

Client Newsletter

In This Issue:

**Legislature Enacts
Massachusetts Stem Cell
Legislation1**

**OHRP Releases Guidance on
Incident Reporting4**

**Senate Introduces Bill on
Specialty Hospitals. 5**

**Congress Investigates Non-
Profit Hospitals6**

**Appeals Court Upholds Denial
of Plaintiff’s Request for
Informed Consent Claim7**

**CMS Releases Funds for
Treatment of Undocumented
Aliens. 8**

**Legislature Enacts Massachusetts
Stem Cell Legislation**

On May 31, 2005, the Massachusetts Legislature overrode Governor Mitt Romney’s veto of Senate Bill No. 2039, “An Act Relative to Enhancing Regenerative Medicine in the Commonwealth” (“Act”), which endorses human embryonic stem cell research in Massachusetts. As a result, the Act now becomes law. Governor Romney vetoed the Act based in part upon his objection to the Act’s allowance of human embryo cloning – the cloning of complete human embryos solely for the purpose of experimentation. The Act allows for research in clinical applications “involving the derivation and use of human embryonic stem cells, including somatic cell nuclear transfer, human adult stem cells from any source, umbilical stem cells, parthenotes and placenta cells.” The following is an overview of the legislation:

1. Commonwealth’s Policy on Stem Cell Research:

The Act provides that it shall now be the policy of the Commonwealth to actively foster research and therapies in the life sciences and regenerative medicine by permitting research and clinical applications involving the use of human embryonic stem cells. The Act further provides that it shall be the policy of the Commonwealth to prohibit human reproductive cloning.

2. Institutional Review Board Approval:

Any research involving the derivation of human embryonic stem cells through the use of human genetic material, shall only be conducted upon the written approval of a duly authorized Institutional Review Board (“IRB”). The approval shall include a detailed description of the research, experimentation or study to be conducted and a detailed description of the research, or a copy of the protocol. The approval shall be maintained as a permanent record by the IRB or by the hospital or institution for which the IRB acts. The University of Massachusetts Medical School shall establish and maintain a Public Institutional Review Board for institutions employing fifty or fewer full-time employees.

**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**

3. Certificate of Registration:

The Massachusetts Department of Public Health (“Department”) shall issue a Certificate of Registration to each institution the Department authorizes to conduct human embryonic stem cell research. The Department shall issue a Certificate of Registration to an applicant institution, provided said institution: (i) pays a fee of not more than Two Hundred (\$200.00) Dollars to the Department; and (ii) provides documentation to the department demonstrating that the institution has an IRB or has a contract with the Public IRB, which shall review the institution’s experimentation, study and procedures involving human embryonic stem cell research. The Certificate of Registration shall be valid for a term of three years from the date of issuance. An institution which has been issued a Certificate of Registration shall submit an Annual Report to the Department providing a summary of the research approved during that calendar year and a statement representing that such research was approved by the institution’s IRB.

4. Physician Disclosure to In Vitro Fertilization Patients:

A physician or other health care provider who provides a patient with in vitro fertilization therapy, shall provide said patient with “timely, relevant and appropriate information to allow the patient to make an informed and voluntary choice regarding the disposition of any pre-implantation embryos or gametes remaining following said treatment.” The physician shall present the patient with the options of “storing, donating to another person, donating for research purposes, or otherwise disposing of or destroying any unused pre-implantation embryos as appropriate.”

A physician or other health care provider treating a woman by any procedure by which an egg is intended to be extracted, shall provide the patient with the following documents to be issued by the Massachusetts Department of Public Health:

- (a) an information pamphlet which describes the procedure by which an egg is extracted from the patient, including potential health impacts of the procedure, the risks involved, any alternatives and their attendant risks, and that the particular treatment may involve currently unforeseeable risks to the patient, embryo or patient; and
- (b) an informed consent form which states that the patient has received, reviewed and understands the above-referenced information, has consulted with her physician, understands the procedure and its attendant risks, and consents to proceed with the procedure.

