
HEALTH CARE PRACTICE GROUP CLIENT NEWSLETTER

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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.

CMS Releases 2009 Final Rule for Hospital IPPS

On July 31, 2008, the Centers for Medicare and Medicaid Services (“CMS”) released the 2009 Final Rule for Hospital Inpatient Prospective Payment Systems (“IPPS”) (the “Final Rule”). The Final Rule brings several important changes to the healthcare industry, including amendments to the regulations for both the Stark Law and the Emergency Medical Treatment and Labor Act, and additions to the list of hospital-acquired conditions which will not be reimbursed by Medicare. This article provides an overview of these important developments.

Stark Law

The Stark Law precludes a provider from referring Medicare or Medicaid beneficiaries for designated health services (“DHS”) to entities with which they, or members of their immediate family, have a direct or indirect financial relationship. The Final Rule made several changes to the CMS interpretation of some of the exceptions to the Stark Law, which when met, exempt arrangements from potential penalties under the Stark Law. The following is a summary of a selection of the key amendments that require attention and possible restructuring of some provider relationships and investment arrangements:

- **“Stand In the Shoes” Provision.** This provision, effective as of October 1, 2008, holds that an individual physician owner or investor “stands in the shoes” (“SITS”) of a physician organization for the purpose of analyzing the financial relationships between DHS entities and referring physicians, if the physician has the ability or right to receive

financial benefits of ownership or investment. However, the Final Rule clarifies that if the physician is only a “titular” owner, meaning he holds no right or ability to receive financial benefit from the referrals, he is not required to stand in the shoes but may do so if he chooses. The same permissibility applies to non-owner physicians. CMS emphasizes that the SITS provisions do not apply to the following:

- arrangements that satisfy the Stark exception for Academic Medical Centers; or
 - arrangements which, during their original term (or then current renewal term), satisfied the requirements of the indirect compensation exception as of September 5, 2007 (arrangements ‘grandfathered’ under the previous SITS provisions).
- **Services Provided “Under Arrangements”.** Prior to the issuance of the Final Rule, a healthcare entity was considered to be furnishing DHS, and therefore subject to the Stark Law, only if that entity was billing Medicare for the DHS. Based on that definition, a hospital could enter “under arrangements” with a service provider in which the hospital had an ownership or investment interest, to allow the service provider to sell its services to the hospital which could then bill Medicare at a higher rate. Therefore, both parties could profit under arrangement without meeting the Stark exception for ownership. However, the Final Rule has revised the definition of a “DHS entity” to include both the entity which *bills* for the DHS and the entity which *provides* the DHS. In light of this amendment, referring physicians will no longer be able to own interests in “under arrangement” relationships with healthcare entities. In addition, CMS asserts that even in the provision of non-DHS, if the hospital bills Medicare for the services as inpatient or outpatient services, the provider will still be deemed a DHS entity. This portion of the Final Rule becomes effective on October 1, 2009.
- **“Per-Click” Lease Arrangements.** Based on existing exceptions for the lease of office space or equipment, CMS addressed its concern that allowing “per-click” lease arrangements may lead to overutilization and heighten the risk of abuse for such lease agreements. “Per-click” leases are those in which the lessor receives a payment each time the leased equipment or space is used by the lessee. The Final Rule amends the Stark exceptions for space and equipment agreements, fair market value, and indirect compensation. The amended provisions prohibit all “per-click” lease arrangements if the lease is for space or equipment used by the tenant/lessee to treat patients *referred by* the landlord/lessor. CMS emphasizes that this prohibition applies regardless of whether the physician is personally leasing the office space or equipment or it is leased by an entity in which the physician has an ownership or investment interest, so long as the landlord or lessor is a DHS entity that refers patients to the physician or physician group. This provision will be effective October 1, 2009, to afford providers adequate time to reassess existing lease agreements to comply with the Final Rule.
- **Percentage-Based Compensation.** CMS has expressed concern in the past regarding percentage-based formulas for compensation. Under this exception, physicians were permitted to use a percentage-based calculation for payment for professional services. The Final Rule prohibits all arrangements which use a formula based on a percentage of revenue for space and equipment leases, regardless of whether the payment is direct or indirect. Therefore, the rental charges for space or equipment leases may not be determined based on a percentage of revenue. Percentage-based formulas may still be used for management agreements, billing services, and

gainsharing arrangements. All other percentage-based lease arrangements must be restructured by the effective date of October 1, 2009, to avoid disqualification.

