

Client Newsletter

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**Board of Registration in Medicine
Proposes New Regulations**

The Massachusetts Board of Registration in Medicine (“BRM”) has issued proposed regulations which could have a substantial impact in the health care community, particularly with respect to physician offices. The following is a brief overview of some of the more significant changes contained within the proposed regulations:

Grounds for Discipline

The proposed regulations provide that the BRM may impose disciplinary action against the licensee for several new additional grounds, including:

- Violating a Board policy;
- Engaging in conduct that has the capacity or potential to place the public health, safety, or welfare at risk;
- Engaging in conduct that undermines public confidence in the integrity of the medical profession.
- Engaging in conduct that demonstrates a lack of good moral character;
- Committing an act that violates recognized standards of medical care;
- Failing to maintain recognized profession physician-patient boundaries; and
- Engaging in disruptive behavior that affects, or has the potential to affect, the delivery of professional medical services.

Summary Suspension

Pursuant to the current BRM regulations, the BRM has the authority to summarily suspend a licensee who may propose “an immediate and serious threat” without hearing evidence to the contrary from the licensee, but a licensee who may impose a “serious threat” is afforded an opportunity to provide evidence to the contrary before the BRM acts. The proposed regulations do not provide such a distinction. The proposed regulations recognize that immediate BRM action is

necessary any time a licensee poses a serious threat to the public health, safety or welfare. The proposed regulations, however, also provide the BRM with additional authority to impose practice restrictions in lieu of suspension. According to the proposed regulations, the imposition of practice restriction would allow the BRM to protect the public, yet preserve the licensee's ability to continue to practice medicine in a limited fashion.

Qualified Patient Care Assessment Programs for Physician Offices

The proposed regulations require that two or more licensees engaged in a group practice, however organized, so long as the practice is wholly owned and controlled by one or more of the licensees or, in the case of a not-for-profit corporation, so long as its only members are one or more of the licensees so associated, will be required to establish a qualified patient care assessment program. A qualified patient care assessment program shall be described in a Patient Care Assessment Plan and shall be reviewed and updated at least annually by the physician office. The Patient Care Assessment Plan shall also be submitted every three years to the BRM's Patient Care Oversight Committee for a determination of whether or not the plan is a qualified patient care assessment plan.

Reporting to the Patient Care Assessment Division at the BRM

The proposed regulations eliminate the four types of major incidents currently used for reporting to the BRM. In its place, all health care facilities, including physician offices (as defined above) will have to report to the BRM on any of 27 different events including, but not limited to, surgery on the wrong body part, surgery on the wrong patient, infant discharged to the wrong person, patient death or serious disability associated with a medication error, sexual assault on a patient, death or significant injury to a patient or staff member resulting from a physician assault in the hospital. The proposed regulations also require health care facilities to report to the BRM any unexpected occurrence related to system or process deficiencies or health care provider concerns, leading to death "or major and enduring loss of function" for a recipient of health care services.

Reportable Occurrences in a Licensee's Office Setting

The proposed regulations provide that in the case of patient care provided in a licensee's office setting (defined as any medical office building affiliated with a health care facility where the practice of medicine occurs, or any other location, structure, building, office, spa, salon, health club, retail location or other environment not defined as a health care facility, where the practice of medicine occurs), the licensee must file an occurrence report with the health care facility where the licensee has his or her primary affiliation in the following circumstances: (a) unplanned transfer to a hospital precipitated by an invasive procedure performed in the licensee's office; (b) an unexpected occurrence resulting from any procedure that requires the administration of minimal or moderate intravenous or intramuscular sedation/analgesia, thus making intra-operative and post-operative monitoring necessary; or from any procedure that requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia or a major conduction blockade.

The proposed regulations have already generated a significant amount of criticism in the health care community. In particular, many believe that the BRM is asserting too much power over physicians. The BRM will announce shortly an official public health pertaining to the proposed regulations. The proposed regulations can be found at: www.massmedboard.org/public/regchanges.shtm. The Rogers Law Firm will continue to monitor the proposed regulations and will provide updates accordingly.

