# Healthcare Risk Management™

**April 2010:** Vol. 32, No. 4
Pages 37-48


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Financial Disclosure: Author Greg Freeman, Managing Editor Karen Young, Associate Publisher Russ Underwood, and Nurse Planner Maureen Archambault report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.


# Tort reform yields sharp drop in med-mal for TN; could be temporary

*Experience may hold lessons for other states seeking reform*

Risk managers across the country cheered when they heard of dramatic decrease in the number of malpractice lawsuits filed in Tennessee after reform efforts there, wondering if the same experience might be replicated in their own states. The results are encouraging, say the analysts consulted by *Healthcare Risk Management,* but it still is not clear whether the decrease is temporary or will be a lasting effect.

The initial experience with Tennessee's malpractice reform has been positive for health care providers, says **Craig Sanders,** JD, a partner with the law firm of Rainey Kizer in Jackson, TN, where he represents health care systems in malpractice litigation. Statistics from 2009 suggest that the state is climbing back from the darkest days when the American Medical Association (AMA) declared the state to be a medical liability "crisis state."

On Feb. 14, 2006, the AMA announced that Tennessee was the 21st state designated by that organization as "in crisis" due to a deteriorating medical liability climate that was jeopardizing patients' access to care. The AMA urged state legislators to enact reforms, noting that from 1995 to 2005, Tennessee physicians saw liability premium increases as high as 127% to 212%. The high cost of liability insurance was pushing many physicians to relocate to other states, leaving many communities without needed specialists, according to the AMA.

## EXECUTIVE SUMMARY

Tort reform efforts in Tennessee have produced a 60% drop in medical malpractice cases, and analysts say the experience could bode well for other states seeking to reduce malpractice costs. The key question, however, is whether the sharp drop is only temporary.

- Tennessee required 60 days notice before filing suit.
- Plaintiffs also must obtain a certificate of merit.
- More cases may be filed after attorneys become accustomed to the new rules.


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State legislators listened and passed a tort reform bill in 2008. Rather than enacting caps on damages, which may have prompted more resistance from tort reform opponents, the legislature created provisions intended to make it more difficult for patients to sue health care providers, Sanders explains. Under the 2008 law, plaintiffs now must give 60-day notice before filing a malpractice suit, and they must provide a certificate of merit from a medical professional stating that the allegations are legitimate.

The reform provisions were in effect for the entire year in 2009, and the results indicate that they are indeed acting as speed bumps for plaintiffs. Though state agencies and legal organizations have reported conflicting numbers, with the most common statistic being a reduction of 60% in the number of suits filed, Sanders says attorneys in the state agree that the number of medical malpractice cases has dropped sharply.

"I've heard different numbers as to how much the filings have dropped, but I can tell you from the front lines, it has been a significant decrease," Sanders says. "I think plaintiffs' attorneys, some of them, saw the amendments and just said it's getting too complicated. They didn't want to make a mistake and get sued for malpractice themselves. So, I think some of the attorneys who were on the periphery, filing a malpractice case every once in a while, just stopped filing them altogether."

Sanders suspects that the requirement for a certificate of merit has had more impact than the 60-day notice rule. Previously, there was no impetus for plaintiffs' attorneys to seek a confirmation that the case had merit, so they waited until well into the litigation process to procure expert opinions.

"It would have been good practice to do that early on, but in reality, not all attorneys were doing that," Sanders says. "Those practitioners either got out of malpractice work or they saw the number of their cases decrease significantly when they started asking medical professionals if their cases had any merit. They started seeing the warts and the problems in cases they might have just filed without question before the amendments."

The drop in cases has not yet been reflected in the cost of malpractice insurance for health care professionals, however. Insurers may be waiting to see if the number of cases will remain low, he says. And their hesitation may be warranted, as Sanders explains that the significant decrease in malpractice suits could be temporary.

"We have to think about whether this is a permanent decrease. Many people assume it is, but I'm not so sure," he says. "I think there will be some increase, but the big unknown is how much. The numbers may not go back to the former levels, but I expect to see some increase."

## Artificial dip in numbers?

A major reason Sanders expects some rise in the number of cases is that the extent of the decrease in 2009 may have been exaggerated by the way

**Healthcare Risk Management**® (ISSN 1081-6534), including HRM Legal Review & Commentary™, is published monthly by AHC Media, LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304.

**POSTMASTER:** Send address changes to Healthcare Risk Management®, P.O. Box 740059, Atlanta, GA 30374.

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Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is valid 24 months from the date of publication.

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plaintiffs' attorneys rushed to file cases before the tort reform took effect. Attorneys filed all their current cases as quickly as they could in 2008, so they would not have to comply with the new rules in 2009, Sanders explains.

"That meant the numbers went up in the latter part of 2008, down in 2009, and the difference looks even bigger," he says. "I also suspect the number of cases may increase as plaintiffs' attorneys get used to the new rules. The amendments weeded out some who didn't want to bother with the added requirements, and probably more have put on the brakes temporarily. But I think over time they will get used to working with the rules, and they will get more aggressive."

**Neil Ekblom**, JD, a health care attorney with the law firm of LeClair Ryan in New York City, also questions whether courts in Tennessee will water down the tort reform rules over time. New York state also requires a certificate of merit, but court rulings have diminished the rule's impact, he notes.

"Courts took the teeth out of it, because it was interpreted as a ministerial or technical requirement, which if not followed to the letter did not warrant dismissal," Ekblom says. "We also had a dip in the number of suits when a certificate of merit was required, but then that number went back up to normal once the courts interpreted the statute in a liberal fashion."

New York state also requires a 90-day notice, similar to the 60-day notice in Tennessee, and Ekblom says that statute has been interpreted more strictly. There are still exceptions that weaken the impact, however.

"The courts here are very antsy about depriving plaintiffs of their day in court on a technicality, and you probably will see the same thing in Tennessee," he says. "Both of these provisions will lose their teeth over time, and the number of suits will come back up again. It is not enough to have these laws on the books. It's about how they are interpreted, and that can change over time."

