
HEALTH CARE PRACTICE GROUP NEWSLETTER

In This Issue:

Massachusetts Issues Proposed Amendments to Hospital and Clinic Licensure Regulations	1
President Obama Reverses Federal Government Position on Stem Cell Research	5
Unauthorized Access to Medical Records Continues to be a Problem for Health Care Providers.	5
Massachusetts Court Denies Right to Immediate Appeal for a Health Care Provider's Challenge to Tribunal Decision	7
Senator Grassley Letter Challenges FDA Commissioner to Clarify Stance on Whistleblower Protections.	8

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Massachusetts Issues Proposed Amendments to Hospital and Clinic Licensure Regulations

The Division of Health Care Quality (“DHCQ”) of the Massachusetts Department of Public Health (“DPH”) recently proposed amendments to Massachusetts’ regulations regarding hospital licensure (105 CMR 130.000 *et seq.*) and licensure of clinics (105 CMR 140.000 *et seq.*). The proposed amendments implement certain provisions of chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care (the “Act”), which was signed into law by Governor Patrick on August 10, 2008. The proposed amendments seek to increase safety and improve quality of care by:

- (1) bringing greater transparency to the health care system;
- (2) prohibiting hospitals and clinics from seeking payment for certain adverse events; and
- (3) requiring hospitals and clinics to form patient councils and to develop methods to respond to a deterioration in a patient’s condition.

HOSPITAL LICENSURE REGULATIONS

The Act added five (5) new requirements to the hospital licensing statutes enumerated at M.G.L. c. 111. In addition to the requirements called for in the Act, DHCQ has proposed changes to the regulations

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concerning cardiac catheterization services and maternal/newborn services. A summary of the proposed amendments follows:

1. Reporting and Reimbursement for Serious Reportable Events (SREs): 105 CMR 130.331-130.332

In 2007, DPH revised its reporting forms to require hospitals to identify and report those incidents that meet the National Quality Forum’s (“NQF’s”) definition of Serious Reportable Event (“SRE”), in addition to the previous reporting requirements. Twenty-eight (28) events currently meet the definition of SRE on the NQF’s most recent list of NQF-endorsed events. The Act requires hospitals to report SREs to DPH and prohibits hospitals from charging or seeking reimbursement for services provided as the result of an SRE that meets criteria established in the statute and by DPH regulations.

The proposed amendment relating to SRE reporting and reimbursement requires hospitals to file a written report with DPH within seven (7) days of discovery of an SRE, and it must also provide a copy of this report to any responsible third-party payor and inform the patient of the SRE within the same 7-day period. The proposed amendment also mandates hospitals to establish policies and procedures for a documented review process to determine whether the hospital may charge or seek reimbursement from a patient or third-party payer for services provided as the result of an SRE, and for notifying a patient or patient’s representative about the occurrence of an SRE.

A hospital may not charge or seek reimbursement from a third party payor or a patient for services provided as a result of an SRE occurring on the premises covered by its license, unless it documents that the SRE was: (1) not preventable; (2) not within the hospital’s control; and (3) not unambiguously the result of a system failure based on the hospital’s policies and procedures.¹ If a hospital determines that the reimbursement criteria in the regulation have been met, the hospital must provide a written report to DPH, the patient, and any responsible third-party payor before it may charge or seek reimbursement for SRE-related expenses.²

2. Reporting of Healthcare-Associated Infections (“HAIs”): 105 CMR 130.1700- 130.1701

In 2008, DPH promulgated an amendment to the hospital licensure regulations requiring hospitals to report HAI process and outcome measures to the National Healthcare Safety Network (“NHSN”) and to grant access to HAI data to DPH and the Betsy Lehman Center. The proposed amendment adds the following definition of HAI: a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that: (1) occurs in a patient in a hospital and (2) was not present or incubating at the time of the admission during which the reaction occurs.

3. Patient and Family Advisory Council (“PFAC”): 105 CMR 130.1800-130.1801

The proposed amendment requires hospitals to establish patient and family advisory councils to facilitate patient and family participation in hospital care and decision-making, information sharing, and policy and program development. The PFAC will advise the hospital on matters including but not limited to: patient and provider relationships, institutional review boards, quality improvement initiatives and patient education on safety and quality matters. The proposed amendment requires hospitals to adopt

¹ “Unambiguously the result of a system failure based on the hospital’s policies and procedures” is defined in the proposed amendment to mean events that have been determined by the hospital to result from: (1) a failure to follow the hospital’s policies and procedures; or (2) inadequate or non-existent hospital policies and procedures; or (3) inadequate system design.

