under 42 USC 1320a-7, unless 15 years have lapsed since the individual completed all of the terms and conditions of his or her sentencing, parole, and probation for that conviction prior to the date of application for employment or clinical privileges or the date of the execution of the independent contract:

"(i) A felony that involves the intent to cause death or serious impairment of a body function, that results in death or serious impairment of a body function, that involves the use of force or violence, or that involves the threat of the use of force or violence.

"(ii) A felony involving cruelty or torture.

"(iii) A felony under chapter XXA of the Michigan penal code, 1931 PA 328, MCL 750.145m to 750.145r.

"(iv) A felony involving criminal sexual conduct.

"(v) A felony involving abuse or neglect.

"(vi) A felony involving the use of a firearm or dangerous weapon.

"(vii) A felony involving the diversion or adulteration of a prescription drug or other medications.

"(c) Has been convicted of a felony or an attempt or conspiracy to commit a felony, other than a felony for a relevant crime described under 42 USC 1320a-7 or a felony described under subdivision (b), unless 10 years have lapsed since the individual completed all of the terms and conditions of his or her sentencing, parole, and probation for that conviction prior to the date of application for employment or clinical privileges or the date of the execution of the independent contract.

"(d) Has been convicted of any of the following misdemeanors, other than a misdemeanor for a relevant crime described under 42 USC 1320a-7, or a state or federal crime that is substantially similar to the misdemeanors described in this subdivision, within the 10 years immediately preceding the date of application for employment or clinical privileges or the date of the execution of the independent contract:

"(i) A misdemeanor involving the use of a firearm or dangerous weapon with the intent to injure, the use of a firearm or dangerous weapon that results in a personal injury, or a misdemeanor involving the use of force or violence or the threat of the use of force or violence.

"(ii) A misdemeanor under chapter XXA of the Michigan penal code, 1931 PA 328, MCL 750.145m to 750.145r.

"(iii) A misdemeanor involving criminal sexual conduct.

"(iv) A misdemeanor involving cruelty or torture unless otherwise provided under subdivision (e).

"(v) A misdemeanor involving abuse or neglect.

"(e) Has been convicted of any of the following misdemeanors, other than a misdemeanor for a relevant crime described under 42 USC 1320a-7, or a state or federal crime that is substantially similar to the misdemeanors described in this subdivision, within the 5 years immediately preceding the date of application for employment or clinical privileges or the date of the execution of the independent contract:

"(i) A misdemeanor involving cruelty if committed by an individual who is less than 16 years of age.

"(ii) A misdemeanor involving home invasion.

"(iii) A misdemeanor involving embezzlement.

"(iv) A misdemeanor involving negligent homicide.

"(v) A misdemeanor involving larceny unless otherwise provided under subdivision (g).

"(vi) A misdemeanor of retail fraud in the second degree unless otherwise provided under subdivision (g).

"(vii) Any other misdemeanor involving assault, fraud, theft, or the possession or delivery of a controlled substance unless otherwise provided under subdivision (d), (f), or (g).

"(f) Has been convicted of any of the following misdemeanors, other than a misdemeanor for a relevant crime described under 42 USC 1320a-7, or a state or federal crime that is substantially similar to the misdemeanors described in this subdivision, within the three years immediately preceding the date of application for employment or clinical privileges or the date of the execution of the independent contract:

"(i) A misdemeanor for assault if there was no use of a firearm or dangerous weapon and no intent to commit murder or inflict great bodily injury.

"(ii) A misdemeanor of retail fraud in the third degree unless otherwise provided under subdivision (g).

"(iii) A misdemeanor under part 74 unless otherwise provided under subdivision (g).

"(g) Has been convicted of any of the following misdemeanors, other than a misdemeanor for a relevant crime described under 42 USC 1320a-7, or a state or federal crime that is substantially similar to the misdemeanors described in this subdivision, within the year immediately preceding the date of application for employment or clinical privileges or the date of the execution of the independent contract:

"(i) A misdemeanor under part 74 if the individual, at the time of conviction, is under the age of 18.

"(ii) A misdemeanor for larceny or retail fraud in the second or third degree if the individual, at the time of conviction, is under the age of 16.

"(h) Is the subject of an order or disposition under § 16b of chapter IX of the code of criminal procedure, 1927 PA 175, MCL 769.16b.

"(i) Has been the subject of a substantiated finding of neglect, abuse, or misappropriation of property by a state or federal agency pursuant to an investigation conducted in accordance with 42 USC 1395i-3 or 1396r."

Sponsor: Paul Opsommer

Status: Referred to Committee on Health Policy

• **HB 6708** — Definition of Human Egg, Clarify as Human Tissue and Prohibit Sale of Human Egg

"A person shall not knowingly acquire, receive, or otherwise transfer a human organ or part of a human organ for valuable consideration for any purpose, including, but not limited to, transplantation, implantation, infusion, injection, or other medical or scientific purpose. A person who violates this subsection is guilty of a felony.

"[This subsection] does not prohibit one or more of the following practices:

"(a) The removal and use of a human cornea pursuant to § 10202, or the removal and use of a human pituitary gland pursuant to § 2855.

"(b) An anatomical gift pursuant to part 101, or the acquisition or distribution of bodies or parts by the department pursuant to §§ 2652 to 2663.

"(c) Financial assistance payments provided under a plan of insurance or other health care coverage.

"Except as otherwise provided in part 101, only an individual who is 1 of the following may surgically remove a human organ for transplantation, implantation, infusion, injection, or any other medical or scientific purpose:

"(a) A physician licensed under article 15.

"(b) An individual acting under the delegatory authority and supervision of a physician pursuant to § 16215(2), but not including an individual whose license has been suspended under article 15. This subdivision includes, but is not limited to, an individual described in § 16215(3).

"(c) For the purposes of surgically removing a human organ that is an eye or a physical part of an eye only, an individual certified by a state medical school as described in § 10105.

"(d) An individual residing in another state and authorized to practice allopathic medicine or osteopathic medicine and surgery in that state who is called into this state by a physician licensed under article 15 and is authorized by a hospital licensed under article 17 to surgically remove 1 or more of the following organs for transport back to the other state:

"(i) A heart.

"(ii) A liver.

"(iii) A lung.

"(iv) A pancreas.

"(v) A kidney.

"(vi) All or part of an intestine.

"(vii) Any other human organ specified by rule promulgated by the department under subsection (6)."

Sponsor: Judy Emmons

Status: Referred to Committee on Health Policy

SENATE BILLS

• **SB 1500** — Recovery for Negligence of an Emergency Room Doctor, and Required Showing of Gross Negligence

"(1) A licensed health care professional or a licensed health facility or agency is not liable in an action based on medical malpractice arising out of the provision of emergency medical care in an emergency department or obstetrical unit located in and operated by a hospital, or in a surgical operating room, cardiac catheterization laboratory, or radiology department immediately following the evaluation or treatment of the patient in an emergency department, unless the plaintiff proves by clear and convincing evidence that the licensed health care professional's actions constituted gross negligence.

"(2) In an action described in subsection (1), the court shall instruct the jury to consider, in addition to all other relevant matters, all of the following:

"(a) Whether the person providing care had the patient's full medical history, including knowledge of preexisting medical conditions, allergies, and medications.

"(b) Whether there was a preexisting licensed health care professional-patient relationship.

"(c) The circumstances that constituted the emergency.

"(d) The circumstances surrounding the delivery of the emergency medical care."

Sponsor: Wayne Kuipers

Status: Referred to Committee on Judiciary

• **SB 1538** — Prohibit and Provide Penalties for Sale of Products Containing Dextromethorphan to Individuals Under 18 Years of Age

"(1) A person who possesses nonprescription cough or cold medicine that contains dextromethorphan for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78, shall not sell that product to an individual under 18 years of age. This section does not apply to a prescription cough and cold medicine that contains dextromethorphan. As used in this section, 'dextromethorphan' means dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts.

"(2) It is an affirmative defense to a citation issued under subsection (1) that the defendant had in force at the time of the citation and continues to have in force a written policy for employees to prevent the sale of nonprescription cough or cold medicine that contains dextromethorphan to persons under 18 years of age and that the defendant enforced and continues to enforce the policy. A defendant who proposes to offer evidence of the affirmative defense described in this subsection shall file and serve notice of the defense, in writing,

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Contact information for state senators can be found at http://senate.michigan.gov.

Contact information for state house representatives can be found at http://house.michigan.gov.

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Pending Legislation
Continued

upon the court and the prosecuting attorney. The notice shall be served not less than 14 days before the hearing date.

"(3) A prosecuting attorney who proposes to offer testimony to rebut the affirmative defense described in subsection (2) shall file and serve a notice of rebuttal, in writing, upon the court and the defendant. The notice shall be served not less than 7 days before the hearing date and shall contain the name and address of each rebuttal witness.

"(4) A person who violates or aids or abets another in a violation of this section is responsible for a state civil infraction as provided under chapter 88 of the revised judicature act of 1961, 1961 PA 236, MCL 600.8801 to 600.8835, and may be ordered to pay a civil fine as follows:

"(a) For the first offense, a civil fine of not more than $1,000.

"(b) For the second offense, a civil fine of not more than $2,000.

"(c) For the third or subsequent offense, a civil fine of not more than $5,000."

Sponsor: Mark Schauer

Status: Referred to Committee on Health Policy

• **SB 1622** — Liability for False or Fraudulent Claims to the Medicaid Program

"(1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false.

"(2) A person shall not make or present or cause to be made or presented a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, that he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards. Each claim violating this subsection is a separate offense. A health facility or agency is not be liable under this subsection unless the health facility or agency, according to a conspiracy, combination, or collusion with a physician or other provider, falsely represents the medical necessity of the particular goods or services for which the claim was made.

"(3) A person shall not knowingly make, use, or cause to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act.

"(4) A person who violates this section is guilty of a felony punishable by imprisonment for not more than 4 years, a fine of not more than $50,000, or both."

Sponsor: Ron Jelinek

Status: Referred to Committee on Judiciary

• **SB 1623** — Clarify a Domestic Stock Insurer Owned by Health Care Corporation's Ability to Own Subsidiaries

"(1) A health care corporation, subject to any limitation provided in this act, in any other statute of this state, or in its articles of incorporation, may do any or all of the following:

"(a) Contract to provide computer services and other administrative consulting services to 1 or more providers or groups of providers, if the services are primarily designed to result in cost savings to subscribers.

"(b) Engage in experimental health care projects to explore more efficient and economical means of implementing the corporation's programs, or the corporation's goals as prescribed in § 504 and the purposes of this act, to develop incentives to promote alternative methods and alternative providers, including nurse midwives, nurse anesthetists, and nurse practitioners, for delivering health care, including preventive care and home health care.