- **“Set In Advance” and Amendments to Agreements.** Prior to the Final Rule, the Stark Law prohibited any amendments to space, lease or personal service agreements during the agreement term as such amendments violate the “set in advance” requirement. This provision would prevent any alterations to the agreement based on referral volume or value because the amount was determined in advance. However, in the Final Rule, CMS reversed this stance and will now permit multi-year agreements to be amended **after the end of the first year of the term** without violating the Stark Law. CMS distinguishes that this amendment is not a change in the regulations but rather, a change in the current CMS interpretation of the “set in advance” requirement. Therefore, amendments will now be permitted provided that the following conditions are met:

- all requirements for the applicable exception are met;
- the amended rental charges or compensation formula is determined before the amendment is implemented and is sufficiently detailed such that it can be verified objectively;
- the amendments do not account for the volume or value of referrals or other business generated by the referring physician; and
- the amended charges or compensation formula remains for at least one year from the date of the amendment.

The amendment requirements will apply to all Stark exceptions for compensation arrangements that require a one-year term.

“Never Events”

Last year, CMS announced that effective as of October 1, 2008, it would not be providing the higher reimbursement payments for eight (8) identified events if those events occur while a patient is under the care of a hospital. These so called “never events” are those which are determined to be reasonably preventable conditions which a patient did not have prior to admission but acquires while under the care of a hospital. In the Proposed Rule, CMS recommended expanding this list to include nine (9) additional conditions. However, in the Final Rule, only the following three (3) conditions were officially adopted:

- surgical site infections following certain elective procedures including certain orthopedic surgeries and bariatric surgery for obesity;
- certain manifestations of poor control of blood sugar levels including but not limited to diabetic ketoacidosis and hypoglycemic coma; and
- deep vein thrombosis or pulmonary embolism following total knee replacement and hip replacement procedures.

CMS maintains that the addition of these conditions will serve as an incentive to improve the quality of healthcare and reduce the never events which occur in hospitals. The original eight (8) conditions include:

- object inadvertently left in patient after surgery;
- air embolism;
- blood incompatibility;
- catheter associated urinary tract infection;
- pressure ulcer (decubitus ulcer);
- vascular catheter associated infection;
- surgical site infection - mediastinitis (infection in the chest) after coronary artery bypass graft surgery; and
- certain types of falls and trauma.

Based on a report published by the National Quality Forum (“NQF”), these events are preventable, and therefore, if not present upon admission but acquired during the patient’s stay, Medicare will not pay the additional costs and nor will the patient be responsible for those costs.

In addition, it is important to note that in July of 2008, the Executive Office of Health and Human Services of Massachusetts announced its adoption of all twenty-eight never events recognized by the NQF.¹ The policy was created as part of the *HealthyMass* initiative and has also been adopted by the Massachusetts Department of Public Health (“DPH”), BlueCross BlueShield of Massachusetts, MassHealth (State Medicaid), Group Insurance Commission, Commonwealth Health Insurance Connector Authority, and the Department of Correction. This policy will take effect in each agency’s next contract cycle, making the Commonwealth the first state to develop a non-payment policy across state government. This initiative also requires entities to report the occurrence of any of these events to DPH who will then publish each hospital’s reports for public viewing.