² At a minimum, the report must include: (1) description of the policies and procedures followed by the hospital in undertaking its reimbursement analysis; (2) narrative description of the SRE; (3) analysis and identification of the root cause of the SRE; (4) analysis of the reimbursement criteria; and (5) description of any corrective measures taken by the hospital following discovery of the SRE.

and implement policies and procedures that govern a PFAC's goals, membership, training, and roles and responsibilities. Hospitals must establish a PFAC no later than September 1, 2009, and must report their compliance with the PFAC requirements to DPH no later than October 1, 2009. The proposed amendment requires that at least fifty percent of the PFAC's members be current or former patients and/or family members, and that the PFAC be chaired or co-chaired by a patient or family member by December 1, 2009. The proposed amendment requires hospitals to provide an annual report to DPH describing the work of the PFAC during the preceding year.

4. Patient Rapid Response Method (“PRRM”): 105 CMR 130.1600

The proposed amendment requires acute care hospitals to adopt an early recognition and response method for staff members, patients and families to request additional assistance directly from a specially-trained individual if a patient's condition appears to be deteriorating. Each acute care hospital must establish an early recognition and response method, such as a patient rapid response method, most suitable for the hospital's needs and resources. The method established by the hospital must be available 24 hours per day. The proposed amendment requires the development and implementation of written policies and procedures describing the PRRM established by the hospital. Policies and procedures must address criteria for activating the PRRM, and education of staff, patients and family members who might activate the PRRM. The proposed amendment mirrors the Joint Commission's 2008 National Patient Safety Goal, which requires hospitals to have in-place an early recognition and response method most suitable for the hospital's needs and resources, and which may be activated by staff, patients and/or family members.

5. Retention of Patient Records: 105 CMR 130.370-130.371

DHCQ has proposed amendments to the hospital licensure regulation governing hospital patient records which would: (1) reduce the record retention period from 30 to 20 years; (2) clarify that the retention period runs from the date of discharge or the final treatment related to the episode of care contained in the record; (3) require hospitals to notify DPH before destroying records; (4) permit hospitals to convert existing paper records to electronic digital format before the expiration of the retention period, and to create original records in electronic digital format; and (5) require hospitals to notify patients in writing of the hospital's record retention and destruction policies.

6. Additional Proposed Changes:

a. Cardiac Catheterization Services: 105 CMR 130.900-130.982

The proposed amendment seeks to eliminate the physician operator minimum volume requirement for diagnostic procedures. This requirement was based on older guidelines from the American College of Cardiology (“ACC”). The current (2001) American College of Cardiology/Society for Cardiac Angiography and Interventions Consensus Document on Cardiac Catheterization Laboratory Standards does not include a recommended operator minimum volume for diagnostic procedures to assure proficiency in diagnostic procedures. Facility volume minimums and a minimum volume requirement for therapeutic procedures remain in the regulations. In addition to eliminating the diagnostic operator volume minimum, DHCQ has:

- Updated some terminology (e.g., references to percutaneous transluminal coronary angioplasty (“PTCA”), a specific type of coronary intervention, have been replaced with the broader term of percutaneous coronary intervention (“PCI”), to include newer techniques).

- Eliminated outdated language that applied to facilities already providing catheterization services in 1997 (at the time of the initial implementation of the cardiac catheterization service regulations).
- Eliminated specific Invasive Cardiac Services Advisory Committee (“ICSAC”) duties related to facility and operator volume minimums.
- Expanded section 130.965 (In-house Evaluation of Quality) to include the hospital’s establishment of a quality assurance assessment and performance improvement program for the service, as well as reporting requirements.
- Revised section 130.935 regarding minimum workload requirements. If a diagnostic lab does not perform 300 procedures per year it must forward to DPH the previous year’s quality assurance reports. If a diagnostic lab performs fewer than 150 diagnostic procedures per year it must, in addition to submitting to DPH the previous year’s quality assurance reports, request a review of the service by a nationally recognized peer review organization and send a copy of that report to DPH.
- Updated the staff training requirements to reflect current ACC PCI Guidelines and Cardiovascular Medicine Core Cardiology Training Guidelines, the training guidelines for fellowship programs.
- Added a requirement of board certification in interventional cardiology for any physician who performs interventional cardiac catheterization procedures, with language included to allow certain exemptions from this certification requirement.
- Included amendments recommended by DPH’s Radiation Control Program (“RCP”) that reference RCP regulations regarding the operation of x-ray systems.
- Added new requirements for those hospitals that provide Electrophysiology services. The proposed amendments require a Director of Electrophysiology, who is board certified in Clinical Cardiac Electrophysiology with five (5) years post-fellowship experience and skill in performing the procedure, and board certification in Clinical Cardiac Electrophysiology for physicians performing electrophysiology procedures.