"(c) For the purpose of providing health care services to employees of this state, the United States, or an agency, instrumentality, or political subdivision of this state or the United States, or for the purpose of providing all or part of the costs of health care services to disabled, aged, or needy persons, contract with this state, the United States, or an agency, in-

See "Pending Legislation," page 12

FDA: Risks of new asthma drugs vary

WASHINGTON (AP) —The blockbuster asthma drug Advair does not appear to have an increased risk of serious respiratory complications seen with similar new medicines, federal health officials announced.

But a less widely used medication, Serevent, had a significantly higher rate of complications when compared to older treatments, the Food and Drug Administration said. Both drugs are made by the same company, GlaxoSmithKline. FDA safety reviewers are recommending that Serevent no longer be approved for treating asthma.

The FDA is concerned about asthma drugs known as LABAs, which already carry warnings. The long-acting medications relax tight muscles around stressed airways and free patients from the need to take a puff from their inhaler every few hours. For many asthma sufferers, that means they can sleep through the night.

But LABAs, for reasons that are still being debated, can increase risks of death and respiratory complications in some patients. The risk may be lower when a LABA is used together with a steroid to treat underlying inflammation deep inside the airways. Current medical guidelines suggest using both kinds of drugs together for patients with chronic asthma who are not responding well to other treatments.

Advair combines both medicines in one inhaler. But Serevent is a LABA-only product.

Asthma is a chronic respiratory illness that leaves patients short of breath, wheezing, and can sometimes send them to the emergency room because of difficulty breathing. Some 22 million people in the United States suffer from asthma, and children account for nearly one out of every three patients. Nearly 3,600 people still die from asthma in this country each year, although symptoms can be controlled with medication to prevent the most serious complications.

The FDA analyzed reams of clinical data on four drugs: Advair, Foradil, Serevent and Symbicort. All four already carry the FDA's strongest warning, but the findings could lead to more specific instructions for patients and greater restrictions, or withdrawal, of some of the medications. The agency has called a special two-day meeting of outside advisers next week to discuss the data and make recommendations.

A review team from the FDA's safety office unanimously recommended that Serevent and Foradil, the two LABA-only drugs, no longer be approved for treating asthma. Safety reviewers also recommended that none of the drugs be used to treat children, because clinical data indicates they are at greater risk of developing respiratory complications with LABAs.

The FDA's outside scientific advisers will vote on whether the drugs should remain on the market for asthma, and whether their use in children should be curbed.

GlaxoSmithKline said the analysis underscored its confidence in Advair, its best-selling medication, with U.S. sales of $2.9 billion in the first nine months of this year. But a spokeswoman declined to comment on a possible withdrawal of Serevent, which had U.S. sales of $97 million in the same period. About 3.9 million U.S. patients now use Advair, and an estimated 162,000 take Serevent.

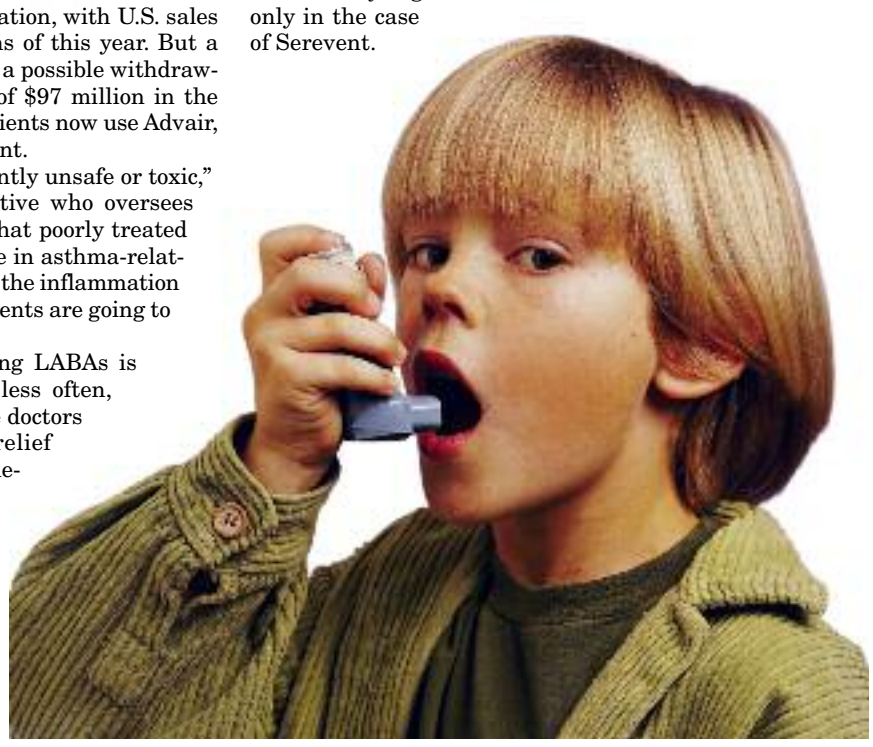
"We don't believe LABAs are inherently unsafe or toxic," said Dr. Kate Knobil, a Glaxo executive who oversees asthma drugs. "What we do know is that poorly treated asthma is what is causing the increase in asthma-related complications. If you don't also treat the inflammation inside the airways [with a steroid] patients are going to have worse outcomes."

For patients, the advantage of using LABAs is that they have to take medications less often, usually once every 12 hours. But some doctors believe that the convenience and relief LABAs offer can mask problems that develop slowly. Deep inside airways in the lungs, passages can become inflamed or clogged with mucus unless patients are also taking a steroid. At some point, that congestion can become acute, leaving patients to gasp for air.

The FDA analysis compared patients taking a LABA drug to those using steroids alone to control their asthma. It compared the number of deaths, hospitalizations and cases where a patient had to have a breathing tube inserted. The agency analyzed findings from 110 clinical trials involving nearly 61,000 patients.

The analysis found 20 asthma-related deaths, of which 16 were in patients taking a LABA drug. All of those deaths were among patients treated with Serevent.

In terms of overall risk of complications, Foradil, Serevent and Symbicort had a higher rate when compared to treatment with steroids. But the FDA said the difference was statistically significant only in the case of Serevent.



"We don't believe LABAs are inherently unsafe or toxic. What we do know is that poorly treated asthma is what is causing the increase in asthma-related complications. If you don't also treat the inflammation inside the airways [with a steroid] patients are going to have worse outcomes." — Dr. Kate Knobil, GlaxoSmithKline

Pending Legislation

Continued from page 11

strumentality, or political subdivision of this state or the United States.

"(d) For the purpose of administering any publicly supported health benefit plan, accept and administer funds, directly or indirectly, made available by a contract authorized under subdivision (c), or made available by or received from any private entity.

"(e) For the purpose of administering any publicly supported health benefit plan, subcontract with any organization that has contracted with this state, the United States, or an agency, instrumentality, or political subdivision of this state or the United States, for the administration or furnishing of health services or any publicly supported health benefit plan.

"(f) Provide administrative services only and cost-plus arrangements for the federal Medicare program established under title XVIII of the Social Security Act, 42 USC 1395 to 1395hhh; for the federal Medicaid program established under title XIX of the Social Security Act, 42 USC 1396 to 1396v; for title V of the Social Security Act, USC 701 to 710; for the program of medical and dental care established by the military medical benefits amendments of 1966, Public Law 85-861; for the Detroit maternity and infant care—preschool, school, and adolescent project; and for any other health benefit program established under state or federal law.

"(g) Provide administrative services only and cost-plus arrangements for any noninsured health benefit plan, subject to the requirements of §§ 211 and 211a.

"(h) Establish, own, and operate a health maintenance organization, subject to the requirements of the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

"(i) Guarantee loans for the education of persons who are planning to enter or have entered a profession that is licensed, certified, or registered under parts 161 to 182 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18237, and has been identified by the commissioner, with the consultation of the office of health and medical affairs in the department of management and budget, as a profession whose practitioners are in insufficient supply in this state or specified areas of this state and who agree, as a condition of receiving a guarantee of a loan, to work in this state, or an area of this state specified in a listing of shortage areas for the profession issued by the commissioner, for a period of time determined by the commissioner.

"(j) Receive donations to assist or enable the corporation to carry out its purposes, as provided in this act.

"(k) Bring an action against an officer or director of the corporation.

"(l) Designate and maintain a registered office and a resident agent in that office upon whom service of process may be made.

"(m) Sue and be sued in all courts and participate in actions and proceedings, judicial, administrative, arbitrative, or otherwise, in the same cases as natural persons.

"(n) Have a corporate seal, alter the seal, and use it by causing the seal or a facsimile to be affixed, impressed, or reproduced in any other manner.

"(o) Subject to chapter 9 of the insurance code of 1956, 1956 PA 218, MCL 500.901 to 500.947, invest and reinvest its funds and, for investment purposes only, purchase, take, receive, subscribe for, or otherwise acquire, own, hold, vote, employ, sell, lend, lease, exchange, transfer, or otherwise dispose of, mortgage, pledge, use, and otherwise deal in and with, bonds and other obligations, shares, or other securities or interests issued by entities other than domestic, foreign, or alien insurers, as defined in §§ 106 and 110 of the insurance code of 1956, 1956 PA 218, MCL 500.106 and 500.110, whether engaged in a similar or different business, or governmental or other activity, including banking corporations or trust companies. However, a health care corporation may purchase, take, receive, subscribe for, or otherwise acquire, own, hold, vote, employ, sell, lend, lease, exchange, transfer, or otherwise dispose of bonds or other obligations, shares, or other securities or interests issued by a domestic, foreign, or alien insurer, so long as the activity meets all of the following:

"(i) Is determined by the attorney general to be lawful under § 202.

"(ii) Is approved in writing by the commissioner as being in the best interests of the health care corporation and its subscribers.

"(iii) For an activity that occurred before July 23, 2003, will not result in the health care corporation owning or controlling 10 percent or more of the voting securities of the insurer or will not otherwise result in the health care corporation having control of the insurer, either before or after July 23, 2003. As used in this subparagraph and subparagraph (iv), "control" means that term as defined in § 115 of the insurance code of 1956, 1956 PA 218, MCL 500.115.

"(iv) Subject to § 218 and beginning on July 23, 2003, will not result in the health care corporation owning or controlling part or all of the insurer unless the transaction satisfies chapter 13 of the insurance code of 1956, 1956 PA 218, MCL 500.1301 to 500.1379, and the insurer being acquired is only authorized to sell disability insurance as defined under § 606 of the insurance code of 1956, 1956 PA 218, MCL 500.606, or under a statute or regulation in the insurer's domiciliary jurisdiction that is substantially similar to § 606 of the insurance code of 1956, 1956 PA 218, MCL 500.606.

"(p) Purchase, receive, take by grant, gift, devise, bequest or otherwise, lease, or otherwise acquire, own, hold, improve, employ, use and otherwise deal in and with, real or personal property, or an interest therein, wherever situated.

