The Rogers Law Firm

April 2005
Volume 5

Client Newsletter

In This Issue:

Proposed Rule Updates Medicare Conditions of Participation for Hospitals. . .1

MGH Reaches Agreement with Patient's Family Regarding End-of-Life Care. 2

Massachusetts Legislature Approves Embryonic Stem Cell Research 3

Senate Finance Committee Continues Inquiry of Public Charities. 4

Health Insurance Bills Filed with Massachusetts Legislature. 5

CMS Sets Forth Procedures for Filing Non-Privacy HIPAA Complaints. 5

The Rogers Law Firm
A Professional Corporation
100 Cambridge Street
20th Floor, Suite 2000
Boston, MA 02114
(617) 723-1100
www.therogerslawfirm.com

Wilson D. Rogers, Jr.
Peter Pommersheim
Michael J. Fazio, Jr.
Wilson D. Rogers, III
Francis J. O'Connor
Mark C. Rogers
Megan M. Grew
Lori M. Nickerson

Proposed Rule Updates Medicare Conditions of Participation for Hospitals

The Centers for Medicare & Medicaid Services ("CMS") issued a Proposed Rule on March 24, 2005, updating the conditions of participation ("CoPs") hospitals must meet to participate in the Medicare and Medicaid programs. The proposals respond to concerns within the medical community that existing CoPs are contrary to current practice and are unduly burdensome. The Proposed Rule updates four of the existing CoPs:

- **<u>History and Physical Exam</u>:** The Proposed Rule expands the number of practitioners who may perform the history and physical examination and the time frame for the completion of the history and physical examination. The current regulations state that a history and physical examination must be done no more than seven days before, or forty-eight hours after, an admission for each patient by a doctor of medicine or osteopathy, or, for patient's admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the Medical Staff in accordance with State law. The Proposed Rule specifies that the history and physical examination must be completed no more than thirty days before or twenty-four hours after an admission for each patient by a physician or other qualified individual who has been granted these privileges by the Medical Staff in accordance with State law. Furthermore, the Proposed Rule requires that the history and physical examination be placed in the medical record within twenty-four hours after admission.

- **<u>Authentication of Verbal Orders</u>:** The Proposed Rule requires that all orders, including verbal orders, must be dated, timed and authenticated by a practitioner responsible for the care of the patient. The Proposed Rule provides for a five-year transition period from the publication of the Final Rule, which would allow all orders, including verbal orders, to be dated, time and authenticated by the prescribing practitioner or other practitioner responsible for the care of the patient.

- **Security of Medications:** The new regulation proposed by CMS requires all drugs and biologicals be kept in secure areas or locked when appropriate, to prevent unauthorized persons from obtaining access.

- **Post-Anesthesia Evaluation:** The Proposed Rule permits the post-anesthesia evaluation for inpatients to be completed and documented by any individual qualified to administer anesthesia. The current CoP requires that the evaluation be performed by the individual who administers the anesthesia.

CMS will be accepting public comments on the Proposed Rule until May 24, 2005. (The Proposed Rule can be located at http://www.cms.hhs.gov.) It is anticipated that a Final Rule will be published by the end of 2006.

MGH Reaches Agreement with Patient's Family Regarding End-of-Life Care

The Massachusetts General Hospital ("MGH") recently reached an agreement with the family of one of its patients regarding the withdrawal of life support. The patient, Barbara Howe, was diagnosed with Lou Gehrig's disease in 1991. At first, Ms. Howe told her family and her physicians that she did not want a tracheostomy. Ms. Howe, however, changed her mind in 1997 after an episode in which she could not breathe and passed out.

Ms. Howe progressively lost control of her bodily functions. Her condition deteriorated to the point where she had to be admitted to MGH in November of 1999. She has remained as a patient at MGH since that time. In August of 2000, she told one of her physicians, Dr. Andrew Putnam, that being alert was more important to her than eradicating pain. Ms. Howe also told Dr. Putnam that she wanted the providers at MGH to continue her aggressive care, even though her ability to interact was fading. Ms. Howe did have a written health care proxy which named her daughter, Carol Carvitt, as her proxy.

MGH's End-of-Life Committee reviewed Ms. Howe's case in July of 2001. Ms. Howe's primary care physician, Dr. Andrew Billings, requested that he be allowed to withdraw Ms. Howe's ventilator. He presented the Committee with a memorandum he had written regarding Ms. Howe's directives for end-of-life care. The memorandum states, in relevant part, as follows:

> "She was asked repeatedly whether she wanted to go on living in her current condition and she always indicated yes when she was mentally clear enough to answer these questions. She indicated that she wanted to be kept alive as long as she could enjoy her family. Did she feel it wrong to let yourself die in the face of terrible illness or suffering? She never said that she should be kept alive in this sort of situation."