CMS also expanded its hospital quality measure reporting program. This program is another way by which CMS uses Medicare reimbursement as leverage, decreasing payment amounts if a hospital fails to participate in the voluntary reporting of standardized quality measures (“QM”). In order to qualify for a full update to their payment rates, hospitals are required to report on thirty (30) specific QMs. The Final Rule has adopted thirteen (13) additional QMs for reporting and retired one (1) pneumonia measure, oxygenation assessment, for a total of forty-two (42) QMs effective as of October 1, 2009.

EMTALA

The Emergency Medical Treatment and Labor Act (“EMTALA”) requires a hospital to provide an appropriate medical screening, within the capability of the hospital’s emergency department, to any person who comes to a hospital’s emergency department and requests

¹ For a complete list of the NQF Never Events, see the Appendix attached to this Newsletter.

treatment for a medical condition. Upon screening, if the patient is assessed to have an emergency medical condition, the hospital must stabilize the patient or effectuate an appropriate transfer to another medical facility, regardless of the patient's ability to pay.

Although the proposed rule attempted to revise the EMTALA regulations to extend applicability to an inpatient that remains unstable with an emergency medical condition, the Final Rule did not adopt this provision. CMS reports that a determining factor in not extending EMTALA to inpatients was the concern for the further increased burden on Emergency Services which may force closures or a reduction in services. The Final Rule did, however, adopt the proposal to allow hospitals the option to participate in a "community call plan" in order to comply with the EMTALA requirement to have a list of on-call specialists. Under the community call plan, two (2) or more participating community hospitals may adopt coverage plans to ensure complete on-call coverage for different specialties across a specific geographic area. With this plan, if a patient presents to one (1) hospital that is unable to provide the specialty coverage needed, that hospital may contact a participating hospital to which the patient may be transferred to receive the appropriate care. The community call plan requires the participating hospitals to establish formal and detailed plans which include each of the following elements:

- a clear delineation of on-call responsibilities for each hospital participating in the plan;
- a description of the geographic area covered by the plan;
- the signature of an appropriate representative of each participating hospital;
- assurances that local and regional emergency medical system protocols include information on community call arrangements;
- a statement reaffirming the obligation of each participating hospital to meet its EMTALA obligations for medical screening and stabilizing treatment with its capacity, and to comply within the EMTALA transfer requirements; and
- an annual assessment of the plan by the participating hospitals.

With these changes to the EMTALA regulations and the refusal to extend the requirements to inpatient treatments, CMS believes it is demonstrating an effort to protect patients while not placing undue burdens on emergency treatment facilities.

Conclusion

The Final Rule presents significant challenges to the healthcare industry. Of particular importance are the amendments to the Stark Law regulations. Healthcare providers need to re-evaluate existing lease arrangements, joint ventures and service arrangements to ensure proper compliance under the amended regulations.

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

HHS Moves to Implement Incentives Program for E-Prescribing

The Medicare Modernization Act of 2003 (“Act”) directed the Secretary of the United States Health and Human Services (“HHS”) to establish regulations that would permit certain arrangements to foster the adoption of electronic prescribing (“e-prescribing”) technology. Although the use of such technology would remain optional for physicians and pharmacies, the Act required drug plans participating in the Medicare Part D Prescription Drug Benefit Program to support e-prescribing. This demonstrated the first of many legislative initiatives to promote e-prescribing in an effort to modernize health care, eliminate prescription errors, and allow the integration of patient medical records with e-prescribing systems to streamline the treatment process. This year, the Centers for Medicare and Medicaid Services (“CMS”) issued its Final Rule for e-prescribing, setting forth standards to be used in the implementation of e-prescribing systems, which will take effect on April 1, 2009. On July 21, 2008, Secretary Michael Leavitt of HHS set forth the agency’s plan to implement an incentives program for healthcare providers to adopt e-prescribing under the recently enacted Medicare Improvements for Patients and Providers Act of 2008 (“MIPPA”).