"(q) Sell, convey, lease, exchange, transfer or otherwise dispose of, or mortgage or pledge, or create a security interest in, any of its property, or an interest therein, wherever situated.

"(r) Borrow money and issue its promissory note or bond for the repayment of the borrowed money with interest.

"(s) Make donations for the public welfare, including hospital, charitable, or educational contributions that do not significantly affect rates charged to subscribers.

"(t) Participate with others in any joint venture with respect to any transaction that the health care corporation would have the power to conduct by itself.

"(u) Cease its activities and dissolve, subject to the commissioner's authority under § 606(2).

"(v) Make contracts, transact business, carry on its operations, have offices, and exercise the powers granted by this act in any jurisdiction, to the extent necessary to carry out its purposes under this act.

"(w) Have and exercise all powers necessary or convenient to effect any purpose for which the corporation was formed.

"(x) Notwithstanding subdivision (o) or any other provision of this act, establish, own, and operate a domestic stock insurance company only for the purpose of acquiring, owning, and operating the state accident fund pursuant to chapter 51 of the insurance code of 1956, 1956 PA 218, MCL 500.5100 to 500.5114, so long as all of the following are met:

"(i) For insurance products and services the insurer, whether directly or indirectly through 1 or more subsidiaries, only transacts worker's compensation insurance and employer's liability insurance, transacts disability insurance limited to replacement of loss of earnings, and acts as an administrative services organization for an approved self-insured worker's compensation plan or a disability insurance plan limited to replacement of loss of earnings and does not transact any other type of insurance notwithstanding the authorization in chapter 51 of the insurance code of 1956, 1956 PA 218, MCL 500.5100 to 500.5114. This subparagraph does not preclude the insurer, whether directly or indirectly through 1 or more subsidiaries, from providing noninsurance products and services as otherwise provided by law.

"(ii) The activity is determined by the attorney general to be lawful under § 202.

"(iii) The health care corporation does not directly or indirectly subsidize the use of any provider or subscriber information, loss data, contract, agreement, reimbursement mechanism or arrangement, computer system, or health care provider discount to the insurer.

"(iv) Members of the board of directors, employees, and officers of the health care corporation are not, directly or indirectly, employed by the insurer unless the health care corporation is fairly and reasonably compensated for the services rendered to the insurer if those services were paid for by the health care corporation.

"(v) Health care corporation and subscriber funds are used only for the acquisition from the state of Michigan of the assets and liabilities of the state accident fund.

"(vi) Health care corporation and subscriber funds are not used to operate or subsidize in any way the insurer including the use of such funds to subsidize contracts for goods and services. This subparagraph does not prohibit joint undertakings between the health care corporation and the insurer to take advantage of economies of scale or arm's-length loans or other financial transactions between the health care corporation and the insurer.

"(2) In order to ascertain the interests of senior citizens regarding the provision of Medicare supplemental coverage, as described in § 202(1)(d)(v), and to ascertain the interests of senior citizens regarding the administration of the federal Medicare program when acting as fiscal intermediary in this state, as described in § 202(1)(d)(vi), a health care corporation shall consult with the office of services to the aging and with senior citizens' organizations in this state.

"(3) An act of a health care corporation, otherwise lawful, is not invalid because the corporation was without capacity or power to do the act. However, the lack of capacity or power may be asserted:

"(a) In an action by a director or a member of the corporate body against the corporation to enjoin the doing of an act.

"(b) In an action by or in the right of the corporation to procure a judgment in its favor against an incumbent or former officer or director of the corporation for loss or damage due to an unauthorized act of that officer or director.

"(c) In an action or special proceeding by the attorney general to enjoin the corporation from the transacting of unauthorized business, to set aside an unauthorized transaction, or to obtain other equitable relief.

"(4) A health care corporation shall not condition the sale or vary the terms or conditions of any product sold by the corporation or by a subsidiary of the corporation by requiring the purchase of any other product from the corporation or from a subsidiary of the corporation."

Sponsor: Alan Cropsey

Status: Referred to Committee on Economic Development and Regulatory Reform

As hospital infections spread, so do lawsuits

By Sylvia Hsieh

A new type of med-mal lawsuit is on the increase — claims based on hospital infections.

Several recent verdicts and settlements illustrate this trend:

• On Nov. 6, a jury awarded $13.5 million to a Massachusetts woman who died of an infection caused by flesh-eating bacteria that she contracted during cancer treatment.

• On Nov. 14, a Utah woman reached a confidential settlement in a $16 million suit she filed, alleging that a hospital failed to detect necrotizing fasciitis, a flesh-eating bacteria, before and after she gave birth, causing her to lose three limbs and several organs.

• In July, a Missouri couple was awarded $2.58 million after the husband contracted a potentially deadly type of staph infection, known as Methicillin Resistant Staph Aureus (MRSA), when doctors inserted a pacemaker. As a result of the infection, the patient lost a kidney and his leg and foot had to be amputated.

The Centers for Disease Control and Prevention in Atlanta has estimated that over 2 million hospital-acquired infections occur annually, resulting in 90,000 deaths. In long-term care facilities, the CDC estimates an additional 1.5 million health-care associated infections occur each year.

"This is the next asbestos. Now that the evidence is overwhelming that nearly all infections are preventable, hospitals that don't follow the proven protocols are inviting lawsuits," said Betsy McCaughy, founder and chair of the Committee to Reduce Infection Deaths, a nonprofit patient safety organization in New York.

According to McCaughy, 26 states have passed laws requiring reporting of hospital-acquired infections.

Plaintiffs' attorneys say that hospitals can no longer argue that these infections are inevitable.

"Anyone providing health care to an individual is no longer going to have immunity for transmitting infections," said Gloria Seidule, an attorney with Seidule & Webber in Stuart, Fla., who is currently litigating a hospital-acquired infection lawsuit involving MRSA, a "superbug" that is resistant to most antibiotics.

> **"This is the next asbestos. Hospitals that don't follow the proven protocols are inviting lawsuits."**
>
> **— Betsy McCaughy, chair of the Committee to Reduce Infection Deaths**

Seidule said that hospitals in general have not taken the initiative on prevention measures, opening the door to litigation.

Mary Coffey, an attorney at Coffey Nichols in St. Louis, said that "a lot of lawyers think they can't ever trace an infection and that getting an infection in a hospital is not necessarily negligent, which is true. But I would say you can prove it."

Coffey won the $2.58 million verdict on behalf of a 69-year-old Missouri man who contracted MRSA through an IV that was administered in the ambulance following a heart attack. When doctors later inserted a pacemaker, the infection spread.

A number of new guidelines and rules are arguably raising the standard of care that applies to hospitals in preventing infections.

As of Oct. 1, 2008, Medicare has stopped reimbursing for certain types of hospital-acquired infections.

Last year, the CDC published guidelines for preventing infections.

In addition, the Joint Commission, a nonprofit organization based in Oakbrook Terrace, Ill., that evaluates and accredits health care programs, released a compendium of strategies for preventing infections in October.

Coffey said that the idea that hospital-acquired infections are preventable is gaining credence and "the standard of care is changing."

"There are CDC standards on infection prevention and lots of published materials that can be used to establish the standard of care," she said.

However, Coffey noted that causation is often the more contentious issue.

A plaintiff "is going to need an expert to say, 'If this precaution had been taken, he would not have gotten this infection.'"

In her case, for example, she was able to show that the patient's IV site was red, tender and swollen, and that the IV had been left in for three days — contrary to CDC guidelines that say an ambulance IV should be switched to a new one upon arrival at the hospital.

She also argued that under CDC rules, the surgeon should have waited to perform heart surgery until the remote site infection cleared up.

At a minimum, attorneys that represent hospitals should advise them to have policies on infection prevention, such as hand-hygiene policies. They should also require clinicians to be trained on preventing recontamination by not opening the privacy curtain once they are in surgical gloves.

The Joint Commission's compendium contains strategies for hospitals to prioritize and address the most common and deadly infections, including central line associated blood stream infections, surgical site infections, urinary tract infections and MRSA.

But McCaughy said the compendium "set the bar too low."

She suggests that attorneys advise hospitals to take stronger measures, such as penalizing those who violate hand-hygiene rules and screening incoming patients for MRSA.

McCaughy said hospitals and doctors are more likely to be sued over infections if they don't implement proven methods to prevent them, such as using a back-up catheter treated with antibiotics to prevent central line blood stream infections.

"Hospitals that fail to use these backup devices are inviting lawsuits, and surgeons who don't ask hospitals to have these devices will be vulnerable," she said.

But Coffey said that in most states, the standard of care is "not the very best of care, but … the ordinary care under the circumstances.

"Until a lot of hospitals start doing these things, it would be difficult to get an expert to say this is what is ordinarily done," she cautioned.

This article originally appeared in another Dolan Media publication.

Attendant care

Continued from page 1

In *Bonkowski v. Allstate Insurance Company*, the court, in a unanimous Oct. 2, opinion authored by Judge Brian K. Zahra and joined by Judges Michael J. Talbot and Mark J. Cavanagh called into question a legal principle that Michigan courts have followed for more than 20 years.

Under Michigan's no-fault law, people providing in-home attendant care services for family members injured in car accidents are entitled to reasonable compensation.

And, in nearly all of the approximately 3,000 first-party no-fault cases filed statewide every year, the question of what constitutes "reasonable" compensation arises.

Before *Bonkowski*, the answer was pretty well settled.

Based on a 1983 Michigan Court of Appeals opinion, *Manley v. DAIIE*, plaintiffs' lawyers have argued and juries have been instructed that the rates charged by health care agencies for nursing, psychological and rehabilitation services are a valid consideration for assessing the reasonable value of "comparable services" provided by an insured's family member.

Defendants, however, have argued unsuccessfully that what matters is not the rate the agencies charge; rather, they say, what should matter is the amount agencies pay their employees, the actual service providers.

In the published *Bonkowski* decision, the defendants' argument finally got traction.

"We question the conclusion reached in *Manley*," Zahra wrote.

Zahra said the agency rates weren't relevant and provided no assistance in determining what the reasonable compensation should be for family members who give such care.

"The focus should be on the compensation provided to the person providing the services, not the charge assessed by an agency that hires health care professionals to provide such services," he said.

Despite his questioning of *Manley*, Zahra didn't outright reject it or call for its overruling because, by his own admission, the issue of agency rates versus individual rates "is not squarely before us in this appeal." (See "Coming to an end?" sidebar for discussion of *Manley*'s precedential value.)

Nevertheless, some no-fault specialists say *Bonkowski*'s treatment of the *Manley* issue holds game-changing significance.

Detroit attorney James G. Gross of Gross & Nemeth PLC, who counts among his major clients Auto Club Insurance Association, said the Court of Appeals "hit the nail on the head."