5. Public Umbilical Cord Blood Bank:

The Department of Public Health and the University of Massachusetts Medical School shall establish and maintain a public bank for umbilical cord blood and placental tissue for the purpose of collecting and storing umbilical cord blood and placental tissue that is donated by maternity patients in Massachusetts. The umbilical cord blood and placental tissue shall be made available for human embryonic stem cell research. Upon establishment of the public bank for umbilical cord blood and placental tissue, all licensed hospitals in Massachusetts shall inform pregnant patients under their care no later than thirty (30) days from the commencement of the third trimester of pregnancy, of the opportunity to donate to a publicly accessible certified cord, blood and placental tissue bank, blood and tissue extracted from the umbilical cord and placenta following delivery of a newborn child. Hospitals shall inform pregnant patients of this information no later than thirty days from the commencement of their third trimester of pregnancy.

An employee or member of the Medical Staff who is “directly affiliated with a sincerely held religious denomination that includes as an integral part of its beliefs and practices, the tenet that blood transfer is contrary to an essential part of his doctrine or beliefs”, shall not be required to comply with the Act’s provisions regarding the public umbilical blood bank.

6. Biomedical Research Advisory Council:

The Act establishes a Biomedical Research Advisory Council (“Council”), which shall make recommendations to the Legislature and the Governor regarding stem cell research. The Council shall submit an Annual Report to the Legislature, which includes its findings and recommendations regarding the implementation of this Act. The Annual Report shall also include an update on the current state of human embryonic stem cell research in Massachusetts.

7. Human Reproductive Cloning:

The Act specifically prohibits human reproductive cloning – “the asexual genetic replication of a human being by transferring a pre-implantation embryo that has been created by somatic cell nuclear transfer, parthenogenesis, or by other asexual means into a uterus or uterine-like environment with the purpose of creating a human fetus or human child.”

8. Religious Practices or Beliefs of Employees:

The Act provides that an employee shall “not be required to conduct scientific research, experimentation or study that involves the creation or use of pre-implantation embryos in relation to human embryonic stem cell research, to the extent that such research conflicts with the sincerely held religious practices or beliefs or the employee.” An institution is prohibited from taking any retaliatory action against an employee for refusing to participate in human embryonic stem cell research.

9. Enforcement:

The Massachusetts Department of Public Health shall enforce the provisions of the Act. An institution which violates the provisions of this Act is subject to a civil administrative penalty of up to \$100,000. An institution which engages in human reproductive cloning in violation of the Act, shall be subject to a civil administrative penalty of up to \$250,000.

The Act is obviously directed at institutions which conduct human embryonic stem cell research. Nevertheless, the Act’s provisions regarding (1) a physician’s duty to disclose information to patients receiving in vitro fertilization of the ability to donate pre-implantation embryos and (2) a hospital’s duty to disclose information to pregnant patients of the ability to donate umbilical cord blood and placental tissue for human embryonic stem cell research, are not limited to institutions which engage in human embryonic stem cell research. The provision requiring a hospital to disclose information to pregnant patients of the ability to donate umbilical cord blood and placental tissue turns upon the establishment of a public bank for the storage of umbilical cord blood and placental tissue. Furthermore, because pregnant women are generally not patients of hospitals prior to the time of delivery, the implementation of this provision will most likely require some additional clarification from the Department of Public Health as to the duty of hospitals to disclose this information to pregnant patients under their care no later than thirty days from the commencement of the third trimester of pregnancy.

Our office will monitor the establishment of the public bank and will provide updates accordingly.

OHRP Releases Guidance on Incident Reporting

The Office for Human Research Protections (“OHRP”) of the Department of Health and Human Services, has issued a Guidance on procedures institutions may use to file incident reports with the OHRP. Incident reports include: reports of unanticipated problems involving risk to subjects or others; serious or continuing non-compliance with HHS Regulations at 45 CFR 46 or the requirements or determinations of the Institutional Review Board (“IRB”); and suspension or termination of IRB approval. The Guidance addresses the following topics: (1) applicability of incident reporting requirements; (2) information to be included in incident reports; (3) time frame for reporting incident reports; (4) OHRP focus on corrective actions when reviewing incident reports; and (5) OHRP’s response to incident reports.