b. Maternal and Newborn Services: 105 CMR 130.616-130.640

DHCQ has also put forth technical corrections to the existing maternal and newborn service sections of the regulation.

LICENSURE OF CLINICS REGULATIONS

The Act adds four new requirements to the clinic licensing statutes, enumerated at M.G.L. c. 111. The proposed amendments to the clinic licensure regulations³ essentially mirror the proposed amendments to the hospital licensure regulations in the areas of SREs, HAIs, and patient record retention. Additionally, the proposed amendments would require physician-owned, Medicare-certified ambulatory surgery centers to submit to Determination of Need (“DoN”) review and obtain a clinic license. The Act exempts from DoN review ambulatory surgery centers that were in operation or under construction as of August 10, 2008. These DoN exempt ambulatory surgery centers, however, are not

³ 105 CMR 140.000 *et seq.*

exempt from having to obtain a clinic license, and they must submit their clinic license applications no later than six (6) months after the effective date of the proposed regulations.

FINAL REGULATIONS

DHCQ intends to bring the final regulations before the Public Health Council for approval in either May or June of 2009. If you have any questions or concerns regarding the proposed amendments to the hospital licensure and/or licensure of clinics regulations, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

President Obama Reverses Federal Government Position on Stem Cell Research

On March 9, 2009, President Barack Obama issued Executive Order 13505 (the “Executive Order”), reversing the Bush Administration’s prohibition on federal funding for human embryonic stem cell research. Specifically, the Executive Order provides that the Secretary of the United States Department of Health and Human Services, through the Director of the National Institutes of Health (“NIH”), may now support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. The Director of NIH must, within 120 days of the issuance of the Executive Order, review existing NIH guidance and “other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards”, and issue new NIH guidance on human stem cell research consistent with the Executive Order.

The Bush Administration prohibited federal funding for human embryonic stem cell research over concerns regarding the destruction of embryos. This type of stem cell research involves redirecting cells from human embryos to produce replacement cells that may eventually be able to cure such ailments as Parkinson’s Disease, Multiple Sclerosis and cancer.

The Rogers Law Firm will continue to monitor the NIH’s promulgation of guidelines consistent with President Obama’s Executive Order and provide updates accordingly. In the meantime, if you have any questions regarding the Executive Order, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Unauthorized Access to Medical Records Continues to be a Problem for Health Care Providers

Bellflower Medical Center in Southern California recently fired fifteen (15) employees for improperly accessing the medical records of Nadya Suleman, the now famous mother of octuplets. Catskill Regional Medical Center in New York fired one (1) of its employees in its medical records department last month after an audit revealed that the employee was inappropriately accessing the medical records of acquaintances and neighbors. These recent incidents highlight the continuing problem

for health care providers of unauthorized access to medical records, or protected health information (“PHI”), by members of their workforce.

The unauthorized access of PHI by a workforce member of a healthcare entity presents a liability exposure to both the workforce member and the entity. The workforce member faces disciplinary action by the covered entity, a potential lawsuit from the individual whose PHI is the subject of the unauthorized access, and criminal fines and/or penalties under both state and federal laws. The healthcare entity faces civil fines and penalties under state and federal law, a lawsuit from the individual whose PHI is the subject of the unauthorized access, and adverse publicity which has the potential to affect patient volume and in turn, revenues.