Finally, he said, a court has said what his clients have been saying for years: "Agency rates are irrelevant" to the reasonable-compensation determination.

Fellow Detroit attorney Daniel S. Saylor of Garan Lucow Miller PC, who represents Allstate in *Bonkowski*, agreed.

"The defense bar has had major problems with using agency rates to justify higher hourly rates for compensating family members who provide in-home attendant care services," he said.

Now, Saylor said, *Bonkowski* "makes clear that agency rates aren't relevant and don't support what an individual should receive for services."

But Bloomfield Hills attorney Nicholas S. Andrews of Liss Seder & Andrews PC, who represents the plaintiff in *Bonkowski*, cautioned against attributing too much significance to the Court of Appeals' decision.

Recall, he said, that Judge Zahra acknowledged the agency rate issue in *Manley* wasn't even before the court.

That means the Court of Appeals' discussion of the issue was non-binding dicta, Andrews said.

Accordingly, "Nobody can say there's been a change in the law," he said.

In *Bonkowski*, the agency rate issue came up in the context of deciding whether Andrew Bonkowski had received reasonable compensation for the 24-hour attendant care services he provided to his son, Shaun, who was paralyzed from the waist down after being struck by a car in 2001.

The Bonkowskis' no-fault insurer, Allstate, had been paying Andrew $19 per hour, which came out to $166,000 per year. But Andrew and Shaun wanted the hourly rate to be higher.

Although the jury didn't specify the hourly rate at which it was valuing Andrew's services, it did conclude, through its $1.7 million verdict in the Bonkowskis' favor, that Allstate should've been paying more.

The Court of Appeals affirmed. The judges said their ruling was, at least in part, based on the fact the agency-rates issue hadn't been properly preserved for appellate review.

Allstate "did not argue in the trial court or on appeal in this court that *Manley* is wrongly decided," Zahra wrote.

Andrews said that, even if *Bonkowski* signals an impending change in the law, the insurance companies that may benefit from such a change must remember they can't have things both ways.

"If juries are going to be limited to considering only what an agency pays its individual employees," he said, "then it's only fair that the juries be made aware of everything the agencies pay, not just the salaries."

For instance, Andrews said, in addition to paying salaries, agencies pay their employees overtime and shift premiums, and they provide fringe benefits such as health insurance, 401(k) and vacation and sick time.

As to overtime and shift premiums, Andrews said he and the Court of Appeals were in agreement.

"Plaintiff presented evidence relating the overtime rates and shift premiums that would be paid to attendant care providers qualified to care for plaintiff," the *Bonkowski* court said. "This evidence is appropriate and independent of any evidence of the rates charged by health care agencies for attendant care services."

Additionally, the court also acknowledged that Allstate had offered to provide Andrew with health insurance.

Southfield attorney and no-fault specialist Wayne J. Miller of Miller & Tischler PC agreed with Andrews.

"If we're no longer going to look at what agencies charge, but instead we're going to look at what they pay, then we must look at everything the agencies pay," he said.

Gross wasn't convinced.

The rule is that compensation must be reasonable, not that there must be absolute parity, he said.

As such, the question is whether the compensation being paid is within the range of what's reasonable, not whether family members are getting exactly what agency employees are getting, Gross said.

Plus, there are differences between the two that may justify differences in compensation, he said.

For instance, Gross said, "Fringe benefits are not essential to the definition of compensation."

And, he said, the fact that agency employees are licensed, while family members usually aren't, shouldn't be overlooked.

"Agency employees who have invested in training and education deserve to have their services valued at a higher rate than unlicensed providers," Gross said.

Miller said he didn't know where the licensed-versus-unlicensed distinction was coming from, as it isn't part of the no-fault law that has developed over the last 25 years.

"The touchstone for compensation to family-member service providers under the No-Fault Act is reasonableness," he said. "There's nothing in the statute about licensing."

The *Bonkowski* court tended to agree with Gross, but the judges acknowledged that "[n]either the medical community nor legal community has established a hard and fast rule to determine the reasonable rate of compensation due to unlicensed individuals who provide necessary health care services to family members."

As such, the Court of Appeals said, "Consideration of rates paid to licensed and trained health care providers is appropriate" in making a reasonable compensation determination.

But, the *Bonkowski* court said, "The law does not require that unlicensed individuals who have not earned a degree in a pertinent health care profession be paid the same compensation paid to licensed health care professionals."

If you would like to comment on this story, please contact Todd C. Berg at (248) 865-3113 or todd.berg@mi.lawyersweekly.com.

Coming to an end?

The Michigan Court of Appeals' published opinion in *Manley v. DAIIE* may not have much life left in it.

That's because the Court of Appeals recently in *Bonkowski v. Allstate Insurance Company* openly questioned *Manley*'s proposition that agency rates are a valid measure of what constitutes "reasonable" compensation for attendant care services provided by an insured's family member.

In *Bonkowski*, Judge Brian K. Zahra, writing for a unanimous panel that included Judges Michael J. Talbot and Mark J. Cavanagh, said, "The focus should be on the compensation provided to the person providing the services, not the charge assessed by an agency that hires health care professionals to provide such services."

Zahra, however, stopped short of rejecting or even overruling *Manley* because the agency rate issue in *Manley* hadn't been properly preserved and, thus, wasn't "squarely before us in this appeal."

But, going forward, *Manley* might not be so lucky, say no-fault specialists.

"The Michigan Supreme Court reversed the Court of Appeals decision in *Manley* on other grounds and vacated the opinion," said Detroit attorney Daniel S. Saylor, of Garan Lucow Miller PC, who represents the defendant, Allstate Insurance Company, in *Bonkowski*.

"That means the *Manley* Court of Appeals decision has no precedential force whatsoever," he said.

Detroit attorney James G. Gross of Gross & Nemeth PLC agreed.

And, alternatively, he said, because the portion of *Manley* that mentioned agency rates wasn't necessarily outcome determinative, that portion of the opinion was non-binding dicta.

Southfield attorney Wayne J. Miller of Miller & Tischler PC said he didn't disagree with the idea that *Manley*'s discussion of agency rates was dicta.

"But so was *Bonkowski*'s," he said. "That's troubling because if the Court of Appeals only discussions about agency rates are dicta, then what's the rule that lawyers and courts should be following for determining reasonable compensable?"





Risk and compliance practices for nursing facilities

Business of Medicine

By Carey F. Kalmowitz, Esq. and Walter S. Wheeler III, Esq.

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Walter S. Wheeler III served as director of legal and legislative affairs for the Michigan Department of Public Health and as the state executive responsible for the licensure and certification of Michigan health care providers. Upon his retirement from state service in 2005, he was director of the bureau of health systems for the Michigan Department of Community Health. He now specializes in health law as principal of Okemos-based Walter Wheeler Associates PLC, in. Contact him at (517) 347-8937 or walterwheeler@walterwheeler.com.

On March 16, 2000, the United States Department of Health and Human Services Office of Inspector General (OIG) published its first "Compliance Program Guidance for Nursing Facilities" (the Guidance, or 2000 Guidance).

The Guidance comprised a set of recommendations to help nursing-facility programs comply with applicable federal regulations. Although the recommendations were not enforceable operating standards, they contained practical advice which, if implemented, would mitigate the regulatory scrutiny to which a nursing facility likely would be subject.

Since the publication of the original Guidance in 2000, there have been significant changes to the regulatory-enforcement environment and the federal payment system for nursing-facility services. There also has been a heightened focus on quality of care, an issue that the Guidance addressed, albeit not with the emphasis currently accorded to the issue.

On Sept. 30, 2008, the OIG published further recommendations in its Supplemental Compliance Program Guidance for Nursing Facilities (the Supplemental Guidance or 2008 Guidance).

The Supplemental Guidance reflects the above-noted transformations in the way nursing facilities deliver, and receive reimbursement for, health care services, as well as the intensification of federal enforcement activity and increased concerns about quality of care in nursing facilities. Together, the original and supplemental guidelines identify risk areas. Such identifying will help nursing facilities evaluate and refine their current compliance program, or develop a new program.

This article reviews the Supplemental Guidance with an emphasis on the areas of risk identified by the OIG, the need for compliance programs in nursing facilities, and the recommendations for reducing risks. This article also will discuss practical steps that, while not specifically addressed in the 2008 Guidance, can substantially increase the likelihood of a nursing facility's remaining compliant, especially if adopted as part of a comprehensive compliance plan that also incorporates the OIG's recommendations.

The 2008 Guidance contains five major sections:

- Overview of the compliance program guidance process;
- Overview of the Medicare/Medicaid reimbursement system;
- Fraud and abuse risk areas;
- Other compliance considerations, including the importance of an ethical culture and regular review of compliance program effectiveness; and
- Self-reporting violations of criminal, civil or administrative law

Compliance program guidance

Both the 2000 Guidance and the 2008 Guidance are intended to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations and program requirements.

The fact that the OIG has published compliance guidance for nursing facilities does not, by itself, suggest that the OIG views compliance problems to be more acute among nursing facility providers; rather, both the 2000 Guidance and the 2008 Guidance are parts of a series of compliance-program guidance that the OIG has issued for hospitals, hospices, ambulance suppliers, durable medical equipment suppliers, physicians, pharmaceutical companies and a number of other segments of the health care industry.

The areas of fraud and abuse risk addressed by the OIG are supplemental to federal certification and state licensure compliance risks. The Supplemental Guidance states:

"Together with our law enforcement partners, we have used, with increasing frequency, federal civil fraud remedies to address cases involving poor quality of care, including troubling failure of care on a systemic level in some organizations. To promote compliance and prevent fraud and abuse, OIG is supplementing the 2000 Nursing Facility CPG (Compliance Program Guidance) with specific risk areas related to quality of care, claims submissions, the (Medicare and Medicaid) Antikickback Statute (the 'Anti-Kickback Statute'), and other emerging areas."

In general, the purpose of a compliance program is to reduce fraud and abuse, with the associated benefit of enhancing health care providers' operations, improving the quality of health care services and reducing their overall cost.

On that point, the 2008 Guidance says: "Compliance programs help nursing facilities fulfill their legal duty to provide quality care; to refrain from submitting false or inaccurate claims or cost information to the federal health care programs; and to avoid engaging in other illegal practices."

An effective compliance program demonstrates a nursing facility's good faith effort to comply with applicable statutes, regulations and other federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions.

Note that there is no one-size-fits-all compliance program that will have the same efficacy for all nursing facilities. Although, as identified in the 2000 Guidance and 2008 Guidance and discussed in this article, there are certain principles that should be incorporated into any plan, any truly effective plan will evaluate the particular risk areas of a specific nursing-facility's operations and formulate a plan in response to those needs.

Reimbursement system overview

The Supplemental Guidance provides a detailed overview of the current reimbursement system for nursing facilities to provide a context for the risk analysis.

