
HEALTH CARE PRACTICE GROUP CLIENT NEWSLETTER

In This Issue:

Massachusetts Proposes Regulations Governing Pharmaceutical and Medical Device Manufacturer Conduct	1
First Circuit Affirms Dismissal of EMTALA Claims Against Hospital.	4
U.S. District Court Allows Trial to Determine Whether Medical Residents' Salaries Are Subject to FICA Taxes	5
Court Upholds Exclusion of Resident Research Time from FTE Count.	7
Institute of Medicine Report Calls for Reduced Hours and Workloads for Medical Residents to Prevent Fatigue-Related Mistakes	8
Illinois Health Network and Medical Center to Pay \$36 Million Settlement after Self-Reporting Possible Healthcare Fraud	9

The Rogers Law Firm

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
Robert E. Driscoll, Jr.
Lawrence P. Donnelly

Massachusetts Proposes Regulations Governing Pharmaceutical and Medical Device Manufacturer Conduct

On December 10, 2008, the Massachusetts Public Health Council ("PHC") released proposed regulations¹ drafted by the Massachusetts Department of Public Health ("DPH"), implementing a law enacted earlier this year governing gift-giving and other sales and marketing practices of pharmaceutical and medical device manufacturers. PHC stated that the proposed regulations, which mandate broad public disclosure of fees, payments, and other compensation by pharmaceutical and medical device manufacturers to healthcare providers, will be some of the most stringent in the nation.

On August 10, 2008, Governor Patrick signed into law Chapter 305 of the Acts of 2008, "An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare". Section 14 of this Act added a new chapter to the General Laws, Chapter 111N, entitled "Pharmaceutical and Medical Device Manufacturer Conduct". With a focus on preventing undue influence in the relationship between health care practitioners and pharmaceutical and medical device manufacturers, Chapter 111N requires that manufacturers adopt and comply with a Marketing Code of Conduct, establish compliance and training programs pursuant to the Marketing

¹ Available online at:
http://www.mass.gov/Eeohhs2/docs/dph/legal/pharmacy_med_device_reg105cmr970.doc.

Code of Conduct, and disclose marketing payments made by pharmaceutical or medical device manufacturers to health care practitioners.

Chapter 111N calls for DPH to implement the statute and enforce its provisions. Specifically, Chapter 111N directs DPH to: (1) promulgate regulations adopting a standard Marketing Code of Conduct for all pharmaceutical and medical device manufacturers that employ persons to sell or market prescription drugs in Massachusetts; and (2) establish a public database of payments to health care practitioners by pharmaceutical and medical device manufacturers that employ persons to sell or market prescription drugs in Massachusetts, as well as to set fees in conjunction with the disclosure requirements of the chapter. The proposed regulations (105 CMR 970.000) recently promulgated by DPH set out what is and is not permissible with respect to marketing prescription drugs or medical devices in Massachusetts, outline the statutory compliance directives, and interpret the contours of the disclosure requirements for pharmaceutical and medical device manufacturers. The proposed regulations largely track the statutory provisions of chapter 111N regarding permissible and prohibited activities of pharmaceutical and medical device manufacturers in their financial relationships with health care practitioners. Where clarification was required, DPH provided interpretation of the statutory language in Chapter 111N.

The proposed regulations would, among other things, prohibit a pharmaceutical or medical device manufacturer, or its agent, from providing the following to a Massachusetts health care practitioner:

- grants, scholarships, subsidies, consulting contracts, or educational items in exchange for prescribing or disbursing prescription drugs or medical devices;
- entertainment or recreational items of any value;
- payments in cash or cash equivalents either directly or indirectly except as compensation for *bona fide* services;
- complimentary items such as pens, coffee mugs, gift cards, or flowers;
- meals that are part of an entertainment or recreational event, offered without an informational presentation, offered outside of a health care provider's office, or provided to a health care provider's spouse or other guest; and
- financial support for the cost of travel, lodging, attendance, or other personal expenses of a non-faculty health care provider in connection with continuing medical education events, conferences, or meetings.

The proposed regulations do not prevent pharmaceutical and medical device manufacturers from providing modest and occasional meals in conjunction with informational sessions in specified clinical training settings, reasonable compensation for substantial professional and consulting services of health care practitioners for a genuine research project or clinical trial, the provision of prescription drug or medical device demonstration and evaluation units, and payments for *bona fide* services, which are defined to include consulting services such as research and participation on advisory boards.