ADDRESSING THE PROBLEM

The first step for a healthcare entity to undertake in order to effectively address the problem of unauthorized access to PHI is to perform an assessment of its current HIPAA Privacy and Security Policies and Procedures. At the time the HIPAA Privacy and Security Rules became effective, many healthcare entities rushed to promulgate the required policies and procedures in order to meet the government imposed deadlines. In doing so, they created the potential for generating inaccurate or inappropriate policies and procedures. Furthermore, the assessment and evaluation of a healthcare entity’s HIPAA Privacy and Security policies and procedures presents an opportunity to incorporate within these policies and procedures the best practices that have developed over the last several years with respect to HIPAA compliance. This includes best practices for detecting and preventing unauthorized access to PHI by a healthcare entity’s workforce members. This in turn leads to the second step a healthcare entity should undertake in order to effectively address the problem of unauthorized access to PHI by members of its workforce -- adoption of best practices.

Obviously, a healthcare entity needs to approach the issue of best practices with a mindset that not all of the practices are best suited for their entity. A healthcare entity needs to go through the exercise of what best practices work for their entity. The following are just a handful of those best practices which healthcare entities have adopted in an attempt to detect and prevent unauthorized access to PHI by members of their workforce:

- **Auditing**: Healthcare entities should enhance their auditing of electronic health records to ensure that members of their workforce are accessing only those records to which access is appropriate. Also, healthcare entities should communicate this enhancement and auditing to their workforce members.
- **VIPs/Workforce Members**: Healthcare entities should engage in targeted auditing of the electronic health records of workforce members and VIPs (celebrities, politicians, sports figures, trustees, donors, etc.) to assess for unauthorized access.
- **Reminders**: Healthcare entities should consistently remind their workforce members that they are prohibited under federal law (and in some instances state law) from unauthorized access to PHI. These reminders should come in varying forms, including e-mails and mailings to their departments, offices and homes. Also, it is worthwhile to have the compliance and/or privacy officer make these reminders in person (such as at departmental meetings).
- **Honeypots**: Healthcare entities should consider using “honeypots”--which is the practice of creating a fictitious electronic health record (oftentimes using the name of a celebrity or VIP) and then monitoring that electronic health record to see if it is inappropriately accessed by a workforce member. The use of honeypots can be utilized as a general

compliance tool or in instances where there is a suspicion that a specific workforce member or department is inappropriately accessing electronic health records.

- Disciplinary Actions: Perhaps the best method for a healthcare entity to demonstrate to its workforce how serious it takes the use of unauthorized access to PHI, is to take strong disciplinary action in response to an incident. It is now common to suspend or terminate a workforce member who engages in this activity. A healthcare entity can get the attention of its workforce by publicizing these disciplinary actions (without identifying the specific workforce member involved).
- Education: The final and perhaps most important step for a healthcare entity to take in order to effectively address the issue of unauthorized access to PHI by members of its workforce is education. Healthcare entities need to educate their workforce about this topic and the consequences they face as individuals as a result of engaging in this type of activity. This education should take place at the time the individual enters the entity's workforce (as part of a more comprehensive HIPAA training program), and should be mandatory. There should also be continuing education programs to reinforce the importance of this issue. These continuing education programs should also be mandatory.

CONCLUSION

Healthcare entities face a significant liability exposure as a result of unauthorized access to PHI by members of their workforce. The most effective way for a healthcare entity to address this serious problem is to undertake (and follow through with) a comprehensive assessment and education plan. Although it is unlikely that a healthcare entity will be able to completely eliminate incidents of unauthorized access to PHI through such a course of action, it will nevertheless serve to minimize the entity's liability exposure and demonstrate its commitment to protecting the health information of its patients.

Massachusetts Court Denies Right to Immediate Appeal for a Health Care Provider's Challenge to Tribunal Decision

On February 26, 2009, the Massachusetts Appeals Court determined that a health care provider is not entitled to immediate appeal as of right, from an unfavorable decision of a medical malpractice tribunal under M.G.L. c. 231, § 60B (the "Statute"). The underlying case began in Peabody District Court with a small claims action brought by Ann Marie Ruggiero alleging medical malpractice by Matteo L. Giamarco, D.M.D. After the case was referred to the Essex County Superior Court for a medical malpractice tribunal as required by the Statute, the tribunal determined that the plaintiff's offer of proof and complaint sufficiently established a legitimate claim appropriate for judicial determination. In response to the tribunal's decision, Dr. Giamarco filed a petition with a single justice of the Appeals Court seeking interlocutory review of the tribunal decision. The single justice denied the petition and declined to grant leave to take an interlocutory appeal. Dr. Giamarco then appealed the matter to the full Appeals Court. The court dismissed the appeal and held that health care providers do not have a right under the Statute to an immediate appeal of an unfavorable tribunal decision.