IRS Sends Out “Compliance-Check Letters” to Hospitals

The IRS is in the process of sending out “compliance-check letters” to approximately 20% of the tax-exempt hospitals and health systems in the United States. The letters contain a questionnaire which seeks detailed information on an organization’s community benefit activities, governance regimes and compensation practices. The questionnaire also seeks information regarding an organization’s medical staff privilege standards, uncompensated care, community outreach programs, compensation practices and billing and collection practices. Although an organization’s response to a compliance-check letter is voluntary, it is highly recommended that an organization respond to the questionnaire.

The IRS compliance-check letters are part of the federal government’s broad review of tax-exempt organizations, particularly in the health care field. Both the U.S. Senate Finance Committee and the U.S. House Ways and Means Committee are seeking to draft legislation aimed at reforming charities and not-for-profit organizations.

OIG Announces New Self-Disclosure Protocol

On April 24, 2006, the Inspector General of the United States Department of Health and Human Services, issued an open letter to health care providers regarding his perspectives on compliance, resolution of health care fraud cases, corporate integrity agreements (CIAs) and the OIG’s Self-Disclosure Protocol (SDP). The open letter also announces an initiative that promotes the use of the SDP to resolve civil monetary penalty liability under the Stark Law and Anti-Kickback Statute pertaining to financial arrangements between hospitals and physicians.

In 1998, the OIG announced the SDP as a mechanism for providers to investigate, quantify and resolve potential fraud matters. Of the 136 self-disclosures made by health care providers since the initiation of the SDP, the OIG has only required CIAs in 27 out of 136 cases. CIAs are agreements between the OIG and a provider as part of a civil settlement in exchange for which the OIG agrees not seek an exclusion of that health care provider from participation in Medicare, Medicaid and other federal health care programs. Most oftentimes, CIAs require a health care provider to either form, or strengthen, their compliance program.

The OIG recently heard from hospitals which are concerned about civil monetary penalties arising from the discovery of improper arrangements under the Stark Law and Anti-Kickback Statute. The OIG has the authority to impose civil monetary penalties of up to \$15,000.00 for each service billed in knowing violation of the Stark Law, and assessments of up to three times the amount claimed for such services. Furthermore, under the Anti-Kickback Statute, the OIG has the authority to impose a civil monetary penalty of \$50,000.00 for each kickback, plus an assessment of not more than three times the amount of remuneration offered, paid, solicited or received. As a means of addressing this potential civil monetary penalty liability, the Inspector General has announced a new initiative which supplements the SDP by providing guidance on how these disclosures will be resolved. Specifically, upon receipt of a disclosure, the OIG will confer with the Department of Justice (“DOJ”) to ensure that it is aware of each disclosure and has the opportunity to opine before the OIG accepts a provider into the SDP. Furthermore, the DOJ is presented with the results of the OIG’s review of the SDP matter before it is resolved under the OIG’s Civil Monetary Penalty authority. The SDP initiative is limited to matters that in the provider’s reasonable assessment, involved conduct that subjects the provider to civil monetary penalty

liability under the Stark Law and Anti-Kickback Statute – in particular situations involving a financial benefit knowingly conferred by a hospital upon one or more physicians. According to the Inspector General, the OIG will generally settle SDP matters for a multiplier of the value of the financial benefit conferred by the hospital upon the physician(s). This is typically a much lower figure than that which would be imposed if the provider had not come forward under the SDP.

The Inspector General has made it clear that a provider’s participation in the SDP is contingent upon full cooperation and complete disclosure of the facts and circumstances surrounding the violation. The degree of a provider’s cooperation is considered by the OIG when determining the appropriate terms of an administrative settlement.

Massachusetts Court Seeks to Expand the Duty to Warn for Physicians

I. Introduction

Most oftentimes a provider’s duty to warn in Massachusetts is thought of in the context of the mental health field. Massachusetts law provides that a licensed mental health professional has a duty to warn or protect a potential victim of a patient if that patient has communicated an explicit threat to kill or inflict serious bodily injury on the potential victim and the patient has the apparent intent and ability to carry out the threat.¹ Outside of the mental health field, however, a provider’s duty to warn is not as clear. This is particularly true in regard to physicians who are treating patients who have experienced a seizure. However, a recent Superior Court decision in the matter of *Medina v. Pillemer, et al.*, 2005 Mass. Super. LEXIS 639 (2005), may lead to the establishment of a common law duty for a provider to advise a patient who is subject to seizures not to drive a motor vehicle.