From a compliance perspective, the fact that skilled nursing facilities (SNFs) are reimbursed under a consolidated billing requirement (i.e., the prospective payment system) triggers a number of potential risks.

For example, because ancillary services, such as therapy, are included within the composite rate, SNFs have a financial incentive to reduce the level of medically necessary therapy services furnished to residents since there is no supplemental reimbursement for such services.

In addition, as a result of the reimbursement system, certain nursing facilities have entered into unlawful "swapping" arrangements by which they refer business to providers or suppliers for services outside the consolidated rate (i.e., that the outside provider or supplier can bill to the federal government) in exchange for that provider or supplier providing the nursing facility with items or services included within the composite rate at below fair market value rates.

Fraud and abuse risk areas

Several fraud and abuse risk areas are particularly relevant to the nursing-facility industry. The nursing-facility's compliance program should carefully evaluate these risk areas and, in coordination with health care legal counsel, identify those to which they have potential exposure. The primary areas of fraud and abuse risk identified by the 2008 Guidance include:

- Quality of care
- Submission of accurate claims
- The Federal Anti-Kickback Statute
- Other compliance considerations

Quality of care: Inadequate staffing, insufficient training and education, lack of oversight, or other factors often lead to a failure of nursing facilities to deliver quality care, resulting in a risk of harm to residents that, in turn, involves licensing and certification issues.

When this failure is systemic and acute, a nursing facility also may be subject to a number of federal authorities and state laws addressing false and fraudulent claims made to the government. Criminal, civil and administrative sanctions may result.

That approach (i.e., charging nursing facility with violations of false-claims statutes on the basis of substandard resident care) has been applied with increasing frequency in recent years.

To reduce potential liability risks under several key federal fraud and abuse statutes and regulations, the OIG recommends that, as a foundation for understanding quality-of-care issues, the key staff and members of a nursing facility understand the Medicare Conditions of Participation for Nursing Facilities.

Additional considerations include sufficient staffing, comprehensive resident-care plans, medication management, appropriate use of psychotropic medications, and resident safety. To reduce risk, the Supplemental Guidance emphasizes:

- A nursing facility must provide sufficient levels of trained, competent staff to attain and maintain the highest practicable physical, mental and psychosocial well-being of its residents. In connection with this obligation, nursing facilities should evaluate whether staff patterns are sufficient to meet patient needs.
- A comprehensive, interdisciplinary care plan must be developed for each resident. A physician must be involved in both the development of the plan and the care of that resident.
- Nursing facilities must demonstrate proper medication management, which includes education of staff on medication management, and ensuring that pharmacist consultants are not receiving improper kickbacks based on the volume or value of drugs prescribed to residents.
- The appropriate use of psychotropic medications must be ensured through the careful monitoring, documentation and review of resident use of psychotropic drugs.
- Nursing facilities must ensure resident safety, protecting against abuse and neglect from both staff and other residents. The 2008 Guidance states that education, internal reporting systems, monitoring, comprehensive staff screening, communication of a firm commitment to resident safety, and other steps can help protect residents.

Submission of accurate claims: The need for accurate reimbursement-claim submissions is a second risk area addressed by the 2008 Guidance. Facilities are advised to regularly review the accuracy of all reported data. Four primary sub-areas of risk exist: proper reporting of resident case-mix, therapy services, screening for excluded individuals, and restorative and personal care services.

- Nursing facilities must ensure that they are not improperly upcoding resident Resource Utilization Group (RUG) assignments. Assessment, reporting, and evaluation of resident case-mix data is a significant and common risk area. Inappropriately elevating the resource intensity of care required by the resident (i.e., in the form of upcoding the RUG), in effect, causes the federal government to pay for a level of care in excess of that which the facility in fact will be providing, and can result in risks for the facility under the false claims statutes.
- Facilities must also ensure that they are providing medically appropriate physical, occupational and speech-therapy services. The OIG found, for example, improper instances of inflating RUG classifications, over-utilization of fee-for-service therapy covered by Part B under consolidated billing, and stinting on therapy services covered by the Part A Prospective Payment System, each of which can result in submission of false claims.
- Pre-employment screening of new employees and periodic screening of existing employees is an essential means of identifying excluded individuals. Employing an excluded individual can subject a facility to penalties under the civil monetary penalties statute.

• If a nursing facility fails to provide necessary restorative and personal care services, it risks violating the fraud and abuse laws for billing for services not rendered as claimed. Facilities should implement procedures to ensure that the quality and amount of services are delivered appropriately.

The Anti-Kickback Statute: Nursing facilities must evaluate numerous factors when contemplating entry into contractual arrangements with referral sources when the arrangements do not fit within one of the safe harbors to the Anti-Kickback Statute. Six specific areas of risk are identified by the OIG: free goods and services, services contracts, discounts, swapping, hospices, and reserved bed arrangements.

• If a facility provides a good or service of independent value to residents at no cost, for the purpose of generating referrals, the facility may be in violation of offering remuneration with the intent to generate business payable by a federal program. This is the hallmark of a violation under the Anti-Kickback Statute. Some examples include supplies offered by a pharmacy, or a hospice nurse's providing nursing services for non-hospice residents.

• Facilities can minimize risk of disguised kickbacks in physician and non-physician service contracts by reviewing arrangements for legitimate need, the actual provision and complete documentation of services, compensation at fair-market value in an arm's-length transaction, and the severing of any correlation between compensation, on one hand, and the volume or value of federal healthcare program businesses, on the other. To completely eliminate the risk, facilities should endeavor to structure services arrangements to comply with the personal services and management contract safe harbor (to the extent reasonably practicable). In those cases where, for one or more reasons, it is not possible to fit expressly within the safe harbor, the arrangement nonetheless should be structured in a manner that conforms as closely as possible to the terms of an applicable safe harbor.

• While the Anti-Kickback Statute contains an exception for discounts, any discounts must be based on the reduced price of a good or service and in an arm's-length transaction. Discounts must be fully disclosed on cost reports and claims.

• Nursing facilities must not accept a reduced price from a supplier or provider in exchange for the facility's referring other federal health care program business for which the supplier can bill Medicare or Medicaid. Such swapping arrangements are expressly not protected by the discount safe harbor.

• A facility should ensure that requesting or accepting benefits from a hospice does not influence the facility's decision to do business with that hospice. For example, a hospice might offer free or below-market goods or services (e.g., when a hospice nurse provides services for non-hospice patients) to induce a facility to refer patients to the hospice. This and other related practices are suspect under the Anti-Kickback Statue.

• If a hospital pays to reserve a bed in a nursing facility, with even one purpose being the potential inducement of referrals to the hospital, this would pose a clear risk under the Anti-Kickback Statue. Reserved bed payments must be for the sole purpose of securing needed beds.

Other risk areas: Additional areas of risk identified in the Supplemental Guidance include: physician self-referrals (including, in particular, Section 1877 of the Social Security Act commonly known as the Stark Law), anti-supplementation, Medicare Part D, and Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules.

• Nursing-facility services, by themselves, are not "designated health services" (or DHS) for the purposes of Stark Law (and, thus, arrangements involving solely nursing facility services do not implicate the Stark Law); nonetheless, certain services (e.g., laboratory services) sometimes offered by the facility are DHS and, as a result, are covered by the Stark Law. Facilities must be conversant with Stark Law, and review all financial relationships with physicians who refer or order DHS, to ensure compliance with Stark. Facilities should pay attention, in particular, to physicians who are owners of, investors in, medical directors of or consultants to the facility.

• Nursing facilities are prohibited from charging residents (or their families) for covered services in excess of the Medicare or Medicaid amount.

• Facilities must ensure that they provide beneficiary freedom of choice when choosing a Part D plan, a right guaranteed under federal law. Nursing facilities must not coach or steer the selection of a plan, and must prevent a pharmacy that services the nursing facility from engaging in this practice.

• Nursing facilities must design policies and procedures that ensure the privacy and confidentiality of protected health information, as required under the HIPAA Privacy Rule and HIPAA Security Rule.

Other compliance considerations

Ethical culture: The 2000 Nursing Facility Guidance stressed the importance for a nursing facility to have an organizational culture that promotes compliance.

OIG commends nursing facilities that have adopted a code of conduct that details the fundamental principles, values, and framework for action within the organization, and that articulates the organization's commitment to compliance.

OIG encourages those facilities that have not yet adopted codes of conduct to do so. Additionally, a nursing facility's leadership should foster an organizational culture that values, and even rewards, the prevention, detection, and resolution of quality of care and compliance problems.

Good compliance practices may include the development of a mechanism, such as a "dashboard." Further information and resources about quality-of-care dashboards are available on the OIG Web site. When communication tools such as dashboards are properly implemented and include quality-of-care information, the directors and senior officers can, among other things:

• Demonstrate a commitment to quality of care and foster an organization-wide culture that values quality of care;

• Improve the facility's quality of care through increased awareness of and involvement in the oversight of quality-of-care issues; and

• Keep track of quality-of-care data (e.g., state agency survey results, outcome care and delivery data, and staff retention and turnover data) to identify potential quality-of-care problems, identify areas in which the organization is providing high quality of care, and measure progress on quality-of-care initiatives.

OIG views the use of dashboards and similar tools as a helpful compliance practice that can lead to improved quality of care and assist the board members and senior officers in fulfilling, respectively, their oversight and management responsibilities.

Regular review of compliance program effectiveness: Nursing facilities should regularly review the implementation and execution of their compliance-program systems and structures, typically on an annual basis. The assessment should include an evaluation of the overall success of the program, as well as of each of the basic elements of a compliance program individually, which include:

- Designation of a compliance officer and compliance committee;
- Development of compliance policies and procedures, including standards of conduct;
- Developing open lines of communication;
- Appropriate training and teaching;
- Internal monitoring and auditing;
- Response to detected deficiencies; and
- Enforcement of disciplinary standards.

Nursing facilities seeking guidance for establishing and evaluating their compliance operations should review the 2000 Guidance, which discusses in detail the fundamental elements of a compliance program.

Other issues a nursing facility may want to evaluate are whether there has been an allocation of adequate resources to compliance initiatives; whether there is a reasonable timetable for implementation of the compliance measures; whether the compliance officer and compliance committee have been vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures; and whether compensation structures create undue pressure to pursue profit over compliance.

Most importantly, nursing facilities should recognize that the development of a compliance program (or, in the case of facilities with existing programs, the refinement of such a program), by itself, does not suffice. There must be an ongoing commitment, reinforced on a regular and continuous basis, to implementing the provisions of the compliance program with a view toward elevating the quality of care at the facility and reducing the facility's regulatory risks.

Self-reporting

If the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the nursing facility should promptly report the existence of the misconduct to the appropriate federal and state authorities.

The reporting should occur within a reasonable period, but not longer than 60 days, after determining that there is credible evidence of a violation.