## Impact may be limited

Ekblom points out that the certificate of merit also has limited impact when, as in New York, any physician can declare the case to have merit, even if that physician is in a different specialty or otherwise has no expertise in the case at hand. In addition, the Supreme Court of the state of Washington recently struck down the statute requiring a certificate of merit there, causing some attorneys to wonder if similar rulings might follow in other states. (**See p. 40 for more information on that ruling.**)

**Stuart Ratzan**, JD, managing shareholder with the law firm of Ratzan & Rubio in Miami, who specializes in medical malpractice cases on the plaintiff side, doubts that either of the Tennessee provisions will result in long-lasting declines in medical malpractice cases.

"Most cases, in almost every state, require the plaintiff to retain someone who can testify at trial that there was negligence. There is very little incentive for any lawyer to initiate and pursue a case for someone unless it is a merit-worthy case, particularly for those working on contingency," he says. "From a business point of view, it should be a good case with merit, or else he's going to lose his shirt."

At best, Ratzan says, the certificate of merit moves up the deadline for getting an expert witness who can certify the case is based on a reasonable allegation of malpractice.

"I don't see the certificate of merit being a trigger for a substantial decrease in the number of malpractice cases filed," he says. "It may be that Tennessee slowed it down as people had to get used to the new system, but I don't expect a huge impact in the long run."

Expecting to see a lasting effect, even if not as good as 2009, Sanders says the important lesson from the Tennessee experience is that damage caps are not the only way to enact tort reform. Other, less contentious strategies may be more effective.

"Sometimes reform ideas, like caps on damages, can't pass because of the politics in the state. But other ideas, like the certificate of merit, can get passed, because both sides of the political spectrum can get behind it," Sanders says. "I think what we've seen in Tennessee is that the less grandiose ideas can still have a substantial effect, and in the end, that is more productive than pushing for something that may never get through the legislature." ■

### SOURCES

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# Washington court says no to certificate of merit

In a ruling that has risk managers and attorneys across the country watching for repercussions, the Supreme Court of Washington state recently ruled that requiring a certificate of merit for a medical malpractice case is unconstitutional.

The court ruled on the case of *Putnam v. Wenatchee Valley Medical Center,* which had originally been thrown out by a lower court because the plaintiff did not file a certificate of merit along with her initial complaint. According to the court ruling, the requirement goes too far and inhibits access to the courts. By requiring the plaintiff to submit evidence before discovery, an undue burden was placed on the plaintiff, the court ruled. *(**Editor's note:** For the full text of the ruling, go to http://www.wrsattorneys.com/library/Washington_Cert_of_Merit_opinion.pdf.)*

Plaintiffs' attorneys in Washington welcomed the ruling, and those in other states saw it as an indication that other states might follow suit. **Benjamin W. Glass III**, JD, a plaintiff's attorney with Benjamin W. Glass & Associates in Fairfax, VA, says the court struck down the rule, because it unfairly denied some plaintiffs their day in court.

"Often, the cost of hiring an expert to simply look at the case before filing excluded not those with frivolous lawsuits — simply those with shallow pockets," he says. "Regardless whether or not the rule was effective, it is now a moot point, as the court has tossed it out. This is an example of supposed tort reform, but the legislators who are trying to cut back on frivolous lawsuits have to understand that they don't have the authority to impose restrictions on access to the courts."

## Case going to trial court

The court's ruling means the case will be sent back to the trial court, and plaintiffs will no longer be required to file a certificate of merit in Washington.

"Now, at least the case will be allowed to go to trial and be heard on its merits rather than thrown out haphazardly," Glass says.

The plaintiff alleged that the defendant medical center and several of its employees negligently failed to diagnose her ovarian cancer. The plaintiff further alleged the delay in diagnosis caused her to miss the opportunity to undergo early treatment, which would increase her likelihood of long-term survival.

In the Washington case, the trial court dismissed the plaintiff's medical malpractice claim for failure to file a certificate of merit, as required by Washington statute RCW 7.70.150, and the plaintiff appealed directly to the Washington Supreme Court. The plaintiff challenged the constitutionality on several grounds, primarily that it unduly burdened her right of access to the courts, according to the court ruling.

The court agreed, saying that it may not be possible to obtain the evidence necessary to obtain the required certificate of merit without the opportunity to interview health care workers or review procedural manuals, which would be possible later through discovery.

## Other states at risk

Any state requiring a certificate of merit could see the same court ruling that struck down the statute in Washington, says **Stuart Ratzan**, JD, managing shareholder with the law firm of Ratzan & Rubio in Miami, who specializes in medical malpractice cases on the plaintiff side.

"This legislation could be declared unconstitutional in any state, at any time. It depends on the particulars of the legislation and the makeup of the court," Ratzan explains.

The likelihood of striking down such a rule depends greatly on local politics and public mood, he says. Ratzan points out that Florida has required a certificate of merit for 20 years, and it has never faced significant challenge in court; and he doesn't expect it ever will. However, caps on damages are challenged much more regularly in any state that enacts them, because they are more universally opposed by some constituencies, and the legal defense for them is less sound.

"They pose a troublesome constitutional issue in most states and are more vulnerable, much more apt to draw a challenge in most states, because they pose more of a threat to a plaintiff's rights than a certificate of merit," he says. "But we've seen in Washington that some courts will strike down the certificate as well. It could happen anywhere." ■

### SOURCES

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# Psychiatry patients can increase liability risks

Risk managers who take a good look at their organization's psychiatric treatment may find reason to worry, because the risk mitigation that works in other areas might not be as effective in this field. The standard of care is more difficult to define in this field than in most others, and there is a tangled web of state and federal regulations that apply, not to mention the legal minefield that can come with involuntarily admitting some psychiatric patients.

One problem is that the concept of the standard of care is quite broad in psychiatry, says **Alan Lambert**, MD, JD, chair of health care practice with the law firm of Butzel Long in New York City. In most other medical fields, the standard of care can be defined with relative certainty, but this is more complicated in psychiatry, because patient rights are deeply entwined in treatment decisions.

"There also is a whole layer of appeals processes for patients to exercise their rights, and then there is accreditation by state agencies, The Joint Commission, CMS. All of that feeds back onto the determination of the standard of care when malpractice is alleged," he says. "The multiple obligations create an additional layer of liability beyond the traditional common-law malpractice standards."

