



Three Strikes Rule: It has been almost six years: Is there any discernable impact of its passage?

GREGORY A. CHAIRES, ESQ.

As many recall, Amendment 8, more commonly known as the “Three-Strikes Rule,” was implemented by the Florida legislature in Senate Bill 940 after the Florida electorate overwhelmingly approved the proposed amendment to the Florida constitution in November 2004. The Bill amended Chapter 458 and 459, Florida Statutes (the Medical Practice Act and Osteopathic Medical Practice Act, respectively). It prohibits physicians who have had three or more incidents of medical malpractice, proven by clear and convincing evidence, from being licensed to practice medicine in Florida. It has been almost six years since the law was amended and there has been little discernable impact of it at this point.

For those not aware, a strike is defined as a final judgment by a court or agency that has been supported by clear and convincing evidence. A strike occurs when and if there is:

1. A final order of an administrative agency following a hearing where the licensee was found to have committed medical malpractice;
2. A final judgment of a court of law entered against a licensee where the licensee was found to have committed medical malpractice in a civil court action; or

3. A decision of binding arbitration where the licensee was found to have committed medical malpractice.

Medical malpractice has been defined as the failure to practice medicine in accordance with the level of care, skill, and treatment as a similar provider under similar circumstances. “Repeated medical malpractice” is defined as three or more incidents of medical malpractice found to have been committed by a medical doctor. It includes any similar wrongful act, neglect or default committed in other states or countries which, if committed in Florida, would have been considered medical malpractice. The critical determination if a strike exists is whether the Florida Board of Medicine determines that repeated medical malpractice has occurred.

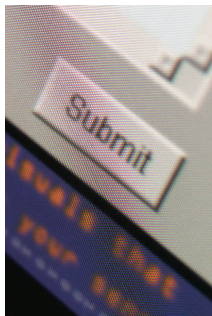
The enabling legislation to the Amendment in Senate Bill 940 provides that the Board of Medicine shall not license or continue to license a medical doctor found to have committed repeated medical malpractice, the finding of which must be based upon clear and convincing evidence. The provision contained at 456.50(2), Florida Statutes, further states that “in order to rely on an incident of medical malpractice to determine whether a license must be denied or revoked under this section, if the facts supporting the finding of the incident of medical malpractice were determined on a standard less stringent than clear and convincing evidence, the board shall review the record of the case and determine whether the finding would be supported under a standard of clear and convincing evidence.”¹

“Clear and convincing evidence” has been defined in various court opinions as an intermediate standard of proof, more than “preponderance of the evidence” standard used in most civil cases, and less than the “beyond a reasonable doubt” standard used in criminal cases. The clear and con-

vincing evidence standard requires that the evidence must be found to be credible; the facts to which the witnesses testify must be precise and explicit and the witnesses must be lacking confusion as to the facts. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established. See Slomowitz v. Walker, 429 So.2d 797 (Fla. 4th DCA 1983).

The plain language of Senate Bill 940 and 456.50 (2), Florida Statutes, indicates that the triggering of a strike is the result of some final action, whether it be by a court of law, the Board of Medicine or through arbitration. However, it would be very unlikely that a court or arbitration panel would make a finding of malpractice by clear and convincing evidence. Such finding has traditionally been the province of the Florida Board of Medicine. It appears that despite the language defining a strike, it really falls upon the Florida Board of Medicine to determine if a strike occurs. So considering malpractice cases in civil courts, how does that happen?

Pursuant to Section 627.912(1)(c), Florida Statutes, all professional liability insurance companies are required to file with the Office of Insurance Regulation ("OIR") within the Department of Financial Services, notification of any payment in excess of \$1.00 if the payment arises from a claim that asserts personal injuries to have been caused by error, omission or negligence in the performance of a physician's services or based upon a claim professional services that were performed without consent. Similarly, pursuant to Section 456.049, Florida Statutes, any practitioner of medicine is required to report to the OIR any claim or action for damages that as-



serts personal injuries to have been caused by error, omission or negligence in the performance of a physician's services or based upon a claim professional services that were performed without consent. When these reports are made by professional liability carriers, they are then reported from the OIR to the Department of Health, which in most cases will initiate what is termed a "closed claim" investigation against the physician licensee. In so doing, it begins the process where there may ultimately be a review by the Board of Medicine of the malpractice action at the clear and convincing evidence standard.