Prompt voluntary reporting will demonstrate the nursing facility's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, prompt reporting of misconduct will be considered a mitigating factor by OIG in determining administrative sanctions (e.g., penalties, assessments, and exclusion) if the reporting nursing facility becomes the subject of an OIG investigation.

To encourage providers to make voluntary disclosures to OIG, OIG published the Provider Self-Disclosure Protocol.

When reporting to the government, a nursing facility should provide all relevant information regarding the alleged violation of applicable federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of legal counsel and with guidance from governmental authorities, may be requested to continue to investigate the reported violation.

Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation.

Such notification should include a description of the effect of the alleged violation on the applicable federal health care programs or their beneficiaries. Note, however, that the decision as to whether or not a facility should self-report typically is complex since an initial determination needs to be made whether the conduct is more accurately characterized as a billing error (for which repayment can be made, without the requirement to self-disclose), or whether the conduct rises to a level that self-disclosure is the appropriate course of action.

Summary

A critical element of a nursing-facility's compliance program is the establishment of a culture of compliance, and a formal commitment to an ethical culture and compliance that begins with senior management and, in turn, permeates all levels of the organization.

Nursing facilities should establish clear policies and procedures to ensure compliance, and should regularly review, revise, and build on this compliance program.

Further, as noted above, there must be an emphasis on continually implementing the principles of the compliance program. It is our sense that, by investing in compliance, a nursing facility can simultaneously take steps to elevate the quality of health care services furnished to residents, while it also mitigates the risks of regulatory violations, which can result in penalties and other sanctions, including closure of the facility).

In light of the heightened scrutiny to which nursing facilities are subject in the current enforcement climate, with significant resources being deployed to find violations, prudence dictates that nursing facilities, in turn, attach a commensurate degree of attention to these risks.

New HHS, Department of Education guidance provides overview of privacy laws

[M]any mental health providers, educational staff and public safety officials nationwide are confused over or incorrectly interpret state and federal privacy laws, thus limiting their ability to legally disclose information about students who may be a threat to themselves or others.

Health Care Justice

By Mercedes L. Varasteh, Esq.

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In response to a federal investigation following the Virginia Tech shootings, the U.S. departments of Health and Human Services and Education recently issued joint guidance detailing the relationship between the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA).

The guidelines are directed at health care professionals and school administrators, and are intended to eliminate confusion over the regulations' privacy requirements, including when certain disclosures can be made relating to health and safety emergency situations.

The April 16, 2007, Virginia Tech shootings claimed the lives of 32 students and faculty members and is considered the deadliest shooting by one person in U.S. history.

Home videos made by the gunman, Virginia Tech senior Seung Hui Cho, were later broadcast on national television, revealing a psychologically damaged person whose erratic behavior had been noted by teachers, campus police and even a Virginia special justice.

Investigations following the shootings revealed that information about Cho's mental problems and violent tendencies should have been shared with his parents or university officials who worked with troubled youths, but a misunderstanding of privacy laws such as FERPA and HIPAA prevented such disclosures.

The findings of a task force assembled by President Bush uncovered that many mental health providers, educational staff and public safety officials nationwide are confused over or incorrectly interpret state and federal privacy laws, thus limiting their ability to legally disclose information about students who may be a threat to themselves or others.

FERPA and HIPAA both have carefully delineated requirements on when information can be shared with parents, schools officials and law enforcement in the interest of the patient's/student's own protection and public safety.

By understanding the differences and similarities between HIPAA and FERPA, health professionals can comply with both and still protect their patients and the public.

FERPA

FERPA is a federal law that protects the privacy of a student's "education records" and applies to all educational agencies and institutions that receive funds under any program administered by the United States Department of Education.

This encompasses almost all public schools and school districts and most private and postsecondary institutions (such as colleges and universities), including medical and other professional schools.

Kindergarten-through-grade-12 private and religious schools generally do not receive funds from the Department of Education and are therefore exempt from FERPA.

"Education records" are generally defined as records that are directly related to a student, and maintained by an educational agency or institution or by a party acting for the agency or institution.

An example at the elementary and junior high/high school level would be a student's health records (such as immunization records or records maintained by a school nurse). That also includes records on special-education students and records on services provided to students under the Individuals with Disabilities Education Act (IDEA).

To qualify as "educational records," they must be maintained by a health care provider under contract with, or otherwise in direct control of, the school.

At post-secondary institutions such as colleges and universities (or for students 18 years of age or older), medical and psychological treatment records are excluded from the definition of "education records" if they are made, maintained, and used only in connection with treatment of the student and disclosed only to those providing the treatment.

These are commonly referred to as "treatment records." A common example would be the medical records of a university student who seeks treatment at a campus health clinic. Since the university receives federal education funding, the student's records are subject to FERPA; however, since the records will be used only for treatment, they do not fall within the broader range of "education records."

HIPAA

HIPAA was enacted in 1996 to improve the efficiency and effectiveness of the health care system, and to protect the privacy and security of individually identifiable health information.

Entities covered under HIPAA include health plans, health care clearinghouses and health care providers that transmit health information in electronic form in connection with covered transactions.

HIPAA requires covered entities to protect patients' health information by implementing strict safeguards limiting unauthorized disclosures.

The main differences between FERPA and HIPAA laws are the heightened privacy protection afforded by HIPAA and the increased penalties for HIPAA violations.

HIPAA violations may carry fines from $100 up to $25,000 per year, and HIPAA violators may also be sent to criminal court where the penalties range up to $250,000 and 10 years imprisonment.

HIPAA also has a more complex consent system. To disclose education or treatment records, FERPA generally requires written permission that is signed and dated, and states the purpose of the disclosure.

Under HIPAA, consent authorization must be signed, dated and specifically refer to the information being disclosed and to the people disclosing and receiving the data. That consent authorization also must contain an expiration date and a statement of a right to revoke the permission in writing, and other data.

In certain situations, FERPA and HIPAA regulations may intersect. For example, a school that provides health care to students in the normal course of business, such as through its health clinic, would be a "health care provider" as defined by HIPAA.

The education records and treatment records of the students who undergo mental health or medical treatment at the university health care center would be covered under FERPA. However, the individually identifiable health care information of the clinic's nonstudent patients (such as staff or faculty members) will be subject to HIPAA privacy rules.

When disclosures are permitted under both HIPAA and FERPA

Both FERPA and HIPAA regulations contain certain delineated circumstances under which the contents of education records and protected health information may properly be shared with third parties.

First, it is important to again recognize the distinction between "treatment records" and "education records" under FERPA. By definition, "treatment records" may be disclosed only to professionals providing the student's treatment, physicians or other professionals of the student's choice.

That means that a student may not inspect or review his or her own treatment records, and if the school chooses to allow the student to do so, such records are no longer "treatment records" and instead fall under the definition of "education records" and are subject to all other FERPA requirements.

FERPA permits a postsecondary institution, such as a college or university, to disclose a student's education records to law enforcement or the student's parents if the institution has reason to think the student presents a serious danger to himself or others.

Again, if an institution decides to use "treatment records" for purposes other than treatment — for example, to disclose to a student's parents that the student presents a danger to himself — the records immediately become "education records."

Education records may also be disclosed without student consent for other specified reasons, as listed in title 34, § 99.31 of the U.S. Code of Federal Regulations. They are including but not limited to:

- Determining eligibility for financial aid for which the student has applied;
- For an audit or evaluation of federal or state-supported education programs, or for the enforcement of compliance with federal legal requirements which relate to those programs;
- To assist an accrediting organization to carry out their accreditating functions, and;
- If the disclosure is made to parents of a dependent student in accordance with tax records.

Under HIPAA, a covered entity may disclose protected health information without patient consent if the covered entity in good faith believes the use of disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.

In addition, the disclosure must be made to a person or persons reasonably able to prevent or lessen the threat. (The HIPAA disclosure standard is broader than Michigan's disclosure standard for mental health providers, which imposes a duty for providers to take action if a patient manifests intent of physical violence in certain circumstances.)

Permissible disclosures under HIPAA are listed in title 45, § 164.512 of the U.S. Code of Federal Regulations. They may also be made for reasons including but not limited to:

- Reporting the commission and nature of a crime that resulted in the provision of emergency health care;
- Reporting to public health authorities certain information for the purpose of preventing or controlling disease, injury or disability;
- Reporting child abuse or neglect; and
- Reporting certain adverse events, problem defects or biological product deviations in FDA-regulated products to appropriate FDA officials.

The Virginia Tech tragedy serves as a stark reminder that a murky understanding of privacy laws can have a more devastating outcome than just warning letters and fines. To that effect, all physicians — especially those working in an educational setting — should strive for a full understanding of applicable laws and regulations, and should not be afraid to seek guidance from legal counsel or the appropriate agency when questions arise.

The full report from the Departments of Health and Human Services and Education can be obtained online at www.hhs.gov/ocr/hipaa.

Under the radar

'Wyeth v. Levine' and the stealth revision of regulatory rulebooks that could preclude scores of state-level tort claims

Health Care Justice

By Ross A. Hammersley, Esq.

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The U.S. Supreme Court is poised to radically alter state law tort liability in a manner that could increase the scrutiny of, and possibly malpractice litigation against, physicians everywhere.

In the matter of *Wyeth v. Levine* (Case No. 06-1249), which will be decided before next summer, the Supreme Court will tackle the issue of whether the FDA's approval of the warning language used on prescription drug labels preempts state law "failure-to-warn" claims brought against pharmaceutical manufacturers.

The argument advanced by petitioner, Wyeth Pharmaceuticals, boils down to an assertion that it should be impossible for a pharmaceutical company to be held liable for what a jury determines to be an inadequate drug label, since the language of that label was approved by the FDA.

Despite evidence suggesting that the FDA's approval of Wyeth's drug Phenergan was arguably based on incomplete or inadequate data, *Wyeth* argues that FDA approval should preempt state law "failure to warn" claims, such as the one brought in this case.

Should the court rule in favor of Wyeth and decide that tort claims against drug manufacturers are preempted by a drug's label — even if the existing wording of that label is inadequate — there could be a profound impact on physicians and health law practitioners throughout the country.

Foreclosing this long-standing avenue of relief for injured patients could lead to an increase in medical malpractice litigation against physicians prescribing these drugs. Such a ruling would also remove a strong incentive for manufacturers to correct and update inadequate labels over time, and could lead to a severe decrease in consumer confidence in the ability of the FDA to protect patients from faulty medical drugs or devices.

Case background

Wyeth Pharmaceuticals was sued by Diana Levine, a Vermont musician who, in response to continuing symptoms of headache-related nausea, received an injection of Wyeth's Phenergan.

The label that Wyeth submitted for marketing, and that the FDA approved, included a general warning that intravenous administration of the drug (through either IV drip or IV push methods) could result in "inadvertent arterial injection and gangrene."