MIPPA establishes a payment system by which Medicare will issue additional payments to physicians who adopt and use e-prescribing systems. The payment plan will begin with a 2% bonus payment in 2009 and 2010 with incremental decreases to 1% in 2011 and 2012, and a .5% bonus in 2013. Notably, beginning in 2012, those physicians who fail to adopt the technology will see a reduction in Medicare payments. In addition, the incentive payments will be part of the Physician Quality Reporting Initiative which will provide eligible healthcare professionals with bonus payments of up to 2% in 2009 and 2010 for reporting certain quality measures. Further details of that initiative will be published in the 2009 Medicare Physician Fee Schedule Final Rule. The Acting Administrator of CMS, Kerry Weems, reports that CMS will be involved with this incentive program and will hold a conference this fall to help physicians and pharmacies connect with the necessary technology to initiate e-prescribing. The implementation of these recent proposals exemplifies the widespread movement to promote e-prescribing across all agencies in order to modernize the delivery of healthcare and develop a value-based system.

OIG Approves Gainsharing Arrangement Between Academic Medical Center and Physician Groups

On August 7, 2008, the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services issued a new Advisory Opinion (Advisory Opinion 08-09), again approving a gainsharing arrangement between an academic medical center and three (3) physician groups that practice at the academic medical rate. This article provides an overview of the OIG’s Advisory Opinion.

Background

Advisory Opinion 08-09 applies to an existing gainsharing arrangement between an academic medical center (“Center”) that participates in the Medicare and Medicaid programs and

three independent specialty physician groups.² The Center entered separate agreements with two (2) orthopedic surgery groups which employ only orthopedic surgeons with medical staff privileges at the Center. The Center also entered an arrangement with a neurosurgery group which only employs neurosurgeons with active medical staff privileges at the Center. All of the participating physician groups (“Groups”) refer patients to the Center for inpatient and outpatient services. The arrangement focuses on one service in particular, spine fusion surgery.

In addition to the parties described above, the Center tasked a Program Administrator (“Administrator”) with the duties of administering and managing the arrangement. In compliance with Stark Law and the Federal Anti-Kickback Statute, the Administrator was compensated with a fixed, fair market value rate, unrelated to the cost savings derived from the arrangement. Based on a study of the historic practices in spine fusion surgery by the Groups at the Center, the Administrator identified thirty-six cost-saving recommendations. Those recommendations were then reviewed and approved by the Groups for medical appropriateness before adopting the final recommendations. The Administrator divided the recommendations into two (2) categories by which the Groups may standardize the use of spine fusion devices and supplies to create cost savings.

The first category is “*Use as Needed*” *Biological* and includes one recommendation that the Groups limit the use of Bone Morphogenic Protein (“BMP”) in spine fusion surgeries to an as needed basis. The surgeons of the Groups made case-by-case determinations on the amount of BMP clinically necessary while ensuring that the limitation did not adversely affect the patient. The second category for the remaining thirty-five recommendations is *Product Standardization*, recommending the Groups standardize the devices and supplies utilized in spine fusion surgeries. Again, the surgeons were to adhere to these recommendations only when medically appropriate following a case-by-case determination. The vendors and devices were selected based on a clinical evaluation by the Groups and the Center. In some instances, these implementations required further changes in clinical practice or additional training for the specific products.

In return for the implementation of these cost-saving practices, the Center agreed to pay the Groups a fifty percent (50%) share of the first-year savings directly attributable to the changes by each respective group. Before initiating the arrangement, an objective analysis of the practices and patient population of the Center was completed in order to establish a “floor” or cap, beyond which no savings would accrue to the Groups. At the conclusion of the first year, the savings were calculated separately for each of the thirty-six recommendations and for each participating group. This breakdown was structured to prevent groups from receiving payment for savings generated beyond the cap while precluding cost-savings from shifting. To calculate the actual payments to the Groups, the total savings were tabulated by deducting the actual costs incurred during the contract year for the thirty-six recommendations (“contract year costs”) from the historic costs for those same items when used by the specific group while performing comparable procedures in the base year (“base year costs”). Any necessary adjustments were then made for any inappropriate reductions in use beyond the cap set in advance of the arrangement. When the final payment is made to each group, the total will be 50% of the difference between each group’s current year costs and base year costs, less 50% of any costs incurred by the Center in the administration of the arrangement. The total payments to each group would then be distributed among its members on a per capita basis.