The proposed regulations require pharmaceutical and medical device manufacturers to make an annual disclosure to DPH by July 1 each year setting forth “the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50” to any health care practitioner in connection with the company’s sales and marketing activities.² The definition of sales and marketing activities included in the proposed regulations excludes payments made as reasonable compensation in connection with a genuine research project or clinical trial.³ Each annual disclosure must be accompanied by a fee of \$2,000 and a certification of accuracy by the disclosing company. The proposed regulations also prohibit a pharmaceutical or medical device manufacturer from knowingly structuring fees or payments to health care practitioners to circumvent the reporting requirements.

The proposed regulations impose an ongoing duty of good faith compliance on every person subject to the regulations. Specifically, the proposed regulations require pharmaceutical or medical device manufacturers to:

- adopt and comply with the most recent Marketing Code of Conduct as adopted by DPH;
- adopt and submit to DPH a description of a training program designed to ensure that all representatives who are employed by or acting on behalf of the company and who visit health care practitioners have sufficient knowledge of the Marketing Code of Conduct, general science, and product-specific information;
- certify to DPH that it is in compliance with the Marketing Code of Conduct;
- adopt and submit to DPH policies and procedures for investigating and taking corrective action in response to instances of non-compliance with the Marketing Code of Conduct; and
- submit to DPH the name, title, address, telephone number, and electronic mail address of the compliance officer it has identified as responsible for operating, monitoring, and enforcing the Marketing Code of Conduct.⁴

Finally, pharmaceutical and medical device manufacturers must certify to DPH that it has performed annual audits to ensure compliance with the Marketing Code of Conduct.

The proposed regulations put forward July 1, 2009 as the deadline for initial compliance with the Marketing Code of Conduct, and July 1, 2010 as the date for submission of the first required disclosure report by pharmaceutical and medical device manufacturers. DPH has set two public hearings on the proposed regulations. The hearings are scheduled to occur on January 9, 2009, at the Public Health Council Room, 250 Washington Street, Boston, MA, at 9 a.m., and on January 12, 2009, at UMASS Medical School, Amphitheater I, 2nd Floor, 55 Lake Avenue North, Worcester, MA, at 1 p.m. If you have any questions regarding

² 105 CMR 970.009.

³ 105 CMR 970.004.

⁴ 105 CMR 970.005.

the proposed regulations, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

First Circuit Affirms Dismissal of EMTALA Claims Against Hospital

The United States Court of Appeals for the First Circuit recently affirmed a district court decision to dismiss a plaintiff's claims against a hospital in Puerto Rico under the Emergency Medical Treatment and Labor Act ("EMTALA"). The Court held that the plaintiff's claims in *Fratlicelli-Torres v. Hospital Hermanos, et al.*, might trigger state-law medical malpractice liability, but they did not amount to violations of EMTALA.

The plaintiff, Nivia Fraticelli-Torres, brought the EMTALA claims against Hermanos Hospital and its providers on behalf of her deceased husband, Guillermo Bonilla Colon. Bonilla went to the hospital's emergency room complaining of severe chest pains. The treating physician ordered a series of tests and concluded that Bonilla had suffered a myocardial infarction. Bonilla was transferred to the hospital's intensive care unit. However, his condition continued to deteriorate and he was transferred to another hospital where he died several weeks later of congestive heart failure.

The plaintiff filed a lawsuit against Hermanos Hospital and its providers as a result of Bonilla's death. In addition to a traditional medical malpractice claim, the plaintiff alleged that the defendants violated EMTALA by (i) failing to subject Bonilla to an adequate cardiac screening examination in accordance with established hospital protocols; (ii) failing to provide Bonilla with adequate medical treatment for his diagnosed heart condition; (iii) failing to immediately transfer Bonilla to another hospital capable of providing the necessary medical care; and (iv) failing to adequately stabilize Bonilla before his transfer to the other hospital. The district court granted the defendants' motion for summary judgment and the plaintiff appealed to the First Circuit Court of Appeals.

EMTALA requires a hospital with a dedicated emergency department to provide an appropriate medical screening, within the hospital's capabilities, to any person who comes to the emergency department and requests, or has a request made on their behalf for, treatment for a medical condition. If it is determined that the individual has an emergency medical condition, the hospital must stabilize the patient or effect an appropriate transfer to another hospital which can stabilize the patient.

The plaintiff argued that because the hospital did not provide Bonilla with anti-clotting therapy within the first twelve hours of the onset of the myocardial infarction, it had violated its own hospital protocol, and therefore, provided disparate treatment to Bonilla. The First Circuit rejected this argument concluding that because anti-clotting treatment is not a diagnostic tool, but rather a treatment option, the decision not to order the treatment did not violate the EMTALA screening requirement. Furthermore, although the decision not to offer anti-clotting therapy implicates EMTALA's stabilization requirement, the Court pointed out that the "stabilization obligation does not impose a standard of care prescribing how physicians must treat a critical patient's condition while he remains in the hospital, but

merely prescribes a precondition the hospital must satisfy before it may undertake to transfer the patient to another hospital.” Therefore, the Court ruled that the failure to order the anti-clotting therapy was not a violation of EMTALA’s stabilization requirement.