However, the label failed to distinguish the level of risk as between these two different intravenous methods of administration, despite the fact that IV push administration carried a significantly higher level of risk than did IV drip.

Unfortunately, it was one such IV push arterial injection that allegedly caused Levine to develop severe tissue deterioration and gangrene in her right arm, leading to its amputation below the elbow and the negligence suit against Wyeth.

Levine alleged, and a Vermont jury agreed, that Wyeth had violated the Food, Drug and Cosmetic Act of 1938 (FDCA) and a state-law *duty to warn* by failing to include in its labeling for Phenergan "'adequate warnings' against 'unsafe dosage or methods or duration of administration or application.'" (Emphasis added.)

Specifically, Levine argued that as early as the 1970s, Wyeth was aware or should have been aware of severe adverse health effects, including multiple amputations, caused by another anti-nausea drug, Pfizer's Vistrol.

Based on those incidents, Pfizer voluntarily removed IV push injection from the accepted administration methodologies for Vistrol. Levine argued that Wyeth had an obligation to follow a similar course with Phenergan, including a voluntary alteration of the language on Phenergan's label so as to ban the IV push procedure completely.

Finally, Levine argued that Wyeth failed to present to the FDA the evidence of the unreasonable risk of "inadvertent arterial injection" associated with IV-push administration of Phenergan.

In contrast, Wyeth argued that the FDA's approval of the Phenergan label precluded Wyeth from making any unilateral revisions to the label's content, and that the FDA's labeling requirements preempt such suits as Levine's for two reasons: that Wyeth could not possibly comply with the common law determinations of individual states while contemporaneously complying with the FDA's labeling requirements; and that state failure-to-warn liability, despite compliance with federal labeling requirements, conflicts with the federal objectives of the FDCA.

Therefore, Wyeth has asked the Supreme Court to set aside the jury's award to Levine and rule that the FDA's "approval of a prescription drug's labeling *preempts* state-law 'failure-to-warn' claims." (Emphasis added.)

Litigation and regulations working in concert

Medical devices and drugs may meet the minimum requirements of the FDCA and applicable regulations while still posing a risk to patients or doctors in unforeseen circumstances or when used for an off-label purpose (i.e., a use inconsistent with the express language approving or authorizing the use of a device or drug).

As such, throughout the 70-year history of the Act, state tort liability and damages have been described as "serv[ing] a complementary purpose to direct government regulation" by providing compensation for injuries and alerting the public to the risks and hazards posed by drugs and medical devices that fall through the cracks of federal oversight.

Although Wyeth contends that there is a conflict between the labeling requirements of the FDCA and state law tort claims, an amicus ("friend of the court") brief filed by former FDA commissioners Dr. Donald Kennedy and Dr. David A. Kessler refutes this assertion, stating, "Until 2002, failure-to-warn litigation was seen by both Congress and FDA as an important adjunct to federal regulation."

Members of Congress similarly filed a brief in support of Levine establishing that state tort suits have been considered complementary to the FDCA by the courts, the FDA and Congress for such a long time that this jointly held understanding has become "well-embedded."

Potential impacts of regulatory preemption

If the Supreme Court issues a decision favoring Wyeth, there are likely to be several foreseeable consequences to both the drug-approval process and health law generally.

First, Phenergan will certainly not be the last drug that obtains FDA approval, only to have its safety called into question by the discovery of unforeseen risks and hazards.

In fact, the *New England Journal of Medicine* recently published a timeline for four such drugs that followed a similar track of initial agency approval followed by subsequent discovery of a variety of drug safety problems: Rosiglitazone, Rofecoxib, Dexfenfluramine and Aprotinin.

Furthermore, the *Journal* points out that FDA approval often involves only "short-term efficacy studies, not long-term safety studies," noting that the FDA is forced to base its approval decisions on manufacturers' own disclosures and revelations because the agency itself has no subpoena power.

A ruling in favor of Wyeth could result in a continuation of inadequate and likely incomplete information on drug safety being provided by manufacturers to both doctors and patients, despite the "approval" of a drug's label by the FDA.

As demonstrated by the voluntary recall of Vioxx (Rofecoxib), the consequences on consumer and professional confidence could be severe.

Second, because people will lose their ability to take legal action against drug manufacturers when the risks associated with such drugs are manifested, another potential impact of a ruling in favor of Wyeth could be an increase in malpractice suits against the physicians who administered the drugs causing the injury or harm to the patient.

Third, the shift from viewing state tort actions as complementary to, rather than in conflict with, regulation is unfortunately not unique to the FDA.

In what some scholars have referred to as "stealth tort reform," or "preemption by preamble," several federal agencies (including the FDA) are now adding language to the preambles of notices in the Federal Register. Such preambles assert that otherwise routine regulatory actions will now be considered to preempt state law tort claims in a broad and, until recently, unprecedented fashion.

If all such tort claims are considered to be preempted, it will be a major reversal of the long-standing and well-settled framework in which state law tort claims serve as a complement to federal regulatory actions.

Not only would a ruling in favor of Wyeth have enormous economic consequences for the pharmaceutical industry, but the reasoning behind this argument could also be extended to a whole host of regulated industries.

This is conceivably why the U.S. Chamber of Commerce described the Wyeth case in *The Wall Street Journal* as "the business case of the century." Therefore, it is clear that the outcome of this case should be closely monitored, not only by doctors and health care professionals, but also by the business community and the public at large, to see just how far this preemption argument will be taken.

Although federal health and safety regulations have operated for decades in concert with civil remedies at the state level, this delicate balance could be upset by a ruling in favor of Wyeth before the end of this Supreme Court term.

Damaged goods

Exclusion of asbestos plaintiff's expert may jeopardize hundreds of cases

By Todd C. Berg, Esq.

Wayne County Circuit Court Judge Robert J. Colombo Jr.'s ruling that excluded the testimony of Dr. R. Michael Kelly of Lansing jeopardizes hundreds of asbestos cases and may mark the end of Kelly's days as a plaintiff's medical expert.

In *Grady Miles v. Sure Seal Products Company, et al.*, on Nov. 19, Colombo granted the defendant's motion to exclude Kelly's "diagnostic opinions" that Miles suffered from asbestos disease. Kelly was to be called as one of the plaintiff's experts.

"This court finds that the plaintiff has failed to sustain its burden of proof that Dr. Kelly's opinions are the product of reliable principles and methods, and that Dr. Kelly has applied the principles and methods reliably to the facts of the Miles case," Colombo said.

The judge explained Kelly hadn't followed the "generally accepted standards governing the diagnosis of asbestos disease" and his asbestos-disease diagnoses had been contradicted by an "overwhelming majority" of hospital radiologists and treating physicians.

James J. Bedortha of Goldberg Persky & White PC in Saginaw, who represents Grady Miles, said he and his partners are studying Colombo's ruling, but it's too soon to say for certain whether he will appeal.

However, he said, an appeal is "very likely."

In the meantime, Bedortha said, Colombo's ruling is significant both for the Miles case and other cases.

"Unless and until the judge's ruling is overruled on appeal," he said, "I'm not inclined to rely on Dr. Kelly's testimony" in the Miles case, other pending cases, or in any future, hypothetical cases.

"It's not my intention to rely on Dr. Kelly's occupational medicine opinions going forward in light of Judge Colombo's ruling," he said.

As such, Bedortha said one of the decisions he and his partners will have to make in the Miles case is whether to find a new medical expert or dismiss.

Bedortha estimated there are 800 to 900 pending cases in which Kelly has provided expert opinions for asbestos plaintiffs and, thus, where Kelly may be vulnerable to challenge.

"This ruling will be clearly used against him elsewhere," he said.

That idea wasn't lost on attorney Edwin Gault of Forman, Perry, Watkins, Krutz & Tardy, LLP, in Jackson, Miss., who represents defendant Sure Seal Products Company.

"Judge Colombo's opinion will have implications in every case in which Dr. Kelly is an expert and has rendered a diagnosis of asbestos disease," he said.

Southfield attorney E. Kelly Cullen of Siemion Huckabay Bodary Padilla Morganti & Bowerman PC, who was co-counsel with Gault in the Miles case, said the number of such of cases is likely higher than Bedortha's calculation.

"I estimate there's 1,200 Michigan cases that involve Dr. Kelly," he said.

Gault said the other cases involving Kelly present the same problems as those that arose in the Miles case.

That's because Kelly uses the same methodology for diagnosing asbestos disease, Gault said.

"There are a number of cases coming up in January that involve Dr. Kelly," he said. "I'm going to be looking at those. I suspect they'll be dismissed."

Grady Miles sued Sure Seal Products Company and other defendants in 2004 for injuries related to asbestos exposure.

To bolster his claim, Miles relied on the diagnosis and opinions of Dr. R. Michael Kelly, who is a board-certified occupational and internal medicine physician.

Subsequently, Sure Seal, arguing that Kelly's methodologies for diagnosing asbestos disease were scientifically unreliable, moved to exclude Kelly's proposed testimony.

After a two-day hearing, Judge Colombo agreed and granted Sure Seal's motion.

The "facts demonstrate that Dr. Kelly's opinion is unreliable and Dr. Kelly is excluded as an expert witness in the Miles case …," said the judge.

Colombo based his ruling on several points.

"Dr. Kelly's diagnosis of asbestos disease in the Miles case is not consistent with the standards for diagnosing asbestos disease," the judge said.

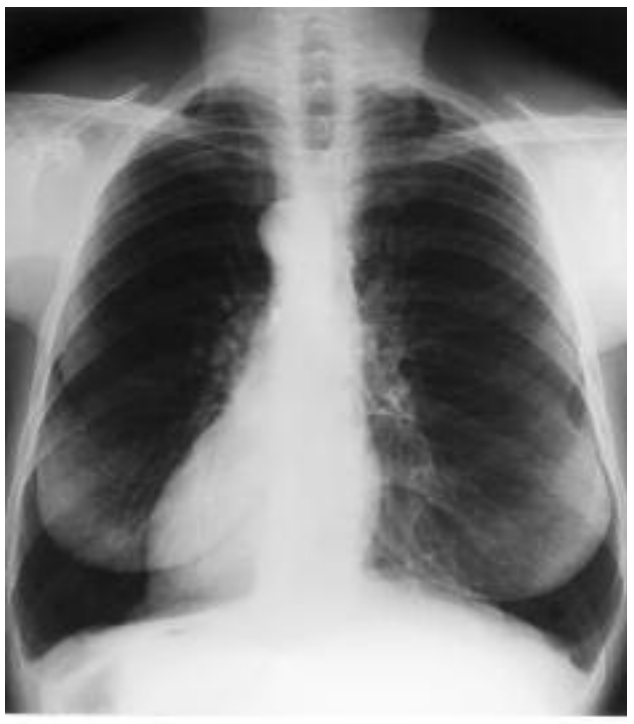
And, Kelly's diagnoses of asbestos disease and its symptoms in a trial group of approximately 80 asbestos plaintiffs were refuted by other medical professionals.