## Many factors involved

Determining the standard of care in psychiatry requires drawing on a number of factors, according to a recent study by **Carla Rodgers**, MD, clinical assistant professor at the University of Pennsylvania School of Medicine in Philadelphia.[1] To a larger extent than in other specialties, the standard of care in psychiatry is dictated by a number of determinants of standard of care, which include court opinions, hospital policies and procedures, psychiatric literature, and state and federal guidelines, she says.

Clinical publications determine the standard of care, of course, but in psychiatry, state and federal legislation and guidelines also are important. "State involuntary commitment laws, for instance, determine how long a patient may be held in a hospital against his will before some type of hearing must take place to decide how long the patient will continue to be held," Rodgers wrote. Involuntary length of stay is a legal issue, for instance, and the standard of care is not determined solely by the psychiatrist.

One of the pitfalls regarding standard of care is interpreting it to mean "exactly what I would do under those circumstances," says **Stephen Dinwiddie**, MD, a professor and director of the Law and Psychiatric Medicine Program at The University of Chicago Medical Center. Given the range of opinion often seen in psychiatry, the standard of care must be defined more broadly than that, he says.

"Another problem is that there is often a significant gap between what is known to be best practice and the treatment actually rendered," Dimwiddie says. "Standard of care is not the same as the optimal level of treatment. It's more like the minimally acceptable level of treatment."

## Involuntary stays bring risks

Most states have statutory limitations on extended involuntary length of stay, Lambert says. One example is the Pennsylvania Mental Health Procedures Act, mandating a judicial hearing within 120 hours of an involuntary hospitalization. The state laws typically include a well-defined, specific process for involuntary admissions, Lambert says. Failing to comply with any step in that process creates a significant liability risk for the provider, he says.

In New York state, for instance, a state service provides lawyers to meet with patients who have been involuntarily admitted to determine if the patient would like a hearing before a judge. And if the patient has difficulty exercising that right, the legal service may request a hearing on his or her behalf.

"So, it is very important that the hospital have good medical records for involuntary psychiatric hospitalizations," he says. "If they fail to follow that process and cause a violation of the patient's

### EXECUTIVE SUMMARY

Risk managers may find psychiatry more challenging than other fields when it comes to defending malpractice allegations and avoiding regulatory sanctions. The standard of care can be harder to define.

- The Joint Commission and other organizations are promulgating new standards for psychiatry.
- Involuntary admissions require strict adherence to legal requirements.
- Workers' compensation claims can be increased with psychiatric patients.

legal rights, they can be subject to liability on that basis."

Self-examination can be your best defense, Lambert says. Too many health care providers forego examining their own data to look for exposures in psychiatric care, he says.

"The hospital needs to have a team that involves someone in senior management, possibly the director of psychiatric services or chief medical officer, along with administrative and health care providers, who constantly review the Joint Commission standards and other criteria to make sure you're in compliance," Lambert says. "You have to drill down to the patient level with random audits and charts. It also is crucial to review cases with adverse events, not only to bring that particular patient back into compliance with the standard of care, but to make the necessary modifications in policies and procedures to be sure other patients are in compliance."

Lambert points out that The Joint Commission has become much more active in collecting quality and patient safety data from institutions providing psychiatric care, which means that risk managers must be aware of the picture that data are painting for regulators.

"Sometimes risk managers can do it on their own, and sometimes they need to hire outside consultants; but they must manage this data in a way that presents their institution in the best possible light to The Joint Commission, CMS, and state regulators, in order to avoid being sanctioned," he says.

## Document thought process

Psychiatric patients can pose a liability risk not usually seen by other patients, says **Charles Kutner**, JD, an attorney in New York City who focuses on malpractice defense. For instance, the psychiatric patient can lead to workers' compensation claims by employees if the patient becomes violent. There also can be third-party liability if the patient harms another person; the health care provider can be sued for not preventing the assault.

"The duty ordinarily ends with the patient, but psychiatry is different in this regard," he says. "Third-party liability seems to be opening up more, especially if you had any kind of knowledge that the patient would harm another."

Dinwiddie stresses that good documentation is crucial to proving that a disputed treatment decision was based on sound reasoning. If the plaintiff alleges later that the psychiatrist erred in treating the patient, the defense must be able to show that the decision met the standard of care, even if other professionals might disagree. There usually is more debate and more room for disagreement on treatment decisions in psychiatry than in internal medicine, for instance.

"It's a lot easier after the fact to criticize a decision, but it becomes a lot more difficult to criticize your decision if you have memorialized your thought process and laid out your thought process in favor of or against a course of action," he says. "Even if the decision turns out not to have been correct, as when a patient is discharged and then goes and takes his life, it is more difficult to second-guess that decision if the physician has been careful to document what steps were taken to prepare the patient and why it was a reasonable decision at the time."

## Medication claims rising

Kutner says a growing area of concern is liability related to medications that produce suicidal ideation and behavior.

"Obviously, the defense to those cases is that you can't stop everyone intent on killing themselves, but there are some medications that produce side effects you must monitor very closely," he says. "It's the medication cases we're seeing more and more of lately."

Good documentation also is key in those cases. The defense must be able to show that the psychiatrist explained, specifically and with great emphasis, that the medication can produce suicidal behavior and what symptoms to watch for, he says. It is important that the warning be conveyed to the parents or other caretakers of the patient as well.

"Psychiatrists are notorious for writing notes that no one else can read," Kutner says. "That can't happen in this situation. The documentation must

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be extremely clear that you warned the patient and the parents and stressed the danger, the need to monitor and act, if necessary. It will all come down to what is in the notes."

**REFERENCE**

1. Rodgers C. Keys to avoiding malpractice standard of care in psychiatric practice. *Psychiatric Times* 2009; Vol. 26, No. 12. ■

# Growing set of standards for psychiatric care

The Joint Commission has been working closely with several other organizations, including the National Association of Psychiatric Health Systems and the National Association of State Mental Health Program Directors, to collect data and further define the standard of care in psychiatry, notes **Alan Lambert**, MD, JD, chair of health care practice with the law firm of Butzel Long in New York City. The groups are developing inpatient psychiatric services core measurement sets that will apply to the standard of care. *(**Editor's note:** For more information on those standards, go to http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/Hospital+Based+Inpatient+Psychiatric+Services.htm.)*

For instance, the basic standard for admissions screening specifies that the patient must be assessed for certain criteria, starting with the potential for violence, Lambert explains. The patient also must be assessed for substance abuse, psychologic trauma, and psychiatric strengths that may affect the treatment process.