II. Medina v. Pillemer, et al.

In December of 2001, Richard Medina (“Medina”) sustained severe injuries as he stepped out of his car in Newton, Massachusetts, and was struck by a car driven by Robert Riskind (“Riskind”).² Medina filed an action against Francine Pillemer (“Pillemer”), the Executrix of Riskind’s estate, for negligence relating to the accident.³ In March of 2005, Medina moved to amend his Complaint to add Dr. Fred Hochberg as a Defendant. After learning that Riskind had experienced a seizure in September of 2000 and was suffering from a malignant brain tumor at the time of the accident, Medina sought to amend his Complaint to add Riskind’s treating neurologist, Dr. Hochberg, as a defendant.⁴ In the proposed Amended Complaint, Medina alleged that Dr. Hochberg “negligently and carelessly treated his patient, Robert Riskind, and negligently and carelessly failed to control his patient by failing to order, advise, caution, warn and instruct his patient, Robert Riskind, to not operate a motor vehicle due to the foreseeable risk of injury to innocent bystanders, such as the Plaintiff, who may be on the public way in the vicinity where the patient, Robert Riskind, was operating his motor vehicle.”⁵

¹ Mass. Gen. Laws ch. 123, § 36B.

² *Medina* at 1.

³ *See id.* Riskind died following the accident before Medina filed suit on January 23, 2004.

⁴ *See id.*

⁵ *See id.* at 1-2.

Judge Raymond Brassard of the Superior Court allowed Medina's motion to amend his Complaint "without opposition". Dr. Hochberg, however, filed a motion for reconsideration of the allowance of Medina's motion on the basis that by the time his insurance carrier received Medina's motion, the time period within which to file an opposition under Superior Court Rule 9A had passed.⁶ Judge Ralph Gants allowed Dr. Hochberg's motion for reconsideration and ruled that he would consider the matters at issue in the motion de novo, as if the motion to amend the Complaint had initially been brought and timely opposed by Dr. Hochberg.

One of the principal arguments raised by Dr. Hochberg as to why he should not be added as a defendant in the case, was that although he owed a legal duty to his patient, Riskind, he did not owe any legal duty to Medina. Massachusetts law does recognize that a "special relationship" exists in certain circumstances which imposes a duty to take affirmative acts to protect against dangerous or unlawful acts of third persons.⁷ As Judge Gants pointed out in his decision, however, Massachusetts has never previously recognized that a physician has a special relationship with either his patient or a foreseeable class of victims which would impose a duty upon the physician to advise a patient who is subject to seizures not to drive a motor vehicle.⁸ Massachusetts courts, however, have found that a special relationship exists in four categories of cases which triggers a duty to a potential victim from harm committed by a third person: (1) when an individual commits an affirmative act that creates or increases the risk that the third person will harm a potential class of victims, the individual owes a duty to the potential victim class to act reasonably in performing that affirmative act; (2) when there is a special relationship between the defendant and an identifiable limited class of persons that includes the plaintiff, the defendant may owe a duty to the plaintiff to protect him from the dangerous or unlawful acts of a third person; (3) when there is a special relationship between the defendant and the third person who commits the harmful conduct, the defendant may have a duty to a foreseeable class of victims to control the third person's conduct or to provide reasonable warning of the third person's conduct; and (4) in certain circumstances public employees have a special relationship with the general public and therefore owe a duty to them when the foreseeable threat posed by inaction is potentially "calamitous", and statutes or ordinances reflect a legislative intent to protect the general public from the threat.⁹

Judge Gants concluded that the *Medina* case does not fit squarely into any of the above categories of special relationships. Nevertheless, Judge Gants held that Dr. Hochberg had a special relationship with the potential victim class, which included Medina, arising from several factors. First, there was certainly a doctor-patient relationship between Dr. Hochberg and Riskind. Second, imposing this special relationship would not require Dr. Hochberg to violate the doctor-patient confidentiality as between himself and Riskind. Third, the Code of Massachusetts Regulations (540 C.M.R. § 24.05(1)) already requires a patient to surrender his license upon suffering a seizure and to not gain reinstatement without a written certification from his physician stating "to a reasonable degree of medical certainty, that the individual's medical condition and medications will not interfere with the safe operation of a motor vehicle."¹⁰ Fourth, there is a severe degree of danger to the potential victim class if the physician fails to reasonably advise his patient not to drive after a seizure. Lastly, there is no meaningful distinction between an affirmative act and an omission in the context of advice offered within a doctor-patient relationship.¹¹ Based upon these conclusions, Judge Gants held that physicians in Massachusetts have a common law duty to the potential victim class to exercise reasonable care in advising a patient who is

⁶ *See id.*

⁷ *See id.* at 14.