There are ways to avoid a "finding" that the physician engaged in medical malpractice. Legal counsel for physicians in medical negligence cases and Department of Health investigations must counsel their clients on the risks of how an Administrative Complaint issued by the Department of Health is challenged. Hearings pursuant to Section 120.57(1) and 120.57(2), Florida Statute, will carry an inherent risk of a strike if a physician has been charged with repeated medical malpractice. In each proceeding the Board of Medicine will ultimately issue findings of fact and if those findings provide that medical malpractice occurred by clear and convincing evidence, then a physician will receive a strike.

In a review of Recommended Orders issued by Administrative Law Judges at the Division of Administrative Hearings where hearings pursuant to Section 120.57(1), Florida Statute, are conducted, this author only found three cases in which a physician was found to have committed malpractice and thus received a strike. There is at least one other case in which a physician appeared before the Board of Medicine on a Section 120.57(2) hearing and the Board adopted the findings of fact and conclusions of law of the pending Administrative Complaint, which alleged medical malpractice. Six years have passed since implementation of the

“Three-Strikes” law, yet a scant number of cases show its effect. It is very difficult to determine the impact, if any, of the three strikes amendment on applicants that may have considered Florida as a place to practice medicine as some physicians may simply have not applied for a medical license.

An analysis of the number of physicians actively practicing medicine in the state of Florida supports that there has been little impact of the statute. A review of MQA Annual Reports from 2004-2009 published by the Department of Health are quite interesting and support a conclusion that there has been little impact of the “Three-Strikes Rule.”

2004-2005:

Active licenses for M.D.:	38,160
Active licenses for D.O.:	3,345
M.D. in training:	2,730
M.D. initial applications received:	3,059
M.D. licenses issued:	2,804
D.O. initial applications received:	375
D.O. licenses issued:	313

2005-2006:

Active licenses for M.D.:	39,016
Active licenses for D.O.:	3,439
M.D. in training:	3,252
M.D. Initial applications received:	2,933
M.D. Licenses issued:	2,656
D.O. initial applications received:	309
D.O. licenses issued:	290

2006-2007:

Active licenses for M.D.:	40,065
Active licenses for D.O.:	3,619
M.D. in training:	3,618
D.O. in training:	390
M.D. Initial applications received:	3,098
M.D. Licenses issued:	3,001
D.O. initial applications received:	300
D.O. licenses issued:	275

2007-2008:

Active licenses for M.D.:	40,936
Active licenses for D.O.:	3,689
M.D. in training:	3,925
D.O. in training:	453
M.D. Initial applications received:	3,028
M.D. Licenses issued:	2,805
D.O. initial applications received:	303
D.O. licenses issued:	289

2008-2009:

Active licenses for M.D.:	41,951
Active licenses for D.O.:	3,886
M.D. in training:	2,984
D.O. in training:	392
M.D. Initial applications received:	2,699
M.D. licenses issued:	2,844
D.O. initial applications received:	321
D.O. licenses issued:	289

The number of licensed physicians has grown each year since the “Three-Strikes Rule” was passed and the number of physicians training in Florida has remained consistent over that period of time. Based upon the foregoing numbers assimilated by the Department of Health, the anticipated impact of a mass exodus of physicians appears to have been perhaps overblown. It is unclear from these numbers whether the amount of specialists have changed and thus, there may be some impact on high-end specialists such as neurosurgeons and obstetric/gynecologists.

The 2008-2009 Board of Medicine Annual Report indicates that from fiscal year 2006-2007 to fiscal year 2008-2009, the amount of Recommended Orders from formal hearings pursuant to ch. 120.57 (1), dropped from 21 to 4. During the same time frame, settlement agreements heard by the Board of Medicine dropped from 265 to 121.

One thing that many fail to appreciate is that pursuant to the Board of Medicine’s penalty guidelines and Section 458.331, Florida Statutes;

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the Board has the authority to revoke a physician’s license based upon one finding of malpractice. While the Board has not traditionally done so, it has always had that authority, even prior to Senate Bill 940. Rule 64B8-8.001, F.A.C., sets forth the range of penalties that the Board of Medicine has in evaluating a penalty for various violations. Pursuant to the penalty guidelines for malpractice under 64B-8.001(2)(t), F.A.C.:

Violation	First Offense	Second Offense
(t) Failure to practice medicine in accordance with appropriate level of care, skill and treatment recognized in general law related to the practice of medicine. (456.50(1)(g), F.S.) (458.331(1)(t), F.S.)	(t) From one (1) year probation to revocation or denial and an administrative fine from \$1,000.00 to \$10,000.00.	(t) From two (2) years probation to revocation or denial and an administrative fine from \$5,000.00 to \$10,000.0.