Other issues addressed in the standards are restraint, seclusion, and patients discharged with multiple antipsychotic medications.

"Another area they're looking at is the post-discharge continuing care plan," he says. "They want to see that there is a plan documented in the medical record. That is important for accreditation, but it also feeds back into the standard of care and liability."

The continuing care plan must be communicated effectively to subsequent health care providers, Lambert says. Failing to do so can increase the risk that the patient will be rehospitalized soon or will harm him- or herself or others.

"Risk managers should be worried about this at a number of levels. First is the accreditation at a state and federal level, because not only do you have the risk of malpractice litigation, but these groups also can come in and levy significant fines and penalties," Lambert says. "Also, once you start putting some of these standards out there, plaintiffs' attorneys start looking at them and trying to feed the standards back into their claims to buttress their allegations of breaches of the standard of care." ■

# MMSEA Section 111 brings headaches for RMs

If your health care organization is self-insured, the government is holding up a new hoop and waiting for you to jump through it.

Known as MMSEA Section 111, the rule requires that self-insured health care providers submit data on all Medicare-eligible participants and make the appropriate benefit determinations. The Centers for Medicare & Medicaid Services (CMS) has publicized the rule extensively, but as deadlines loom, risk managers must ensure they are ready to comply.

Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) adds new mandatory reporting requirements for group health plans (GHPs), nongroup health plans (NGHPs), and for liability insurance (including self-insurance), explains **Saghi Fattahian**, JD, an attorney with the law firm of Morgan Lewis in Chicago.

The MMSEA imposes the reporting obligation of certain data elements upon the Responsible Reporting Entity (RRE). Generally, the RRE on a fully insured arrangement is the insurer, and on self-insured arrangements, the RRE is the plan sponsor, Fattahian explains. The purpose of the mandatory reporting obligation is to enable CMS to pay appropriately for Medicare-covered items and services furnished to Medicare beneficiaries by

**EXECUTIVE SUMMARY**

Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 brings new reporting requirements to health plans and self-insured entities. The rule is intended to ensure that Medicare is a secondary payer.

- Large penalties are possible if the provider fails to report properly.
- The rule will affect many health care providers that self-insure.
- CMS still has not said whether write-offs after adverse events will trigger reporting.

determining primary vs. secondary payer responsibility. In the NGHP context, the reporting obligations alert CMS to settlements or other payments made to Medicare beneficiaries that compensate the Medicare beneficiary for Medicare-covered items and services.

## Rule intended to help Medicare

The rule is intended to help Medicare with its goal of being the second payer, behind other insurers, whenever possible, explains **Diane Wilkerson**, senior vice president, CPHRM, part of the national clinical health care consulting team with the consulting firm Marsh in Charlotte, NC.

"CMS hasn't given us final guidance on several important issues, which might create the obligation to register and comply with Section 111, one of which is the question of risk management write-offs," Wilkerson says. "It has been common practice for risk managers and claims managers to offer a write-off of patient charges after an adverse event, as a way of making amends and helping smooth out the situation. If they're dealing with a Medicare beneficiary, the question becomes whether those write-offs are reportable under Section 111."

CMS has not yet provided an answer to that question. Wilkerson says she advises health care providers to start thinking about how they would collect that information if it is deemed reportable.

"Risk managers don't hear every time somebody tells the patient they will make sure the charges are waived," Wilkerson says. "This has been one of the unsettling parts of this rule, because we just don't have an answer yet."

All GHPs began official reporting on Oct. 1, 2009. All NGHPs are expected to begin official reporting by July 1, 2010. CMS recently announced an important deadline change, extending the date for reporting MMSEA Section 111 claim input files to CMS until Jan. 1, 2011. CMS advised all NGHP RREs that the date for first production NGHP Input Files has been changed from April 1, 2010 to Jan. 1, 2011.

CMS also has posted the latest version of the "Section 111 NGHP User Guide" and a number of alerts relating to particular NGHP policy issues, as well as an alert for NGHP RREs describing the steps those RREs can take to assure their ongoing compliance with the Section 111 reporting requirements. *(**Editor's note:** For those alerts and other MMSEA Section 111 information, go to http://www.cms.hhs.gov/MandatoryInsRep/04_Whats_New.asp#TopOfPage)*

To comply with Section 111, RREs must first register with CMS. **(See p. 45 for more information on registering.)**

## Health providers affected

The rule will affect many health care providers, says **Vickie Patterson**, an associate director in the Atlanta office of Protiviti, a risk consulting firm. She explains that the MMSEA Section 111 includes in the definition of a "Group Health Plan organization that must report under Section 111" an entity serving as an insurer or third-party administrator (TPA) for a group health plan that is self-insured and self-administered, a plan administrator, or fiduciary.

"Many health care providers are self-insured for employee medical benefits, as well as workers' compensation. Most utilize TPAs to administrate the health and workers' comp plans," she says. "In these cases, the TPA has the responsibility for the reporting requirement. For providers with self-administered plans, they bear the reporting responsibility."

These providers may contract with an agent to submit reports on their behalf; however, the accountability for submitting the reports in the manner and form stipulated by the government and the accuracy of the information will rest with the provider.

CMS will provide information on the format and method of identifying agents for reporting purposes, Patterson explains. If an agent is used, the provider also will need to develop communication protocols. The Medicare Secondary Payer Recovery Contractor (MSPRC) will issue demand letters for repayment if Medicare has erroneously paid a claim.

"Failure to repay the amount promptly can lead to the MSPRC reporting the debt to the Department of the Treasury for offset and ultimately the Department of Justice for legal action if payment is severely delayed," Patterson says.

To the extent they have not yet done so, self-insured providers will need to implement internal policies and adequate procedures to identify, collect, and submit data on all Medicare-eligible participants and to make the appropriate benefit determinations, Fattahian says.