1. Applicability of Incident Reporting Requirements

Reporting requirements generally apply to all non-exempt human subjects research, which research that is: (1) conducted or supported by HHS; (2) conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (“FWA”) determined to be appropriate for such research; (3) or covered by an FWA, regardless of the funding source. The Guidance provides a simple chart which sets forth questions institutions should ask themselves when trying to determine whether or not an incident should be reported to the OHRP. Such questions include: “Did the incident occur in non-exempt human subjects research, and is it an unanticipated problem?” and “Did the incident occur in research that is HHS supported or conducted?” By answering these types of questions and following along with the chart, an institution can determine whether or not an incident should be reported to OHRP.

2. Information to be Included in Incident Reports

Based upon the type of incident an institution is reporting to OHRP, the Guidance sets forth the information to be included in these incident reports. The types of incidents include: unanticipated problems risks to subject or others; serious or continuing non-compliance; and suspension or termination. Although the specific information contained within the incident reports is specific to the type of incident being reported, the general information to be included in each of the reports include: name of the institution conducting the research; title of the research project and/or grant proposal involved; name of the principle investigator on the protocol; number of the research project assigned by the IRB; a detailed description of the problem, non-compliance or reason for suspension or termination; and the action the institution is taking in response to the incident.

3. Time Frame for Reporting Incidents

The current OHRP regulation only specified that an institution report an incident “promptly”. The regulations do not set forth a specific time frame. The Guidance states that for serious incidents the matter should be reported to OHRP within days. However, for a less serious incident, a few weeks may be sufficient. The Guidance suggested that it may be appropriate to send an initial report and indicate that a follow-up or final

report will follow by the earlier of: a specific date; or when an investigation has been completed or a corrective action plan has been implemented.

4. OHRP Focus on Corrective Actions when Reviewing Incident Reports

The Guidance states that reviewing an institution's report of an unanticipated problem, the OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Specifically, OHRP addresses whether or not the corrective actions will help ensure that the incident will not happen again. The OHRP recommends that when appropriate, corrective actions be applied institution-wide.

5. OHRP Response to Incident Reports

After OHRP receives and evaluates an incident report from an institution, it will respond in writing and state that the report was adequate or request additional information.

The OHRP Guidance is available at www.hhs.gov/ohrp/policy/incidreport_ohrp.html. The Guidance states that for further questions on reporting, institutions may contact the Director of the Division of Compliance Oversight at 301-496-7005.

Senate Introduces Bill on Specialty Hospitals

On May 11, 2005, Sen. Charles Grassley, Chairman on the Committee on Finance, and Sen. Max Baucus, ranking minority member of the Senate, introduced legislation which would prohibit physicians from referring Medicare and Medicaid patients to use specialty hospitals in which they have an ownership interest. The number of specialty hospitals in the United States has grown rapidly in the last several years, particularly those focusing on cardiovascular and orthopedic procedures. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, established an eighteen month moratorium on physician referrals to specialty hospitals in which they have an ownership interest. The moratorium was brought about due to concerns about the rapid growth of these facilities, physician self-referrals and the overall impact these hospitals may have on healthcare as a whole. The moratorium expired on June 8, 2005.

The legislation introduced by Senators Grassley and Baucus, entitled "The Hospital Fair Competition Act of 2005", prohibits physicians from referring Medicare and Medicaid patients to specialty hospitals in which they have an ownership interest. According to the press release from the U. S. Senate Committee on Finance, the legislation was introduced due to information from recent hearings and government reports which show that these specialty hospitals treat patients who are less sick, and hence more profitable, do not have lower costs than community hospitals and treat lower shares of Medicaid patients. Therefore, physician-owned specialty hospitals treat the most profitable patients, leaving community hospitals to treat a disproportionate share of less profitable patients. Although the legislation would permanently ban physician ownership of new specialty hospitals, physician-owned specialty hospitals already in operation or under development before November 18, 2003, would be exempt from the ban if they met certain conditions. These conditions include: not adding physician investors, not increasing the percent of physician investment, not adding new beds or operating rooms and not expanding current services.

A day after the Hospital Fair Competition Act was introduced, the Centers for Medicare and Medicaid Services (“CMS”) published a report to Congress on physician-owned specialty hospitals. The report states that CMS will, over the next six months, undertake a review of its procedures for enrolling specialty hospitals in the Medicare Program. Furthermore, CMS will undertake a series of steps to reform Medicare payments that may provide specialty hospitals with an unfair advantage over other types of providers, such as community hospitals and ambulatory surgical centers. The CMS report directs its regional offices to not issue new specialty hospital provider agreements or authorize an initial survey by the state survey agency for new specialty hospitals during CMS’ review of procedures for enrolling specialty hospitals in the Medicare program. According to the report, CMS plans to complete its review process by January, 2006.