Finally, the Court rejected the plaintiff’s argument that EMTALA was violated as a result of the hospital’s failure to transfer Bonilla to another hospital that could provide necessary treatments (e.g. angioplasty). The Court noted that EMTALA does not impose any positive obligation on a covered hospital to transfer a critical patient under particular circumstances to obtain stabilization at another hospital. Rather, EMTALA merely restricts the conditions under which a hospital may transfer an unstabilized critical patient. The Court held that “a hospital’s negligent medical decision not to transfer a critical patient promptly to another hospital to receive necessary treatment might trigger state-law medical malpractice liability, but it could not constitute an EMTALA anti-dumping violation.”

The First Circuit’s decision in *Fraticelli-Torres v. Hospital Hermanos* is important, as First Circuit decisions do serve as precedent in Massachusetts Federal District Court cases. Furthermore, the case provides helpful guidance between stabilization and treatment under EMTALA.

If you have any questions or concerns regarding this case or EMTALA, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

U.S. District Court Allows Trial to Determine Whether Medical Residents’ Salaries are Subject to FICA Taxes

The Federal Insurance Contributions Act (“FICA”) of the Internal Revenue Code imposes taxes on the wages a person receives with respect to employment.¹ Until November of 2003, Partners Healthcare System, Inc. (“Partners”) paid FICA taxes on the salaries of its medical residents. In 2003, Partners filed for refunds of these payments, citing that resident salaries were scholarship grants and exempt from FICA taxes. The Internal Revenue Service (“IRS”) credited Partners for over \$24.2 million in refund payments then subsequently claimed the refund was made in error and brought an action against Partners to recover that amount plus interest. The United States District Court of the District of Massachusetts recently held that payments to medical residents do not qualify as scholarships and are therefore subject to taxation under FICA. However, the Court further held that a determination of whether residents fall under the “student exception” to FICA must be resolved by formal fact-finding at trial.

Internal Revenue Code

The Internal Revenue Code imposes taxes under FICA in order to support funding for the Social Security system. FICA collects taxes on employment wages, which are defined as “all remuneration for employment, including the cash value of all remuneration (including

¹ 26 U.S.C. § 3101(a).

benefits) paid in any medium other than cash.”² The Code then provides a list of twenty-one exceptions to this requirement, including benefits or payments that are qualified scholarships or fellowship grants used for qualified tuition and related expenses.³ Although this FICA exception does not define “scholarship” or “fellowship grant,” Treasury Regulations set forth a two-pronged primary purpose test that requires: (1) the primary purpose of the payment must be to enable the recipient to pursue studies or research; and (2) the payment must not be compensation for services.⁴ In addition, the United States Supreme Court has described a scholarship or fellowship as a “relatively disinterested, ‘no-strings’ educational grant, with no requirement of any substantial *quid pro quo*”⁵ from the recipients.”⁶

FICA defines “employment” as “any service, of whatever nature, performed by an employee for the person employing him.”⁷ This section provides a “student exception” that excludes services performed in the employ of a school, college, or university if the service is performed by a student enrolled and regularly attending classes at that school, college, or university.⁸

Analysis

The Court divided the case into two issues: determining whether the salaries of medical residents constitute wages under FICA and if so, whether medical residents are excluded from FICA taxes under the “student exception”. Partners claimed that despite its previous FICA payments for residents, the residents’ salaries are actually stipends rather than wages. The IRS contended that although residents are physicians in training, their salaries represent compensation for the patient care services they provide. The Court used the “quid pro quo” standard advanced by the Supreme Court and found that despite the learning process of the resident training through patient care, the salary is still compensation given in exchange for services rendered. The Court granted the IRS motion for summary judgment on this issue, concluding that medical resident salaries are wages within the terms of FICA.

After concluding that medical resident wages are taxable under FICA, the court then addressed the second issue, whether residents fall within an employment exception. Partners argued that resident status under the “student exception” should be assessed on a case-by-case basis. Partners offered evidence that its residency program is a school at which residents are students enrolled in classes as required by the plain meaning of the exception. In contrast, the IRS responded that a fact-based analysis is not necessary because the legislative history of the statute⁹ indicates that medical residents are per se ineligible for the student exception. The Court looked to recent case law precedent set by other Circuits addressing this issue which have often refused to adopt a per se rule because the statute does not categorically exclude residents which would call for case-specific analysis rather than a categorical ineligibility for certain classes of employee-students.¹⁰ The Court denied the IRS motion for

² *Id.*

³ 26 U.S.C. § 117(b)(1).