⁸ *See id.*

⁹ *Medina* at 15-21.

¹⁰ *See also* "Seizure and Loss of Consciousness Policy Statement", Commonwealth of Massachusetts Registry of Motor Vehicles (June 2004).

¹¹ *See id.* at 31-32.

subject to seizures not to drive a motor vehicle.¹² Therefore, the court allowed Medina's motion to amend his Complaint to add Dr. Hochberg as a defendant.

III. Impact of Medina

The significance of the Court's decision in *Medina* may, in fact, be minimal. As acknowledged by Judge Gants himself, it will require a ruling by the Massachusetts Supreme Judicial Court to establish a common law duty by physicians to warn patients who are subject to seizures not to drive a motor vehicle. Moreover, it is reasonable to suspect that most providers, whether they are primary care physicians, neurologists, or emergency room physicians, will advise a patient who experiences a seizure not to drive a motor vehicle until such time as a physician believes it is reasonably safe to do so. As a point of fact, in July of 2003, the Massachusetts Medical Society published a guidebook for physicians entitled "Medical Perspectives on Impaired Driving."¹³ The guidebook is intended to serve as a "starting point for clinicians" who are treating patients whose ability to safely operate motor vehicle are compromised by issues of medical impairment.¹⁴ The guidebook specifically discusses the issues of seizures and driving and states that physicians who are treating a patient with a single, unprovoked seizure should advise the patient to immediately stop driving vehicles of any kind.¹⁵

Although the court's ruling in *Medina* is not yet established common law, providers should undertake the following actions when treating a patient who has experienced a seizure:

- Advise the patient that they should not drive until such time as their primary care physician or treating neurologist believes it is safe to do so;
- Document in the patient's medical record that he advised the patient not to drive a motor vehicle until such time as the patient's primary care physician or treating neurologist has advised the patient that it is safe to do so;
- Advise the patient that the Code of Massachusetts Regulations requires that a driver who has experienced a seizure to immediately surrender his driver's license until the licensee has been episode free for a minimum of six months; and
- Document in the patient's medical record that he advised the patient that in accordance with the Code of Massachusetts Regulations the patient should voluntarily surrender his or her driver's license to the Registry of Motor Vehicles.

Some physicians may question whether or not further affirmative action beyond the above actions is necessary to minimize their potential liability exposure. It is in this regard that physicians should be aware of the legal duty to protect the confidentiality of medical information. The confidentiality of medical information is well-established in the Commonwealth of Massachusetts.¹⁶ Taking further action, such as informing law enforcement authorities of the potential danger arising from the operation of a motor vehicle by a patient who is subject to seizures, necessarily results in the disclosure of the patient's confidential medical information. The

¹² See *id.* at 42-43.

¹³ "Medical Perspectives on Impaired Driving", Massachusetts Medical Society (July 2003).

¹⁴ See *id.* at Introduction.

¹⁵ *Medina*, at 16.

¹⁶ See e.g. Mass. Gen. Laws ch. 214, § 1B; Mass. Gen. Laws ch. 111, §§ 70 and 70E; *Alberts v. Devine*, 395 Mass. 59 (1985); *Commonwealth v. Brandwein*, 435 Mass. 623 (2002); and 45 C.F.R. Parts 160 and 164.