Despite the memorandum of Dr. Billings, Ms. Howe's daughter remained adamant that her mother wanted aggressive treatment until she became semi-comatose and was unable to enjoy and respond to her family. The Committee agreed with Ms. Carvitt and denied the request of Dr. Billings to withdraw the ventilator.

On June 5, 2003, MGH's End-of-Life Committee met again to discuss Ms. Howe. Her condition had deteriorated to the point where the tissue on her right cornea had dried and torn because she could no longer blink to lubricate her eyes. Dr. Edward Cassem, the Chairman of the Committee, wrote a summary of the meeting which reads as follows:

> "There is now 100% unanimous agreement that this inhumane travesty has gone far enough. This is the Massachusetts General Hospital, not Auschwitz."

Ms. Howe's right eye was removed the next day. Later that month, Counsel for MGH asked the Suffolk County Probate and Family Court to intervene in the dispute. Judge Smoot ruled that there was not sufficient cause to overturn Ms. Carvitt as her mother's health care proxy. Judge Smoot did, however, advise Ms. Carvitt to refocus her assessment from her mother's wishes to her mother's best interests.

On January 13, 2005, Ms. Howe's physicians again asked the MGH End-of-Life Committee to order the withdrawal of life support. Ms. Howe was now in danger of losing her left eye. After further discussions, an agreement was finally reached between Ms. Carvitt and MGH which provides for the withdrawal of life support for Ms. Howe by June 30, 2005.

The case of Barbara Howe places a renewed focus on health care proxies. Massachusetts General Laws, c. 201D, authorizes an individual (the "Principal") to execute a health care proxy which appoints a health care agent to make health care decisions for the Principal, subject to any limitations set forth in the proxy. The authority of an agent under a health care proxy begins when the Principal is determined to lack capacity to make or communicate health care decisions. In the case of Ms. Howe, the Suffolk County Probate and Family Court upheld the authority of Ms. Carvitt to act as her mother's health care proxy.

Massachusetts Legislature Approves Embryonic Stem Cell Research

The Massachusetts Senate and House of Representatives have overwhelmingly approved legislation which endorses the creation of human embryos for stem cell research. The Senate and House of Representatives passed different versions of the stem cell bill, and therefore, a consensus will need to be reached before the bill is sent to Governor Mitt Romney for approval. Governor Romney publicly stated that he will not sign into law a stem cell bill which permits the cloning of human embryos for research. Despite Governor Romney's position, it is expected that the Senate and House of Representatives will easily be able to override the Governor's veto.

The stem cell legislation passed quickly through the Massachusetts Legislature at the urging of researchers who argued that such legislation was necessary to protect the stem cell research industry in Massachusetts. Both California and New Jersey have already enacted legislation endorsing embryonic stem cell research. Although Massachusetts scientists already conduct embryonic stem cell research, they are currently required to obtain approval from the local District Attorney prior to using embryos. The stem cell legislation passed by the Senate and House of Representatives removes this requirement. The legislation also provides the Massachusetts Department of Public Health with licensing authority over researchers conducting human embryonic stem cell research.

Both versions of the stem cell bill from the Massachusetts Legislature require a physician or other health care provider, who treats a patient for infertility, to provide the patient with information sufficient to allow the patient to make an informed decision regarding the disposition of unused embryos after treatment. The paitient shall be presented with the options of storing an unused embryo, donating it to another person, discarding the embryo, or donating the embryo for research.

The Rogers Law Firm will monitor the stem cell legislation and will provide updated accordingly.

Senate Finance Committee Continues Inquiry of Public Charities

The United States Senate Finance Committee continued its inquiry of charities and non-profits at a hearing in Washington, D.C. on April 5, 2005. The Finance Committee began examining the non-profit sector last summer after discovering several localities and transit systems were collecting fees for allowing corporations to benefit from tax shelters designed to help finance public works. At the recent hearing, IRS Commissioner Mark Everson testified that abuses by non-profit corporations during recent years are due in part to the failure of non-profit management and boards to effectively monitor their organization's finances, tax filings, business deals and executive pay. Commissioner Everson raised particular concern about non-profit hospitals, stating that it has now become difficult to distinguish them from for-profit hospitals.

The Chairman of the Senate Finance Committee, Senator Charles Grassley, R-Iowa, expressed his intent to move forward with legislative reforms in the non-profit sector. It is likely that such reforms will coincide with proposed legislation by President Bush that would create billions of dollars in tax breaks to encourage charitable giving. Senator Grassley indicated that such legislation must be accompanied by reforms in both charitable governance and giving.