In addition to prohibiting physicians from referring Medicare and Medicaid patients to new specialty hospitals in which they have an ownership interest, the Hospital Fair Competition Act also seeks to make several changes to the Diagnostic Related Groups, or DRG System. Specifically, the legislation directs CMS to recalibrate DRG’s weights based on costs at least once every five years. The legislation also directs CMS to calculate relative weights based upon hospitals’ specific data rather than on the national average of charges. Furthermore, the legislation directs CMS to examine the current DRGs to ensure that they appropriately capture patients’ differing severity of illness.

The Rogers Law Firm will monitor the Hospital Fair Competition Act of 2005 and will provide updates accordingly.

Congress Investigates Non-Profit Hospitals

The United States Congress continued its inquiry into non-profit organizations last month by focusing on the non-profit healthcare sector. At a House Ways & Means Committee hearing on May 26, entitled “A Review of the Tax-Exempt Hospital Sector”, the hearing addressed the following issues: the history of hospital exemption; IRS oversight of tax-exempt hospitals; the need for congressional oversight of hospital exemption; and federal policies that subsidize the provision of hospital services to the indigent. At the hearing, the Committee was told that the non-profit hospital tax exemption is worth more than \$50 billion dollars a year. Nevertheless, IRS Commissioner Mark Everson testified that he was “comfortable” with the current community benefit standard used by the IRS in determining hospitals’ tax-exempt status. He stated that he had no specific recommendations for changing tax-exempt policy for non-profit hospitals. He did note, however, that oftentimes revocation of exempt status is not desirable because it imposes a disproportionate hardship on those who need help from that particular non-profit.

The hearing occurred the day after Senate Finance Committee Chairman Charles E Grassley (R-Iowa) sent a letter to ten hospitals and hospital systems asking them to answer over forty questions about the charity care they provide to their patients, the activities benefiting hospitals’ communities; and their billing-collection activities. The Senate Finance Committee has been conducting their own hearings of the non-profit sector. The hospitals are expected to reply to Sen. Grassley’s letter by July 11.

The increasing focus of the non-profit sector by both the House Ways & Means Committee and the Senate Finance Committee suggests that Congress will consider passing legislation requiring non-profit hospitals to justify their federal tax exemptions.

Appeals Court Upholds Denial of Plaintiff's Request for Informed Consent Claim

The Massachusetts Appeals Court recently upheld a trial court judge's decision that a breast cancer patient was not entitled to submit an informed consent claim to the jury as part of her medical malpractice action against the radiologist who allegedly failed to properly read her mammogram and therefore, failed to perform an ultrasound. The Plaintiff in Roukounakis v. Messer, et al, 63 Mass. App. Ct. 482 (2005), alleged that the radiologist breached his duty of informed consent as a result of his failure to inform her about a questionable nodular area on her mammogram and offer her an ultrasound. The Appeals Court, however, ruled that the trial court was correct in not submitted the informed consent claim to the jury because the Plaintiff's expert acknowledged during the trial that if the radiologist did not believe there was anything suspicious regarding the Plaintiff's mammogram, there would be no reason to inform her about an ultrasound.

The Plaintiff, Laila Roukounakis, had a routine mammogram in February of 1993. After additional x-ray films were taken, Ms. Roukounakis was informed that the mammogram was normal. Approximately ten months later, Ms. Roukounakis began feeling fatigued and developed a tender area in her left breast. Her primary care physician arranged for another mammogram, which revealed a suspicious mass. An ultrasound and subsequent surgical biopsy showed a mass of 4 to 5 centimeters. Ms. Roukounakis underwent a mastectomy and was treated with chemotherapy. During her treatment, Ms. Roukounakis obtained the films from the 1993 mammogram and discovered that the report noted a "questionable nodular area" in her left breast. Ms. Roukounakis subsequently filed a medical malpractice against the radiologist, Dr. Ronald Messer, alleging that he was negligent in failing to diagnose her cancer and also that he had failed to obtain her informed consent by not disclosing to her all significant medical information and material for her to make an intelligent decision with respect to her decision.