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|---|--|--|
| <p>1. Gross Malpractice.</p> | <p>1. From one (1) year suspension followed by three (3) years probation to revocation or denial and an administrative fine from \$1,000.00 to \$10,000.00 and licensee shall be subject to reexamination.</p> | <p>1. From suspension or denial to revocation or denial and an administrative fine of \$5,000.00 to \$10,000.00, and an evaluation or reexamination by a physician evaluation program approved by the Board.</p> |
| <p>2. Repeated Malpractice as defined in Section 456.50, F.S.</p> | <p>2. Revocation or denial and an administrative fine from \$1,000.00 to \$10,000.00.</p> | |

When the amendment was initially passed there was understandably a great deal of concern as to its impact. The penalty of “three strikes and you’re out” assured that if there were three findings that a physician committed malpractice by clear and convincing evidence, that the physician would no longer be eligible to practice medicine in Florida. However, the Board of Medicine had that authority long before the Amendment was passed, which it used sparingly to revoke medical licenses.

Despite the fact that it has now been almost six years since Amendment 8 was passed, no significant impact is apparent. The Board of Medicine continues to regulate the practice of medicine, with fewer disciplinary cases, but with a push for more punitive sanctions. The future of the impact of the



“Three-Strikes Rule” is unknown, and may ultimately be difficult to ascertain. One thing is certain: its impact will further complicate an industry that is already heavily regulated. It underscores the possibility that forthcoming health care overhaul will have a much more significant impact on the citizens of the State of Florida as it relates to access to specialty care, timeliness of medical treatment, and its cost. That is an issue that will be debated for many years to come.

¹Note that the “clear and convincing evidence standard” for repeated malpractice was created by the enabling statute (§456.50 Florida Statutes) passed after the Amended was voted upon. There is no indication in the language of the amendment that the clear and convincing evidence standard should be used. While there has been no constitutional challenge of Amendment 8’s enabling statute one must be mindful that Amendment 7’s enabling statute has been eviscerated by the Florida Supreme Court. Only time will tell if the Amendment 8 enabling statute suffers the same fate.



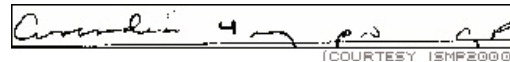
For Doctors’ Scrawl, Handwriting’s on the Wall

Georgette Samaritan, RN, BSN

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Physicians’ handwriting has long been a joke. However, poor handwriting among healthcare providers is increasingly being diagnosed as a threat to patients. Nearly all of the prescriptions issued each year in the United States are written by hand. According to the Institute for Safe Medica-

tion Practices, indecipherable or unclear prescriptions result in more than 150 million calls from pharmacists to physicians asking for clarification, a time-consuming process that costs the healthcare system billions of dollars per year in wasted time. Experts say that up to 25 percent of medication errors may be related to illegible handwriting: A pharmacist misreads an illegible prescription; one drug is mixed up with another.



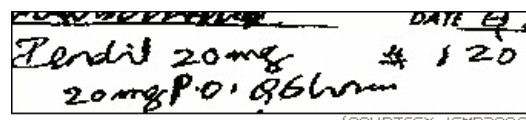
AVANDIA (rosiglitazone) or COUMADIN (warfarin)? Avandia treats type 2 diabetes; Coumadin is an anti-clotting agent used in treating heart and stroke-related problems. Avandia is the prescribed drug in this case.

Jury Blames Doctor’s Bad Handwriting for Patient Death

In 1999, a Texas jury awarded a woman \$450,000 after her husband suffered a fatal heart attack while taking the wrong medication. At issue was a prescription the cardiologist wrote for 20 mg of Isordil (for angina) every six hours. The pharmacist misread “Plendil” for “Isordil.” A day later, taking what equaled a 16 percent overdose of Plendil, the patient had a fatal heart attack. The overall quality of the care received was never an issue.

The defense attorney presented compelling evidence that the medication error had not caused the patient’s death.

The trial was held in a conservative part of Texas where physicians typically enjoy courtroom success.

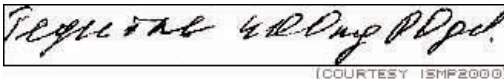


ISORDIL(r) (isosorbide dinitrate) or PLENDIL(r)

(felodipine)? Isordil is a treatment for chest pains and can cause extremely low blood pressure; Plendil is prescribed for hypertension, or high blood pressure. Isordil was the intended drug.

Sending a Message with a Verdict

The jury later indicated that the award would have been much higher if the patient's lawyer had put a price tag on the case. This first negligence judgment against a doctor purely for illegible handwriting focuses on the need for system changes and provides a needed wake-up call.



TEGRETOL (carbamazepine) or TEQUIN (gatifloxacin)? Tegretol relieves the convulsions associated with epilepsy; Tequin is an antibiotic used in treating respiratory infections. The prescription is for Tequin.