In reaching this determination, the court first pointed to the statutory intent of the medical malpractice tribunal requirement. The Statute was enacted to provide a barrier to frivolous medical malpractice claims in order to better control malpractice insurance rates by distinguishing legitimate claims from unfortunate medical outcomes. All treatment related claims¹ must pass before the medical malpractice tribunal before proceeding to court. The standard of review for the tribunal requires that the plaintiff's offer of proof and complaint be "sufficient to raise a legitimate question of liability appropriate for judicial inquiry."² If a tribunal finds this standard has been met, the action then continues to court. However, if the preliminary evidence fails to meet this burden, the plaintiff must file a bond as security against the costs of experts and attorney fees in the event the plaintiff does not prevail in the final judgment in order to continue the case.

The Statute does not make any provision for interlocutory appellate review of tribunal decisions because doing so would defeat the purpose of eliminating needless delay and the costs of court proceedings. The court noted that a health care provider aggrieved by a tribunal decision may obtain interlocutory appellate review of the tribunal decision, if at all, only by the discretion of a single justice.³

Senator Grassley Letter Challenges FDA Commissioner to Clarify Stance on Whistleblower Protections

On March 24, 2009, Senate Finance Committee ranking member Charles Grassley (R-IA) sent a letter to Frank M. Torti, M.D., MPH, Acting Commissioner at the Food and Drug Administration ("FDA"), seeking to clarify whistleblowers' rights. Senator Grassley expressed concern about a recent memorandum Dr. Torti sent to FDA employees warning them of their obligations to keep certain information confidential. The Senator stated that while he understood that "some information, including certain business trade secrets, needs to be protected from unauthorized disclosures, [he had] serious concerns that [the] memorandum goes beyond legitimate privacy concerns and appears to run contrary to many statutes protecting executive branch communications with members of Congress."

Senator Grassley specifically noted that the memorandum stated that certain information acquired from businesses and industry is protected as confidential and may only be disclosed in limited circumstances. The memorandum, which cited the Food, Drug, and Cosmetic Act, the Freedom of Information Act ("FOIA"), the Trade Secrets Act, and the Privacy Act, as well as FDA regulations as the controlling authority for determining when a document or information may be disclosed, added that FDA employees who violate these provisions may face disciplinary sanctions and criminal liability.

Senator Grassley expressed concern with the timing of the memorandum, "given some recent high profile matters concerning [the FDA] and the release of information that has shown failures in FDA's regulatory mission." He went on to state that "this recent memorandum could be viewed by some as an effort to chill and/or prevent FDA employees from exercising their rights under whistleblower protection laws to communicate with Congress." The Senator cited examples where: (1) recently released internal FDA documents seemed to suggest that lobbying may have influenced the decision on a device approval; and (2) an internal document showed that a physician was removed for inappropriate reasons from a recent safety panel. Senator Grassley did not believe that Congress would have been notified unless whistleblowers had spoken up.

¹ These claims may include tort actions, contract actions or M.G.L. c. 93A claims.

² *Ruggiero v. Giamarco*, 73 Mass. App. Ct. 743 (2009)(quoting *Kopycinski v. Aserkoff*, 410 Mass. 410, 413 (1991)).

³ M.G.L. c. 231, § 118.

Senator Grassley also warned Dr. Torti in the letter that “denying or interfering with employees’ rights to furnish information to Congress is also against the law” and that “federal officials who deny or interfere with employees’ rights to furnish information to Congress are not entitled to have their salaries paid by taxpayers’ dollars.” The letter recommends that Dr. Torti “should take the further step of issuing a second memorandum to FDA employees outlining their rights and whistleblower protections, as well as outlining the FDA’s responsibilities for respecting those protected disclosures” in order to ensure that the FDA remains “committed to the principles of open Government and transparency.”

The Rogers Law Firm will monitor the FDA’s response, if any, to Senator Grassley’s comments, and provide updates accordingly.

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