The penalty for failure to report is $1,000 per day per Medicare beneficiary claimant for any failure to report settlements, awards, or other payments to Medicare beneficiaries as required.

In light of the new mandatory reporting requirements for NGHPs, companies must establish and

implement protocols to collect Medicare information from claimants and CMS to determine whether a claimant is a Medicare beneficiary and to report settlements or amounts paid under any of the NGHPs to Medicare beneficiaries in a timely manner. In a litigation context, consideration should be given to the language contained in settlements and release agreements, Fattahian says.

The collection of some data elements, such as a participant's health insurance claim (HIC) number or Social Security numbers, which TPAs may not currently be using to identify a participant, may prove to be challenging, Fattahian says.

"The data collection will likely require a cooperative process between the plan sponsor and the service provider," she says. "This process will add an additional administrative expense, which the insurer or TPA will want to pass on to the plan sponsor, along with a requirement that the plan sponsor indemnify the insurer or TPA for any failures to identify and report all of the Medicare-eligible participants."

Plan sponsors should request adequate assurances in writing that their insurer or TPA is assuming responsibility for the data collection and reporting process, Fattahian says. Plan sponsors currently in negotiations with a service provider should negotiate the cost and responsibility for the data collection and reporting process and ensure that the responsibility for the process is clearly stated in the service agreement, she advises.

Wilkerson cautions risk managers that they must make sure defense counsel contracted to settle claims with Medicare beneficiaries are up to speed with Section 111.

"What's required now in settling a claim is no more hiding behind the veil of claiming you didn't know there were Medicare payments involved," Wilkerson says. "Medicare may have been paying bills for a couple of years without knowing there was a claim or a lawsuit filed. All this forced reporting will alert Medicare to the fact that they should be secondary." ■

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## Must register with CMS to comply with MMSEA

To comply with the reporting requirements of MMSEA Section 111, an affected health care provider must first register with the Centers for Medicare & Medicaid Services (CMS) Coordination of Benefits Contractor (COBC).

The following information is summarized from the CMS web site at http://www.cms.hhs.gov/MandatoryInsRep/01_Overview.asp#TopOfPage.

During registration, the responsible reporting entity (RRE) must identify an authorized representative. This will be an employee of the RRE who has legal authority to act on behalf of the RRE. The authorized representative registers the RRE on the COBC secure web site (COBCSW) at www.section111.cms.hhs.gov.

The authorized representative does not have to be responsible for all future reporting. He or she may identify an agent who will be responsible for reporting after registration. CMS will provide a unique RRE identification number and a secure folder on the COBCSW for the RRE. The RRE will upload the required reports into this folder. ■

## Tread carefully when police ask for patient info

It's a common scenario in any health care facility, especially hospital emergency rooms: The local police ask the nurse or doctor for information about a patient who is either a suspect, a victim, or a witness to a crime. Or perhaps the risk manager receives a more formal request for records. How much can you tell them without violating the Health Insurance Portability and Accountability Act (HIPAA)?

Health care providers must be careful not to react too quickly to such requests with either a positive or negative response, cautions **Patrick Hurd**, JD, senior counsel and leader of the health care industry group with the law firm of LeClair Ryan in Norfolk, VA. Hurd also is a former hospital risk manager.

HIPAA compliance has been drilled into everyone working in health care so much that the initial response to a police request might be an automatic no, but that would be a mistake, Hurd says.

"We sometimes overreact and say we can't disclose anything. That's not the case," he says. "When I was risk manager in a hospital, I made sure we trained our people in what you can disclose without the consent of the patient, the things you must disclose by state law, and the things you can disclose only if you [receive] permission of the patient or guardian."

## HIPAA allows disclosures

HIPAA was never intended to prevent necessary communication with law enforcement and allows certain disclosures to police, but the details of day-to-day compliance can be tricky, says **Gerry Hinkley**, JD, co-chair of the health care industry team with the law firm of Pillsbury Winthrop in San Francisco, who regularly counsels clients on HIPAA-related issues. (**See p. 47 for the law enforcement exclusions in HIPAA.**)

"HIPAA provides a clear road map without requiring a subpoena for disclosure to law enforcement of protected health information by HIPAA-covered entities," he says. "However, HIPAA does not pre-empt more restrictive state laws, so HIPAA-covered entities are cautioned to confirm what the laws of their state require for such disclosures to police investigations."

Providers should obtain a declaration in writing that the information is needed for a legitimate law enforcement purpose, Hinkley says. That can be accomplished in a couple of ways. The hospital can provide a checklist form that you ask the officer to complete for each request, or you can ask the local law enforcement to provide a blanket form for all requests.

"You can ask that the district attorney or police chief provide you a simple letter each year that states that when a police officer in uniform or displaying proper credentials asks for information that may be released, the hospital may have confidence that they are doing so for a legitimate law enforcement purpose," Hinkley says. "Then you can just keep that on file."

**Lourdes Martinez**, JD, an attorney with the law firm of Garfunkel Wild in Great Neck, NY, cautions that HIPAA is not the only concern. State laws can be more restrictive, as in New York state.

"By HIPAA it might not be a violation, but it still could be a violation of state law," she says. "That's the situation with a lot of requests in New York state that might be granted more easily in other states."

Policies and procedure must cover both HIPAA and state laws, Martinez says. Training of front-line staff also is crucial, she says.

"I used to be a prosecutor, so I know that sometimes when the police or a prosecutor come asking for information, it can be a little intimidating," she says. "If the people on the front line don't know what they can and can't say, they might be intimidated into saying something that perhaps they shouldn't."

## Consider the situation

Each situation must be carefully assessed, the attorneys say. For instance, if a police officer inquires about a crime victim, usually the victim must agree to the release if he or she is capable, Hurd explains. But if the victim is not capable of consent, the provider can release the information as long as the authorities stipulate that it is not to be used against the victim.

"If the police say they are hunting for the perpetrator and the investigation will be hindered if they wait until the victim wakes up or is out of surgery, the health care provider is allowed to use their professional judgment to release information," Hurd says. "Obviously, you need to verify the credentials of the law enforcement person before you release anything. It's always a good idea to document the officer's name and badge number in the chart and what reason the officer stated for needing the information."