The Panel on the Non-Profit Sector ("Panel"), an independent organization comprised of leaders of non-profit organizations from across the United States, has already responded to the inquiry from the Senate Finance Committee. The Panel promulgated an Interim Report detailing a series of recommendations designed to strengthen charitable organizations and their operations. The Interim Report encourages all charities and foundations to:

- Adopt and implement a Conflict of Interest Policy;
- Ensure its Boards include individuals with financial literacy skills; and
- Develop specific practices and procedures to encourage and protect whistleblowers.

The Panel is expected to issue a final report later this spring which will address such topics as compensation practices and revisions to IRS Form 990 Returns.

Health Insurance Bills Filed with Massachusetts Legislature

Governor Mitt Romney and Senate President Robert Travaglini recently announced separate health care bills designed to extend health insurance coverage to the uninsured population of Massachusetts. Governor Romney and Senator Travaglini proposed their plans after growing concern over the number of uninsured individuals in the state. It is estimated that seven percent, or 460,000, of Massachusetts residents do not have health insurance. Many of these individuals are employed by small businesses that either do not offer health insurance or are part-time or contract workers who are not eligible for benefits through their job.

Governor Romney's plan establishes the "Commonwealth Care Health Insurance Exchange", which will supervise a comprehensive health insurance product costing approximately $200.00 a month. The plans, which will be offered by private insurers, will offer the following categories of coverage: Preventative and Primary Care; Emergency Services; Surgical Benefits; Hospitalization Benefits; Ambulatory Patient Care; Mental Health Benefits; and Prescription Drug Coverage. The Commonwealth Care Health Insurance Exchange will facilitate the pre-tax payment of premiums by working individuals, resulting in a fifteen percent to thirty percent savings off their health insurance bill depending upon their yearly income. By using pre-tax dollars, working individuals will be able to purchase the new health plans for a cost of between $134.00 and $160.00 a month. The family of a working individual would be able to purchase a health plan for approximately $350.00 a month. A participant's company will also be able to make a financial contribution toward a worker's plan.

Senator Travaglini's health plan seeks to reduce by half the uninsured population of Massachusetts. His plan provides for the use of $168 million in state reserves to reduce medical costs and increase the number of Massachusetts residents with health insurance. He has designated $116 million of the $168 million to increase payments to Medicaid providers. Senator Travaglini will also seek to force companies that employ 50 or more people and do not provide health care coverage to their employees, to reimburse the state when their employees seek treatment from the public free-care pool.

The Rogers Law Firm will monitor and provide updates accordingly on the progress through the Massachusetts Legislature of the health plans of Governor Romney and Senator Travaglini.

CMS Sets Forth Procedures for Filing Non-Privacy HIPAA Complaints

On March 25, 2005, the Centers for Medicare & Medicaid Services ("CMS") published procedures for filing a complaint of non-compliance by a covered entity with certain provisions of the Health Insurance Portability and Accountability Act ("HIPAA"). The procedures address the filing of complaints with CMS related to a covered entity's non-compliance with the following HIPAA Administrative Simplification Provisions: Transaction and Code Set Rule; National Employer Identifier Number Rule; Security Rule; National Provider Identifier Rule; and National Plan Identifier Rule. The procedures do not address the filing of complaints related to the HIPAA Privacy Rule. The Office of Civil Rights of the United States Department of Health and Human Services, has already established procedures for filing complaints related to a covered entity's non-compliance with the HIPAA Privacy Rule.

The CMS procedures for filing non-privacy HIPAA complaints are intended to facilitate the investigation and resolution of complaints. All non-privacy HIPAA complaints must meet the following requirements:

- Be filed in writing, either on paper or electronically. (Complaint forms may be downloaded at http://www.cms.hhs.gov.)

- Describe the acts or omissions believed to be in violation of the applicable administrative simplification provisions.

- Provide contact information, including name, address and telephone number for the complainant and the covered entity that are the subject of the complaint.

- Be filed within 180 days of when the complainant knew or should have known that the act or omission that is the subject of the complaint occurred, unless this time limit is waived by CMS for good cause shown.

CMS undertakes an initial review of the complaint to determine if it has been filled out properly and alleges a failure to comply with an administrative simplification provision. If the complaint has been filled out properly and alleges a failure to comply with a HIPAA administrative simplification provision, CMS will begin a formal investigation of the complaint. CMS will ask a covered entity to respond to the alleged compliance failure by submitting in writing: (1) a statement demonstrating compliance; or (2) a statement setting forth, with particularity, the basis for its disagreement with the allegations; or (3) a corrective action plan. If CMS accepts a corrective action plan from a covered entity, it will actively monitor the plan and require the covered entity to periodically report its progress toward compliance. CMS will notify the complainant and the covered entity when the investigation is closed.

The procedures for filing non-compliance HIPAA complaints become effective on April 25, 2005.

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.