Addressing the Problem of Illegible Medication Orders

Handwriting's role in medication errors has not escaped notice within organized medicine. Physicians are urged to:

- Improve the legibility of handwritten orders for medications and review all orders for accuracy and legibility after writing them.
- Note the "purpose" of a prescription to avoid confusion on the part of either pharmacists or patients.
- Use direct, computerized order entry systems, or print or type medication orders.
- Evaluate new electronic point-of-care software that not only prints legible prescriptions, but also alerts doctors to potential drug or allergy interactions, using up-to-date databases of medications

that are linked to the patient's records.

- Avoid using decimals, nonstandard abbreviations or the letter "u" (which can easily be misread as a zero) as shorthand for "units."
- Consider preprinted prescriptions, on which physicians merely have to note the dosage and add their signature and DEA number.
- Take the time to educate patients or family members about the drug and dosage ordered. The patient should be asked to repeat the information to ensure they've understood.



The Radiation Overdose Sentinel Event

Libby Brateman, PhD,
FACR, FAAPM
Associate Professor, College
of Medicine, Department of
Radiology and
Affiliate Associate Profes-
sor, College of Engineering,
Department of Nuclear and

Radiological Engineering

The Joint Commission has defined a radiation overdose sentinel event to be a patient peak skin dose of 15 Gy from fluoroscopic procedures within a 6-to-12 month period. The Joint Commission FAQ sheet on the radiation overdose sentinel event includes neonatal serum bilirubin > 30 mg/dl and prolonged fluoroscopy with cumulative dose > 1500 rads [15 Gy] to a single field or any delivery of radiotherapy to the wrong region or > 25% above the planned dose. The commonality among these three situations is:

*These events could be associated with death or major permanent loss of function,
These outcomes often do not occur for months or years after the event itself, and
These events are considered to be preventable.*

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Therefore, after identification of any of these events, hospitals are required to conduct a root cause analysis and are encouraged to report the event *even though the outcome has not yet become evident*. The FAQ sheet goes on to say “the purpose of the Sentinel Event Policy is to promote improvement in patient safety, not to regulate practice. The parameters defining these sentinel events were intentionally selected to identify only the most extreme cases—those that should never occur.”

One might wonder why fluoroscopic radiation at this skin dose level was chosen to be defined as a sentinel event, particularly because of The Joint Commission’s definition of a sentinel event:

“A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response.”

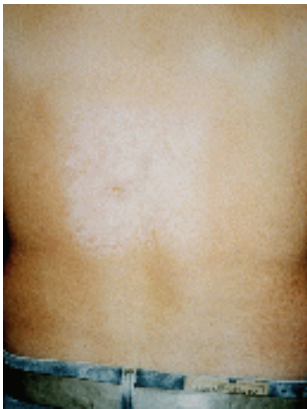
It may come as a surprise that fluoroscopic procedures have the potential to cause risk of serious injury. Certainly the media have been announcing the extreme situations in which radiation from diagnostic CT scans has caused patient injuries. (See, for example “Radiation Overdoses Point Up Dangers of CT Scans,” Oct. 15, 2009, and “After Stroke Scans, Patients Face Serious Health Risks,” July 31, 2010, in The New York Times.) In these situations, patients have suffered hair loss and attained the potential for cataracts. Perhaps hair loss is not seen as a serious injury in a medical sense, but when the patient is an elementary school teacher with a

student who vomits because of seeing her patchy hair loss, the impact is not inconsequential.

The fact is that any user of fluoroscopes has the potential to cause, not only hair loss, but also cutaneous radiation injury (CRI) that includes serious skin burns that often do not show up until some time after the patient has been discharged. Injury to the skin may occur and appear to heal but then return with a vengeance some time later. See, for example, the classic images on the FDA website (<http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm116682.htm>) that were presented in a 1995 medical conference.



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The top photo (on the previous page) is at 6-8 weeks following multiple procedures involving angiography and angioplasty. The shape of the radiation field on the skin of the patient is apparent. The center photo at 16-21 weeks shows only a small ulcerated area present, with the appearance of general healing. However, the bottom photo, taken at 18-21 months post-procedures, shows tissue necrosis that required skin grafting. Specific dose information was not available, but the estimated dose was greater than 20 Gy.

All radiation injuries, indeed all serious injuries and illnesses associated with the use of medical

devices, are supposed to be reported under the Safe Medical Devices Act of 1990. The Joint Commission encourages voluntary reporting of sentinel events.