Massachusetts Supreme Judicial Court has held that although there is a common-law duty not to disclose confidential medical information, such information may be disclosed by a physician if faced with a serious danger to the patient or others.¹⁷ Furthermore, the HIPAA Privacy Rule specifically provides that a physician may disclose protected health information if the physician believes in good faith that the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and such disclosure is to a person or persons reasonably able to prevent or lessen the threat.¹⁸

Therefore, currently there is no obligation by a physician in Massachusetts to take affirmative action, such as notifying law enforcement authorities, to prevent a patient who has experienced a seizure from operating a motor vehicle. However, if a physician believes that such action is necessary from a moral perspective, physicians should be aware that the disclosure of the patient's confidential medical information may present a liability exposure to the physician unless the physician believes that such disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of the individual or to the public. In this regard, the physician should consider only disclosing the patient's confidential medical information if the physician has warned the patient not to continue to drive a motor vehicle and the patient has informed the physician that he intends to continue driving despite the physician's warning.

IV. Conclusion

Although it is unclear as to whether or not the court's decision in *Medina* will become established common law in Massachusetts, physicians can take actions to help protect themselves from potential liability exposure resulting from the operation of a motor vehicle by a patient who is subject to seizures. In particular, the physician should advise the patient not to operate a motor vehicle until the patient's primary care physician or treating neurologist has declared that it is safe to do so. The physician should also advise the patient to voluntarily surrender his license to the Registry of Motor Vehicles. And most importantly, from a liability standpoint, physicians should document their patient advice directly in the patient's medical record.

Massachusetts Senate Approves Licensing of Pharmaceuticals

The Massachusetts Senate has passed a floor amendment to the State Budget, which requires the Department of Public Health, in consultation with the Board of Registration of Pharmacy, to promulgate regulations requiring the licensing of all pharmaceutical representatives. As a prerequisite to such licensure, pharmaceutical representatives will be required to complete continuing education approved by the Department of Public Health. The amendment also provides for a ban on pharmaceutical companies providing physician and health care facilities with entertainment, gifts, payments or anything of value.

In order for the amendment to become law, it will need to be approved by the Massachusetts House of Representatives after a House-Senate conference committee approves a compromise budget plan. Senator Mark Montigny has also filed a separate bill in the Massachusetts Senate, which incorporates the amendment's proposed reforms. He has stated that if the floor amendment is not enacted he intends to press forward with the bill.

¹⁷ *Alberts v. Devine*, 395 Mass. 59 (1985).

¹⁸ 45 C.F.R. 164.512(j)(i).

CMS Proposes New Discharge Requirements for Hospitals

The Centers for Medicare and Medicaid Services (“CMS”) recently issued a proposed rule which provides new requirements for hospital discharge notices under both Medicare and the Medicare Advantage Program. The proposed rule requires hospitals to comply with a two-step notice process when discharging patients. CMS has indicated that the intent of the proposed rule is to provide a more consistent approach to communicating appeal rights to Medicare and Medicaid Advantage beneficiaries. There is already a two-step discharge process for home health agencies, skilled nursing facilities, rehabilitation facilities and hospices.

The proposed rule provides that hospitals will be required to deliver, prior to discharge, a standardized, largely generic notice of non-coverage to each Medicare beneficiary whose physician concurs with the discharge decision. Hospitals will be required to deliver the notice on the day before the patient’s discharge. The notice will include the prospective discharge date and description of the appeal rights. If a patient exercises his or her right to an expedited review by a Quality Improvement Organization (“QIO”), the hospital will be required to deliver a detailed notice by the close of business of the day of the QIO’s notification of the patient’s request for an expedited review. The detailed notice shall include: (1) detailed information of why services are no longer reasonable and necessary or are otherwise no longer covered; (2) a description of any applicable Medicare coverage rule, instruction or other Medicare policy, including citations to the applicable Medicare policy rules or information about how the beneficiary may obtain a copy of the Medicare policy; (3) facts specific to the beneficiary and are relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary’s case; and (4) any other information required by CMS. The proposed rule will require that any information inserted in the detailed notice should be individualized and written in plain language to facilitate the patient’s understanding.

It should be emphasized that this is only a proposed rule from CMS. The Rogers Law Firm will continue to monitor the proposed rule and will provide updates accordingly.

This Newsletter is published by The Rogers Law Firm to keep its clients informed of developments in health law. The Newsletter should not be construed or relied upon as legal advice or legal opinion on any specific facts or circumstances. If you have any questions or concerns regarding the articles contained in the Newsletter or would like legal advice or legal opinion concerning a specific matter, please do not hesitate to contact any of the attorneys at The Rogers Law Firm, at (617) 723-1100.