Health care providers must be careful not to go too far and become actively involved in a criminal investigation, Hurd says. HIPAA allows the release of certain data, but staff should simply provide that information to the officer without editorializing.

State laws can supersede some HIPAA privacy concerns, such as when laws require the reporting of gunshot wounds, Hurd says. The issue can be more difficult when there are allegations of child, spousal, or elder abuse, Hurd says. State laws will vary on what must be reported, but in Virginia, for instance, health providers are required to report child and elder abuse. Information about abuse related to an adult, however, cannot be provided without the patient's consent, Hurd says.

The health care provider also may receive subpoenas and search warrants involving patient records. The legal order provides solid legal backing

for the release of information, but that release still should be handled carefully, Hurd says. The goal is to make sure you release only the information covered in the subpoena or search warrant.

"Once you've verified that the search warrant is proper, I would gather the appropriate parties to oversee this release — the risk manager, your in-house counsel, the compliance director, and health information management," Hurd says. "The police officers are going to be a little perturbed that they have to wait, but it's a good idea to have all those people involved and verifying the proper release of the information. Then you should make a copy for the hospital of all the information released to the officers, document how and to who it was released, and risk management should hold on to that, along with a copy of the search warrant."

**Layna Cook**, JD, an attorney with the law firm of McGlinchey Stafford in Baton Rouge, LA, notes that HIPAA does not prevent health care providers from notifying law enforcement that there is a fugitive on the premises or that they suspect a crime has been committed. The key, she says, is to limit the information you provide to law enforcement.

"The goal is to provide the minimally necessary, pertinent, factual information and then allow law enforcement to take it from there," Cook says. "You don't call the police and just tell them everything you know about this person. If there is a specific reason for bringing this person to their attention, that's what you do and then let the police investigate as necessary. From that point, each request for more information has to be considered in light of the allowable exceptions under HIPAA." ■

### SOURCES

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## HIPAA allows some disclosures to police

HIPAA states that covered entities may disclose protected health information to law enforcement officials for law enforcement purposes under the following six circumstances, and subject to specified conditions:

1) as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests;

2) to identify or locate a suspect, fugitive, material witness, or missing person;

3) in response to a law enforcement official's request for information about a victim or suspected victim of a crime;

4) to alert law enforcement of a person's death, if the covered entity suspects that criminal activity caused the death;

5) when a covered entity believes that protected health information is evidence of a crime that occurred on its premises;

6) by a covered health care provider in a medical emergency not occurring on its premises, when necessary to inform law enforcement about the commission and nature of a crime, the location of the crime or crime victims, and the perpetrator of the crime. ■

## CNE OBJECTIVES

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

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

## COMING IN FUTURE MONTHS

■ Wandering and elopement — latest advice

■ Reprocessing gains more favor, but risky?

■ What reform effort could bring for RMs

■ Improving your visibility as a leader

# CNE QUESTIONS

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

13. What does Craig Sanders, JD, expect to happen with malpractice claims in his state, which dropped significantly after tort reform?
A. The number of cases may not go back to the former levels, but he expects to see some increase.
B. The number of cases will drop even further throughout 2010.
C. The number of cases will remain steady at 2009 levels.
D. The number of cases will go back to former levels and possibly even higher.

14. What does attorney Charles Kutner, JD, say about malpractice claims related to psychiatric medicine and patient suicides?
A. That type of claim is decreasing.
B. That type of claim is increasing.
C. That type of claim has been barred by most state supreme courts.
D. That type of claim could be successful but no one has ever filed such a suit.

15. Regarding MMSEA Section 111, what has CMS said about whether writing off a patient's charges after an adverse event will trigger reporting obligations?
A. CMS has said it will.
B. CMS has said it will not.
C. CMS has said it will trigger reporting only in a very few scenarios.
D. CMS has not said whether write-offs will trigger reporting obligations.

16. According to Gerry Hinkley, JD, which of the following is true regarding patient information and police investigations?
A. HIPAA does not pre-empt more restrictive state laws, so HIPAA covered entities are cautioned to confirm what the laws of their state require.
B. HIPAA pre-empts more restrictive state laws in all cases.
C. HIPAA pre-empts more restrictive state laws only in some states.
D. HIPAA pre-empts more restrictive state laws only if they were passed before HIPAA became law.

**ANSWERS: 13. A; 14. B; 15. D; 16. A.**

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

# Allegation: Failure to perform hysterectomy causes death; $950,000 settlement in New York

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**News:** A pregnant woman presented to a hospital emergency department (ED) for delivery of her third child. Because of her high-risk pregnancy, the woman was scheduled for a cesarean. The cesarean was performed, followed by a hysterectomy. However, complications arose during the hysterectomy, and the woman slipped into a coma and died three days later. The hospital settled with the woman's family for $950,000.

**Background:** A 43-year-old factory worker was pregnant with her third child and presented to a hospital for delivery. The woman suffered from placenta accreta, a condition where the placenta attaches itself too deeply into the wall of the uterus. A common risk of placenta accreta during delivery is the possibility of hemorrhaging during manual attempts to detach the placenta. As a result of this condition, the woman was scheduled for a cesarean. Ultimately, the woman went into labor, and a cesarean was performed, followed by a hysterectomy due to a ruptured placenta. Complications arose following the hysterectomy, and the woman slipped into a coma, later dying.

A lawsuit was filed against the hospital, claiming medical malpractice for the hospital physician's failure to timely start the hysterectomy. The plaintiff alleged that due to the woman's condition, a hysterectomy tray, blood transfusions, and other necessary medical devices should have been prepared in the event a hysterectomy was found to be necessary. According to records, the child was born at 2:46 p.m., and the hysterectomy was not performed until 30 minutes later, despite the fact that the hemorrhage occurred at 2:49 p.m. However, interviews with the hospital's anesthesiologist revealed that he or she had no recollection of the time the procedure was performed and had not completed any notes regarding the procedure. A nursing note identified that the completion time of the hysterectomy was 3:49 p.m. This was, however, crossed out and replaced with "3:15 p.m." The plaintiff argued that someone had crossed out the correct time of completion in an attempt to hide the delay.