At trial, a radiologist testified as an expert witness on behalf of Ms. Roukounakis and stated that the area noted to be questionable in the 1993 mammogram needed further investigation. The expert also discussed the information he considered a patient should receive in such circumstances: "When you find an abnormality in the breast that you cannot exclude carcinoma as being the cause of the abnormality, then you are obligated to tell the patient that." On cross-examination, however, the expert stated that if the radiologist did not believe there was anything suspicious, there would be no reason for an ultrasound or biopsy. During his testimony at the trial, Dr. Messer stated that he did not think the questionable area on Mrs. Roukounakis' mammogram was suspicious for cancer, but rather he thought it was more likely a compression artifact. He testified that after he ordered a stop compression film, the area on the film "thinned out." Therefore, the questionable nodular area, in his opinion, was a compression artifact with "no clinical significance" in that "nothing [was] there."

At the Charge Conference before the jury received the case, the trial judge ruled that the informed consent claim had not been made out and refused Plaintiff's request to give an instruction regarding that issue. The judge suggested that had Dr. Messer acknowledged that he had some doubt about the mammogram, he might have allowed the question of informed consent to go to the jury. However, weighing the need for accommodation of the Plaintiff's right to know, fairness to Dr. Messer and society's interest that medicine be practiced without unrealistic or unnecessary burdens being placed on practitioners, the judge refused to allow the jury to consider the question of informed consent. The jury subsequently found Dr. Messer was not negligent with respect to his care of Ms. Roukounakis.

Ms. Roukounakis appealed the trial court's decision, alleging that it was error for the trial court to refuse to instruct the jury on the claim of informed consent. The Appeals Court, however, upheld the trial court's

decision not to allow the informed consent claim to go to the jury. The Court stated that the informed consent standard in Massachusetts, as stated by the Massachusetts Supreme Judicial Court in Harnish v. Children's Hosp. Med. Center, 387 Mass. 152, 155 (1982) is as follows: "A physician owes to his patient the duty to disclose in a reasonable manner, all significant medical information that the physician possesses, or reasonably should possess, that is material to an intelligent decision by the patient, to undergo a proposed procedure." The information a physician reasonably should possess is that information possessed by the average qualified physician or, in the case of a specialty, by the average qualified physician practicing that specialty. Therefore, the Court held that in informed consent cases, the first step is determined by expert evidence, what the physician should know. The Appeals Court noted that the Plaintiff's expert agreed on cross-examination that if Dr. Messer did not have reasonable suspicion for the finding on the 1993 mammogram . . . [he] wouldn't expect Dr. Messer to do anything more than he did." Dr. Messer testified at trial that he excluded carcinoma and had no suspicions regarding Ms. Roukounakis' mammogram in 1993. The Court ruled that a physician's duty to disclose information to a patient as part of the informed consent doctrine does not arise until the physician becomes aware of the condition. Therefore, although Ms. Roukounakis' allegations against Dr. Messer for failure to diagnose her condition gives rise to a claim for negligence, it does not support a claim for informed consent.

CMS Releases Funds for Treatment of Undocumented Aliens

The Centers for Medicare and Medicaid Services ("CMS") recently released funds to help hospitals provide emergency care and treatment to undocumented aliens. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, set aside \$1 billion dollars through 2008, to help hospitals and emergency providers recoup some of the expenses of providing critical care to undocumented aliens. Pursuant to the Emergency Medical Treatment and Labor Act ("EMTALA"), hospitals participating in the Medicare program must screen all persons, including undocumented aliens, seeking emergency care, and provide the treatment necessary to stabilize those who have an emergency condition.

The funding will be provided to states based on the formula established in the MMA. States with higher estimates of undocumented aliens, including California and Texas, will receive the most money under this program. According to the MMA, funds can be used to cover all medically necessary and appropriate services which physicians furnish to a hospital patient who receives emergency services required under EMTALA, as well as related hospital inpatient and outpatient services and ambulance services. CMS will designate a single contractor for the purposes of enrolling providers, receiving claims, calculating provider payment amounts and effectuating payments. Providers can claim payment for emergency services furnished to eligible patients beginning May 10. All claims will be filed electronically with the CMS designated contractor.

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.