Almost all of the hospital radiologists who interpreted the same plaintiffs' X-rays as Kelly did concluded that there was no asbestos disease, Colombo said.

Plus, the judge said, the treating physicians for the plaintiffs in the trial group "overwhelmingly concluded that plaintiffs do not have the symptoms found by Dr. Kelly or the asbestos disease diagnosed by Dr. Kelly."

Gault said that, while Colombo's ruling will likely lead to future challenges to Kelly's testimony, it offers a valuable lesson to both lawyers and judges.

"When you have a doctor who has rendered as many opinions as Dr. Kelly has, you should examine his reports for reliability," he said. "That means closely scrutinizing the doctor's diagnoses of asbestos disease."



"Judge Colombo's opinion will have implications in every case in which [Dr. R. Michael Kelly, of Lansing] is an expert and has rendered a diagnosis of asbestos disease."

— Attorney Edwin Gault of Jackson, Miss.-based Forman, Perry, Watkins, Krutz & Tardy, LLP, who represents defendant Sure Seal Products Company

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HIPAA

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of the protective order."

According to federal HIPAA regulations, a qualified protective order limits parties' use of protected health information to the litigation at issue, and requires the return or destruction of the information once the litigation has concluded.

Southfield attorney Marc E. Lipton of The Lipton Law Center said the ex parte interview issue is important to plaintiffs, and their lawyers, because they perceive the interview as a defense tool to beat up on the plaintiff's case.

Defense attorneys have used ex parte interviews, he said, "to trick, cajole, and even threaten physicians into providing testimony that [is] favorable to the defense and contrary to the best interests of the patients."

Lipton said he knows some defense lawyers have used such ex parte interview strategies as suggesting that the plaintiff's treating physician may see his liability insurance rates go up if he criticizes the defendant doctor, or "selectively present[ing] facts of the case to bias physicians into reaching improper conclusions."

Schaffer countered that the "possibility or threat of witness coercion or influence exists on both sides," whether the ex parte interview is being conducted by the defense or the plaintiff's lawyer.

So long as the interviews are used for the purpose they were intended, which is to learn "the likely testimony of a potential witness before the time of trial," there is no harm in allowing ex parte interviews, he said.

Ferndale attorney Jana M. Berger of Foley & Mansfield PLLP, who regularly handles HIPAA issues in her commercial litigation defense practice, agreed.

She added that Michigan's long-standing practice of allowing ex parte interviews is justified by the fact that they level "the playing field inasmuch as defense counsel have the opportunity to conduct candid, ex parte discussions with a plaintiff's treating physician just as plaintiff's own counsel is able."

In 1991, five years prior to HIPAA's passage, the Michigan Supreme Court decided *Domako v. Rowe*, which specifically allowed defense attorneys to meet with plaintiffs' treating physicians as part of the discovery process.

In 2005, Andrea Holman filed a wrongful-death medical-malpractice lawsuit against Dr. Mark Rasak on behalf of Linda Clippert's estate.

When Rasak asked for Clippert's medical records, Holman gave them to him. But she refused, on HIPAA grounds, to allow Rasak's lawyer to conduct an ex parte interview with Clippert's doctor.

Rasak asked the court for a qualified protection order to allow the ex parte interview, but the trial court denied the request in 2007, concluding "'the HIPAA provision relative to a protective order only … pertains to documentary evidence' and 'that HIPAA does not authorize ex parte oral interviews.'"

The Court of Appeals reversed and remanded.

Acknowledging *Domako* and pre-HIPAA Michigan law permitted ex parte interviews, the court said HIPAA didn't do away with them, but set forth the circumstances under which they could occur.

In cases such as *Holman*, in which the plaintiff refuses to consent to the ex parte interview, one of the defense attorney's options is to submit a discovery request that is accompanied by proof the defense attorney has made reasonable efforts to secure a qualified protective order, the judges said.

The court rejected the argument that neither HIPAA nor the federal HIPAA regulations specifically authorized ex parte interviews.

Oral or spoken information isn't excluded "from the regulations governing disclosure of protected health information," the court said.

Bloomfield Hills attorney Julie McCann O'Connor of O'Connor, DeGrazia, Tamm & O'Connor, P.C., who represents Rask, said that, although HIPAA changed some of the procedural aspects of securing ex parte interviews, *Holman*'s application of HIPAA is right in line with what Michigan law has always been.

"The policy behind Michigan law allowing ex parte interviews is not inconsistent with HIPAA's structure," she said.

McCann O'Connor said Michigan policy, which has recognized ex parte interviews as a "cost-saving method of informal discovery" that allowed "equal access to relevant evidence," was reinforced by the Supreme Court's decision in *Domako*.

Southfield attorney Joseph L. Konheim, who represents the plaintiff in *Holman*, declined to comment.

According to the Michigan Court of Appeals Web site, no application for leave to appeal to the Supreme Court has been filed as of Nov. 26.

Caveats to the ex parte interview issue under HIPAA

Schaffer

Olsman

Lipton

Berger

Although the Michigan Court of Appeals has held that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) permits ex parte interviews between defense attorneys and plaintiffs' treating physicians, that's not necessarily the end of the story.

Questions persist, such as:

- Are treating physicians free to decline to participate in ex parte interviews with defense attorneys?
- Are there any rules that prevent a treating physician from recording (video, audio, notes) the ex parte interview and sharing the recording with the plaintiff and-or plaintiff's counsel?

Michigan Lawyers Weekly posed those questions to HIPAA specialists.

All agreed that a plaintiff's treating physician doesn't have to participate in an ex parte interview with defense counsel — or even plaintiff's counsel — if he or she doesn't want to.

The comment of Flint attorney Robert H.S. Schaffer, who is president of the Michigan Defense Trial Counsel, is representative.

"Treating physicians are still free to decline, and some do, participating in ex parte interviews regardless of who requests the encounter," he said.

The same unanimity is not evident in the specialists' answers to the second question, Are there any rules that prevent a treating physician from recording (video, audio, notes) the ex parte interview and sharing the recording with the plaintiff and-or plaintiff's counsel?

- "Not that I am aware of." Berkley attorney Jules B. Olsman, chair of the State Bar of Michigan's Negligence Section and president of Olsman Mueller, P.C.
- "No. Michigan law permits one party to a conversation to record that conversation, and does not even require disclosure of the fact of the recording." Southfield attorney Marc E. Lipton of The Lipton Law Center
- "Notes — no problem. As with any other statement, recording with permission is permitted." Flint attorney Robert H.S. Schaffer, president of the Michigan Defense Trial Counsel
- "This is tricky. Arguably, a treating physician could run the risk of an unauthorized disclosure in this instance if the HIPAA compliant qualified protective order does not permit the recording and disclosure to plaintiff's counsel." Commercial litigation defense attorney Jana M. Berger of Foley & Mansfield PLLP in Ferndale

"Put the time into your NOIs. By telling the defendants your theories about who did what wrong, you'll force them to investigate."

— Elliot B. Grysen

Nonparty fault

Continued from page 1

do, he said, "so the NOI should've tipped them off that there was a possible defense out there."

"Consequently," he said, "they lose out on the benefits of a nonparty fault notice, which is that a jury can assign fault to the provider, but the provider can't be held liable and the plaintiff can't collect."

Still, said Grand Rapids attorney Jon D. VanderPloeg of Smith Haughey Rice & Roegge PC, who represents Battiste and the other defendants in *Snyder*, the ruling won't prevent his clients from asking the jury to return a "no cause of action" verdict based on the nonparty's negligence.

Michigan law requires that fault and, thus, liability be apportioned among parties and nonparties. But the Michigan Court Rules require that, before a jury or a judge can assess a nonparty's fault, the defendant must serve timely notice of "a claim that a nonparty is wholly or partially at fault," which the Court of Appeals said the defense did not do.

Medical-malpractice defense attorney Robert P. Siemion of Siemion Huckabay Bodary Padilla Morganti & Bowerman PC in Southfield said *Snyder* sheds light on an important, albeit unusual, aspect of NOIs.

"If the NOI says that doctors A, B, and C committed malpractice, but only Dr. A is sued, then the defense lawyer representing Dr. A should look hard at Dr. B and Dr. C for nonparty fault purposes," he said.

VanderPloeg said in an e-mail statement the Court of Appeals decision "turns the question of diligence on its head."

He said it was inconsistent to criticize the defendants for not recognizing sooner the nonparty's potential fault, yet overlook the fact that the plaintiffs didn't, ultimately, sue the nonparty because their investigation "had not discovered evidence to support a claim against the other doctor."

In February 2005, Margaret Snyder sued her doctor, Dr. Jennifer Battiste, Caledonia Family Practice and Advantage Health Physicians for failure to diagnose uterine cancer.

In October 2006, 19 months after the defendants filed their answer to her complaint, they asked the court to allow them to file a late notice of nonparty fault.

Michigan Court Rules require such notices to be filed within 91 days of the answer being filed, unless the defendant can show "reasonable diligence" wouldn't have brought the nonparty to its attention any sooner.

Snyder objected to the defendants' motion because the defendants knew years earlier about the nonparty, the radiologist at Saint Mary's Mercy Medical Center who performed an ultrasound on Snyder.

Snyder said she alleged in her July 2004 NOI that the radiologist had misinterpreted the ultrasound results, and that Battiste and Snyder relied on that misinterpretation. Plus, she said, the lawyer who represented Battiste and the other named defendants had represented St. Mary's at the time the NOI was filed.

The defendants countered that they didn't have reason to suspect the radiologist may be at fault until after his deposition in April 2006. Snyder's lawyer, they contended, led them to believe the radiologist wasn't at fault when, in 2004, Snyder's lawyer said he wasn't going to sue the radiologist because he hadn't found evidence to support a claim.

The trial court allowed the defendants to file their notice, but the Court of Appeals reversed.

The plaintiffs' NOI, and even their complaint, laid out for the defendants the "potentially viable defense or partial defense … that (the radiologist) misdiagnosed the mass and Dr. Battiste merely relied on the misdiagnosis," said the *Snyder* panel.

"The exercise of reasonable diligence would have involved undertaking some direct and independent action to investigate this potential defense, yet, despite having 'reason to suspect' that this potential defense existed, defendants undertook no independent investigation," the Court of Appeals judges concluded.

Grysen said *Snyder* teaches medical-malpractice plaintiffs' lawyers a good lesson.

"Put the time into your NOIs," he said. "By telling the defendants your theories about who did what wrong, you'll force them to investigate."

And, as the *Snyder* opinion makes clear, Grysen said, "Shame on them if they don't."

VanderPloeg said his clients haven't decided whether they will seek leave to appeal to the Michigan Supreme Court.

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