The defense denied negligence, and the obstetrician testified that the hysterectomy was performed timely. Defense counsel contended that the hemorrhage and later death were unfortunate risks associated with the woman's condition.

**What this case means to you:** The woman in this case was diagnosed with placenta accreta prior to delivery. According to the American Pregnancy Association, 1 in 2,500 pregnancies result in this condition. The specific cause of placenta accreta is unknown, but it can be related to previous cesarean deliveries. The woman in this case was pregnant with her third child; however, it is unclear as to her previous obstetric history. According to the literature, a cesarean delivery increases the possibility of a future placenta accreta. The more cesareans, the greater the incidence.

The risks of placenta accreta to the mother include hysterectomy, which is a common

therapeutic intervention, but the results involve the loss of the ability to conceive. There is nothing a woman can do to prevent placenta accreta, and little can be done to treat the condition once diagnosed. If the placenta accreta is severe enough, a hysterectomy may be needed. This condition is associated with massive blood loss at the time of delivery. The peripartum management of the patient should be by a multidisciplinary team to help reduce morbidity and mortality.

According to the American College of Obstetricians and Gynecologists (ACOG), postpartum hemorrhage is a complication associated with placenta accreta. Postpartum hemorrhage is one of the top five causes of maternal mortality. Ninety percent of accretas have postpartum hemorrhage, and 50% of those result in a hysterectomy. The key management issues are early detection — and immediate and appropriate intervention. There is a potential for massive blood loss, which could be > 2,500 cc. If this situation is not managed urgently and appropriately, it has a 50% mortality rate.

One of the issues identified in the case background information includes the timeliness of the surgical intervention. The clinical information presented demonstrates the importance of emergent treatment, including a plan for a hysterectomy. The surgical team needs to be competent and have all of the necessary equipment at the time of the cesarean.

According to The Joint Commission (TJC), the hospital and its staff must conduct a pre-procedure verification, which includes making sure that related equipment is available prior to the start of the procedure. This would include required blood products, implants, devices, and/or special equipment for the procedure (UP.01.01.01 EP 2).

The second issue is the lack of documentation present in the medical record. The delivery is noted to be at 2:46 p.m., and the hysterectomy information states it was performed 30 minutes after; however, the hemorrhage was documented in the record at 2:49 p.m. The anesthesiologist had no recollection of the time when the procedure was performed and had not completed any documentation regarding the procedure. This is not in compliance with the TJC Standard PC. 03.01.05, which states that the hospital monitors the patient during operative or other high-risk procedures and/or during the administration of moderate or deep sedation or anesthesia. The Element of Performance (EP) #1 in this standard states, "During operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously." TJC Standard RC. 02.01.03 EP #8, states that the medical record contains the following postoperative information: vital signs, level of consciousness, any medications, including IV fluids and any administered blood, blood products, and blood components, any unanticipated events or complications, and the management of those events. EP #15 requires that the hospital keep a complete and up-to-date operating room register that is, "inclusive of total time of operations."

According to the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoPs) for Hospitals and Anesthesia services, the delivery of anesthesia services must include an intraoperative anesthesia record. Likewise, the American Society of Anesthesiology (ASA) Statement on Documentation of Anesthesia Care (Oct. 22, 2008) states that, "documentation is a factor in the provision of quality care and is the responsibility of an anesthesiologist." Intraoperative anesthesia is a time-based record of events where the following items are recorded: patient's vital signs, doses of drugs and agents used; and the times of administration, types, and amounts of fluids used, including blood and blood products and the times of administration; and the technique and patient position, IV lines and airway devices inserted and the location, unusual events during the administration of anesthesia, and the status of the patient at the conclusion of anesthesia.

The ASA further states in the Standards For Basic Anesthetic Monitoring, Standards and Practice Parameters (Oct. 25, 2005) that during all anesthetics, the patient's oxygenation, ventilation, circulation, and temperature shall be continually evaluated.

Based on the interviews with the hospital anesthesiologist, it appears that he or she did not comply with TJC Standards, the CMS CoPs, the ASA Statements on Basic Anesthetic Monitoring nor the ASA Statement on Documentation of Anesthesia Care. In most facilities, the anesthesia record is quite detailed and is time-based. It would be quite unusual to have nothing in the record to support the care given during this time period. The lack of documentation could lead one to believe that the team was not ready to perform the hysterectomy immediately following the cesarean. A hemorrhage occurred during the operative period and, based on the research, was most likely a significant blood loss. The only postoperative information given on this patient was that she slipped into a coma and died three days later. This may have been a result of the blood lost during the procedure and the apparent delay.

The final issue is that the nurse who completed the notes identified the completion time of the

hysterectomy as 3:49 p.m. This was later crossed out and replaced with the time 3:15 p.m. The change in the entry suggests that it was done to hide a delay. Usually, if an entry is incorrect, it is crossed out, the error is noted next to the entry, the correct entry is documented, and the initials of the person making the change to the entry are noted. It appears that this common documentation correction process was not followed.

The settlement by the defense appears appropriate in this case. There were several system failures involving the scope of practice of the physicians and nurses under the circumstances.

**REFERENCE**

• Supreme Court, Second Judicial Circuit, Kings County, New York, No. 16281/08. ■

# Negligent drug dispensing alleged: $3.8M settlement

**News:** A young girl was brought to a hospital for an infection following the removal of her appendix and was admitted to the pediatric intensive care unit. An antifungal drug suitable for children was prescribed, but due to an alleged pharmacy error, the adult version of the drug was dispensed and administered. The girl had an adverse reaction to the drug and suffers from post-traumatic stress disorder (PTSD). A settlement was reached between the parties for $3,850,000.