FDA concerns led to a Public Health Advisory (9/30/1994) that identified procedures that typically involve extended fluoroscopic times:

- *percutaneous transluminal angioplasty (coronary and other vessels)*
 - *radiofrequency cardiac catheter ablation*
 - *vascular embolization*
 - *stent and filter placement*
 - *thrombolytic and fibrinolytic procedures*
 - *percutaneous transhepatic cholangiography*
 - *endoscopic retrograde cholangiopancreatography*
 - *transjugular intrahepatic portosystemic shunt*
 - *percutaneous nephrostomy*
 - *biliary drainage/urinary/biliary stone removal*
- (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm063084.htm>)

The FDA stated in the above advisory: "Physicians performing these procedures should be aware of the potential for serious, radiation-induced skin injury caused by long periods of fluoroscopy during these procedures. It is important to note that the onset of these injuries is usually delayed, so that the physician cannot discern the damage by observing the patient immediately after the treatment."

Fluoroscopy time is not the only parameter that affects skin dose. Studies with high doses could almost always have been performed with lower doses by the operator knowing how the equipment was designed to work and using features associated with lower radiation doses by optimizing work practices. Physicians who use fluoroscopy

equipment throughout the hospital need to have as much knowledge as possible about how to use the equipment. Starting with the most basic imaging principles, such as which end of the C-arm fluoroscope is the x-ray tube, and which end should be kept as close to the patient as possible (the imager), all physicians who operate fluoroscopes need to know how to keep the radiation doses to their patients, other staff and themselves as low as reasonably achievable in the process of making images with appropriate image quality.

How do we know the radiation dose? All fluoroscopes manufactured after June 10, 2006 are required by the FDA to have dose meters installed on them. Some earlier (“vintage”) equipment may also have these meters, and some can be upgraded to have meters installed. With such meters, the dose can be monitored during the study, and then a value can be obtained after the study. This meter value is not actually the patient skin dose, but instead, this reported value can be used by a medical physicist in conjunction with various additional parameters when a personalized estimate of the patient peak skin dose is necessary. However, dose meter values can be used as first estimates, and they can be tracked for patients so that alerts can identify patients whose peak skin doses are likely to be high.

What is the significance of the 15-Gy dose level at which The Joint Commission set the threshold for the radiation sentinel event? The CDC has a “Radiation Fact Sheet for Physicians” that gives detailed information regarding CRI and what effects to expect at various radiation levels. These effects are divided into grades of injury, and the CDC separates a Grade I CRI from a Grade II injury at 15 Gy. (<http://emergency.cdc.gov/radiation/criphysicianfactsheet.asp>) According to this report, radiation effects include: edema of subcutaneous tissues and blisters with moist desquamation at 5-6 weeks post-exposure, blood vessel

damage at 10-16 weeks post-exposure, with possible ulceration; and late effects of recurrence of ulceration and possible tissue necrosis as well as telangiectasia up to 10 years later.

The Joint Commission radiation sentinel event definition, therefore, is at the break-point between the CDC-defined Grade I and Grade II CRI. This definition refers to a peak skin dose in a single field over a period of 6 months to a year, because “skin sensitivity is, to a degree, repairable.” Radiation oncologists are well aware that radiation effects can be controlled by a well-planned fractionation regimen, but unexpectedly lengthy fluoroscopic procedures do not fall in that category. Note that the sentinel event is defined for the peak skin dose received from fluoroscopic procedures, but the patient’s skin effects are related to the total dose received by that same portion of skin from all x-ray procedures, including CT and radiography in general—and including the doses from x-ray studies done elsewhere. Note also that, while the skin is the organ of interest for the sentinel event definition, doses to other sensitive organs might be of concern as well. In fact, some organs, such as the lens of the eye, can be damaged at doses much lower than 15 Gy, depending on the fractionation.

The Department of Radiology at Shands UF has been developing procedures for monitoring and tracking patient radiation doses and a policy for managing high doses with the goal of preventing CRI. A review has found that high peak skin doses involving embolization procedures place patients who require multiple embolization procedures at a higher risk.

The Joint Commission understands that “The terms ‘sentinel event’ and ‘medical error’ are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.” Depending on a patient’s diagnosis, high peak skin doses may be a necessary and unavoidable part of

their treatment regimen, and patients should be informed of the potential for adverse radiation effects when they are known to exist.

References:

(http://www.jointcommission.org/NR/rdonlyres/10A599B4-832D-40C1-8A5B-5929E9E0B09D/0/Radiation_Overdose.pdf)
(http://www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf)

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Altamont Springs, FL 32701
407-834-2777

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Send comments and/or article suggestions to: rmeduc@shands.ufl.edu

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