⁴ 26 C.F.R. § 1.117-4(c).

⁵ “*Quid pro quo*” is a Latin term meaning something in exchange for something else.

⁶ *Bingler v. Johnson*, 394 U.S. 741 (1969).

⁷ 26 U.S.C. § 31212(b)(A).

⁸ 26 U.S.C. § 3121(b)(10).

⁹ 26 U.S.C. § 3121(b)(10).

¹⁰ *University of Chicago Hospitals v. United States*, 2008 WL 4301442, (7th Cir. Sept. 23, 2008).

summary judgment on the second issue and held that any consideration of developing something such as a per se rule requires formal fact-finding.

The Rogers Law Firm will continue to monitor *United States v. Partners Healthcare System, Inc.*, and will provide updates as appropriate.

Court Upholds Exclusion of Resident Research Time from FTE Count

The United States Court of Appeals for the First Circuit recently upheld the decision by the Secretary of the United States Department of Health and Human Services (“HHS”) to exclude from a hospital’s Indirect Medical Education (“IME”) adjustment the Full-Time Equivalent (“FTE”) count pertaining to the time residents spend performing research unrelated to patient care. The Court in *Rhode Island Hospital v. Levitt* (First Circuit, No. 07-2673) held that the Secretary’s interpretation of the applicable regulation was not plainly erroneous or inconsistent with the regulatory language.

Rhode Island Hospital, which is a large acute care facility in Providence with a significant graduate medical education program, requested that its fiscal intermediary include 290 FTE residents in its calculation of the hospital’s IME adjustment. The fiscal intermediary, however, ruled that the Medicare regulations precluded counting research time in a hospital’s FTE count. As a result, the fiscal intermediary reduced the hospital’s FTE count by 12.06, which resulted in decreasing the hospital’s IME adjustment by roughly \$1 million. Rhode Island Hospital appealed the decision to the Provider Reimbursement Review Board (“PRRB”), which reversed the fiscal intermediary’s decision and concluded that the administrative regulation governing a hospital’s FTE count was unambiguous and did not exclude residents’ education research time.

The Secretary exercised his right to review the decision of the PRRB and determined that the IME payment was only intended to reimburse teaching hospitals for the costs of increased patient care and that residents performing educational research were not assigned to an eligible area of the hospital as contemplated by the applicable IME FTE regulation. Therefore, the Secretary reversed the decision of the PRRB and held that the time residents spent performing research could not be included in a hospital’s IME FTE count. Rhode Island Hospital appealed the Secretary’s decision to the United States District Court in Rhode Island. The District Court concluded that the Secretary had misread the plain language of the applicable FTE regulation and upheld the decision of the PRRB. The Secretary responded by appealing the decision to the First Circuit Court of Appeals.

On appeal, the Secretary argued that residents assigned to perform education research are not assigned to an area or portion of the hospital subject to the prospective payment system. The Secretary claimed that residents assigned to a research rotation are not integrated into a unit of the hospital dedicated to patient care services reimbursable under the PPS and therefore do not count toward a hospital’s FTE count. The hospital responded to the Secretary’s position by arguing that for purposes of the FTE count, the nature of a resident’s

work is immaterial as long as the resident is assigned to an area of the hospital not specifically excluded from PPS billing. The Court of Appeals held that the decision of the Secretary was not arbitrary or capricious. Specifically, the Court found it reasonable to conclude that residents assigned to perform purely educational research unrelated to patient care are not assigned to an area or portion of the hospital subject to the PPS and therefore, the research time should be excluded from a hospital IME FTE count. The Court held that in order to be assigned to an area of the hospital subject to PPS billing (and therefore included within the hospital's IME FTE count) a resident must be integrated into a hospital unit dedicated to a form of patient care subject to PPS billing. According to the Court, such areas do not include locations where residents perform purely education research.

If you have any questions or concerns regarding the Court's decision in *Rhode Island Hospital v. Levitt* or the exclusion of resident research time from the FTE count, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Institute of Medicine Report Calls for Reduced Hours and Workloads for Medical Residents to Prevent Fatigue-Related Mistakes

The Institute of Medicine ("IOM")¹ released a report on December 2, 2008, which proposes revisions to medical residents' duty hours and workloads to decrease the chances of fatigue-related medical errors and to enhance the learning environment for these doctors in training. The report does not recommend further reducing residents' work hours from the maximum average of 80 per week set by the Accreditation Council for Graduate Medical Education ("ACGME") in 2003, but rather proposes several measures, including: reducing the maximum number of hours that residents can work without time for sleep to 16; increasing the number of days residents must have off; and restricting moonlighting during residents' off-hours.