**Background:** A 9-year-old girl was brought to a hospital by her parents. She was admitted to the pediatric intensive care unit for a systemic infection following the removal of her appendix. Physicians at the hospital prescribed an antifungal drug suitable for the girl's condition. Despite the fact that the prescription specified that the children's version of the drug should be dispensed, the hospital pharmacy dispensed the adult version. After administering the drug, the girl began convulsing, bleeding from various orifices, and experiencing system failure. The girl's sister was present in the room and witnessed her sister's declining condition. Once the nurse noticed the girl's reaction, she discontinued administration of the drug. The girl was resuscitated and was sent to another hospital that had specialized pediatric services. While at this hospital, the girl again coded and had to be resuscitated. During her hospitalization, the girl went through numerous blood transfusions. She was discharged six weeks later and continues to suffer from PTSD.

The parents sued the hospital and its staff pharmacists, alleging medical malpractice. Also included were claims for emotional distress.

According to reports, the defense conceded liability but emphasized the good recovery the girl made due to the quick and thoughtful action on the part of the hospital's nursing staff.

A similar situation occurred in 2006 but involved the death of a 2-year-old girl. The girl had been diagnosed with an abdominal tumor and had been undergoing chemotherapy at a children's hospital in Ohio. Following her last treatment of chemotherapy, the girl woke up in severe pain, vomiting violently. It was later found that the hospital pharmacy technician had compounded her own normal saline base solution using more than 23 times the concentration of sodium chloride instead of using a commercially pre-packaged IV solution bag. The compound poisoned the girl, who slipped into a coma and died. In that case, the hospital settled, and the pharmacist was arrested and criminally charged.

**What this case means to you:** This is a case of a 9-year-old girl who was readmitted with a postoperative infection following an appendectomy. An antifungal medication was prescribed to treat the infection. The case background does not specify what antifungal medication was prescribed; however, it does appear that the patient was admitted to receive this medication intravenously. Antifungal medications also are known to cause anaphylaxis. The symptoms of anaphylaxis include abdominal pain, confusion, diarrhea, breathing difficulties, dizziness, hives, nausea, vomiting, rapid pulse, and palpitations. An anaphylactic reaction can be life-threatening.

The young girl in this case suffered severe trauma due to the anaphylactic reaction. She experienced a cardiopulmonary arrest and was promptly resuscitated; however, her condition after resuscitation warranted a higher level of medical care, and she was transferred to a hospital that that specialized in pediatric medicine. According to the information given, this patient experienced another cardiopulmonary event, was given numerous blood transfusions, and remained confined to the hospital for six weeks.

The patient developed PTSD, which has traditionally been associated with combat veterans and disaster victims but has now evolved to include medical disorders. There is growing literature on

PTSD among medical patients. People with PTSD tend to avoid places, people, or other things that remind them of the event and are extremely sensitive to normal life experiences. The statistics on PTSD in children reveals that up to 40% have endured at least one traumatic event, and a higher percentage involves females. The research shows that children seem to have a greater risk in developing PTSD after a traumatic event. Treatment for this type of disorder involves teaching the patient new ways to think about the trauma, giving him or her practical approaches to coping with disturbing symptoms, providing family counseling and the use of antidepressants, as well as other medications to improve the patient's mood and to decrease anxiety.

It appears that the main cause attributed to this patient's abrupt decline is the administration of the antifungal medication, which was later discovered to be the wrong dosage for a pediatric patient. Hospitals are required to have safety systems in place so that an event such as this can be prevented. This case demonstrates several system failures in the medication management process.

According to The Joint Commission (TJC), medication errors are among the top five sentinel events reported each year. TJC has been collecting sentinel event data and issuing *Sentinel Event Alerts* since 1995. Many of the *Sentinel Event Alerts* have focused on medication issues such as high-alert meds, look-alike/sound-alike meds, and unsafe use of medication abbreviations. Despite the focus on medication safety, the number of voluntarily reported medication sentinel events has not demonstrated any significant improvement.

The safety measures that failed in this case occurred in the pharmacy and in nursing care. The issues involved include medication preparation, review, and administration. TJC and the Centers for Medicare & Medicaid Services(CMS) publish medication management and pharmacy services standards that address the responsibility of the hospital pharmacist. The pharmacist is responsible for reviewing all medication orders. The orders are reviewed for allergies, potential interactions, appropriateness of the medication dose, frequency, and route of administration, impact on lab values, and other contraindications. *(**Editor's note:** See TJC MM. 05.01.01 EP1, EP4-10.)*

There also are TJC and CMS Standards governing medication administration which affect nursing. Before the administration of medication, the nurse must do the following: verify that the medication matches the medication order; visually inspect for discoloration; verify that the medication has not expired; verify that no contraindication exists; and verify that the medication is being administered at the right time, in the correct dosage, by the correct route. Before the medication is administered, the patient and family need to be informed about any potential significant adverse drug reactions or concerns with this new medication. *(**Editor's note:** See TJC MM. 06.01.01 EP 3-9.)*

The pharmacist in this case missed the dose error by not verifying it was prepared correctly before dispensing it to the patient care unit and allowed this patient to be put at risk. The nurse was responsible for verifying the medication before administration to ensure patient safety. The verification process includes verifying the following: right patient, right medication, right dose, right time, and right route. The verification process is an essential step that was missed by both professionals, thus placing this child in a dangerous situation and causing a serious event.

This case is clearly one of liability and demonstrates the need for strict medication management systems, including redundancy. Many hospitals are using bar coding to prevent such medication errors at the point of administration. While there is technology in the pharmacy to keep high alert and look-alike medications separated, the pharmacist needs to be diligent in reviewing orders when comparing them to the medication preparation.

The situation cited from 2006 involving the little girl receiving the wrong dose/concentration of chemotherapy falls under the same medication standards. The pharmacy technician should have used a premixed concentration for the base solution. It appears that the pharmacist did not review the mixture prior to dispensing the medication for administration. It is unusual that the pharmacist was criminally charged rather than pursuing disciplinary procedures through the State Board of Pharmacy. This pharmacist was negligent, but a prison term seems excessive. He or she certainly made a mistake and should have had disciplinary sanctions applied to his/her practice as a licensed pharmacist, but placing this pharmacist in jail sends a different message to other pharmacists, as well as to all health care providers. It discourages health care professionals from reporting errors. This can have a significant effect on the health care provider's ability to learn from their mistakes and to have an effect on improving the quality of health care.

## REFERENCE


• Superior Court of New Jersey, Law Division, Bergen County, BER-L-2816-07. ■