The report stresses that altering residents' work hours alone will not ensure patient safety. The report emphasizes that there is a need for greater supervision of residents by experienced physicians, limits on patient caseloads based on residents' levels of experience and specialty, and overlap in schedules during shift changes to reduce the chances for error during the handover of patients from one doctor to another. According to the report, financial costs and an insufficient health care work force are the biggest barriers to further revising resident hours. The report proposes additional funding for teaching hospitals, estimating that the additional costs associated with shifting some work from current residents to other health care personnel or additional residents could reach \$1.7 billion per year.

Studies illustrating the detrimental effects of fatigue on human performance underlie the report's recommendations to reduce maximum shift lengths and to increase opportunities for residents to catch up on sleep. Because no single model of scheduling fits all training

¹ The Institute of Medicine (IOM) of the National Academies is a nonprofit organization created for the purpose of providing science-based advice on matters of biomedical science, medicine, and health.

facilities or medical specialties, the report offers two (2) options for dealing with extended shifts. Residents either could work a maximum shift of 16 continuous hours or they could work a 30-hour shift, provided that they get an uninterrupted five-hour break for sleep after working 16 hours. Sleep breaks during shifts should count toward the 80-hour limit. In addition, the report recommends:

- defined off-duty periods between shifts based on the timing and duration of shifts;
- increased number of mandatory days off; and
- restriction of medical moonlighting by residents during their off-hours.

According to the report, violations of the current limits of on-duty hours occur frequently and are underreported, and it recommends strengthening ACGME's monitoring of training hospitals' compliance with the limits by having more frequent visits and making them unannounced.

A major concern stemming from the ACGME duty hour regulations is the effect they have had on the availability of staff to handle teaching hospitals' caseloads and provide quality care while also providing residents with adequate supervision and training. The report acknowledged its recommendations will increase the number of residents, midlevel providers, and trained physicians needed to provide 24-hour coverage in training hospitals and clinics. To implement the report's recommendations, some of the work currently performed by residents would have to be done by others.

If you should have any questions regarding the report, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Illinois Health Network and Medical Center to Pay \$36 Million Settlement after Self-Reporting Possible Healthcare Fraud

Condell Health Network, parent corporation of Condell Medical Center, a 283-bed hospital in Illinois, agreed to pay the United States and the State of Illinois \$36 million for filing false claims for reimbursement, after voluntarily disclosing that it received improper Medicare and Medicaid payments. Condell made the voluntary disclosure earlier this year while in the process of being acquired by Advocate Health Care. The settlement involves three aspects of the relationship between Condell and its physicians from 2002 through 2007: (1) leases of medical office space at rates below fair market value; (2) improper loans to physicians; and (3) hospital reimbursement to doctors who performed patient services without required written agreements. By voluntarily disclosing these improper practices, Condell avoided a government lawsuit under the federal False Claims Act and was able to negotiate a settlement at a discount. The settlement agreement calls for Condell to pay the United States \$33.12 million to resolve claims relating to Medicare patients and \$2.88 million to the state of Illinois to settle claims relating to Medicaid patients. The False Claims Act provides that

parties who voluntarily disclose possible violations are liable for double damages, instead of triple damages, and civil penalties between \$5,500 and \$11,000 for each violation.

According to the settlement agreement, Condell leased space in medical office buildings it owned to physicians in violation of federal laws and regulations governing Medicare and Medicaid reimbursement because either the rental rates were below fair market value or Condell abated or deferred collection of rental payments. Condell had also given loans to physicians and improperly allowed them to “work off” the debts at hourly rates that were greater than fair market value, as well as with activities that did not benefit the community. Furthermore, Condell extended loans to doctors without assessing whether there was a particular community need for such physicians; provided loans to doctors already in the hospital’s service area; gave loans that benefitted individual doctors or physician groups rather than the community; and entered into multiple loan agreements with the same physician or medical group. Condell also paid its physician recruiters incentive bonuses and its financial support agreements prohibited doctors from obtaining admitting privileges at any other hospital. In addition, the settlement covers Medicare and Medicaid reimbursements that Condell paid to doctors for performing services at the hospital without required written agreements.

IRS CIRCULAR 230 DISCLOSURE: To ensure compliance with requirements imposed by the Internal Revenue Service, we inform you that any U.S. federal tax advice contained within this communication (including any attachments) was not intended or written to be used, and cannot be used, by any person for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

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.