² The OIG notes that although this is an existing arrangement for which the Groups have not yet been compensated, nonpayment of monies owed in a contractual agreement does not absolve parties from liability under the applicable fraud and abuse laws.

The compensation to the Groups was calculated subject to the following limitations:

- If the volume of procedures payable by a Federal health care program performed by each group in the contract year exceeded that group's volume of similar procedures in the base year, no cost saving was allotted for the additional procedures.
- The case severity, ages, and payors of the patient population treated by the Groups were monitored by a committee. If it was indicated that a surgeon altered his referral pattern in a manner beneficial to the Center, that specific surgeon would be terminated from participation. (This did not occur.)
- The arrangement set forth projected cost saving amounts and the aggregate of payments to a group is not to exceed 50% of its share of the projected cost savings. In addition, each group is compensated only for its own savings.

OIG Analysis

In examining this arrangement, the OIG identified several of the same concerns set forth in the OIG's January 2008 Advisory Opinions 07-21 and 07-22. Those concerns include: stinting on patient care; "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; payments in exchange for referrals; and unfair competition among hospitals offering cost savings programs to foster physician loyalty and attract more referrals.

The OIG then addressed the legal implications of the arrangement as it triggers an analysis under the Civil Monetary Penalty³ ("CMP"), the Federal Anti-Kickback Statute⁴ ("Anti-Kickback"), and the Stark Law⁵. However, because the Stark Law regulations are beyond the scope of the OIG's Advisory Opinion authority those regulations are not addressed, leaving the Stark analysis unanswered. The OIG also notes that arrangements such as this, if implemented by a non-profit hospital, would raise issues of private inurement and private benefit under regulations by the Internal Revenue Service tax regulations.⁶ Despite the finding that the arrangement falls under the restrictions of both the CMP and the Anti-Kickback regulations, the OIG concluded that it would not seek sanctions under either authority because of the safeguards in place to limit fraud and abuse.

CMP Analysis

The CMP provides for the enforcement of a civil monetary penalty against any hospital that knowingly makes a payment, directly or indirectly, to a physician (and the physician receives that payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. For this arrangement, the OIG analyzed the proposed cost-saving recommendations for potential inducement and concluded that the CMP is implicated. However, the OIG then pointed to the following safeguards which it found sufficient to prevent sanctions under the CMP:

- Specificity and Transparency. The specific cost-saving actions and resulting savings were clearly and separately identified. Because the patients were informed of the

³ Social Security Act § 1128A(b)(1)-(2).

⁴ Social Security Act § 1128B(b).

⁵ Social Security Act § 1877.

⁶ Internal Revenue Code § 501(c)(3).

arrangement, the transparency allowed public scrutiny and physician accountability for any adverse effects.

- Credible Medical Support. The parties provided credible medical support to evidence that the implementation of the recommendations did not adversely affect patient care and the arrangement was periodically reviewed to confirm there was no adverse impact on clinical care.
- Uniform Payments. The amounts to be paid were calculated based on all surgeries regardless of the patients' insurance coverage and the spinal fusions were not disproportionately performed on Federal health care program beneficiaries.
- No Inappropriate Reductions. The arrangement utilized objective historical and clinical measures to establish a baseline beyond which no savings accrued to the Groups in order to prevent inappropriate reductions in services.
- Continued Access to Products. Both categories of cost-saving recommendations ensured that individual physicians still had available the same selection of devices and supplies.
- Full Disclosure. The Groups and the Center provided written disclosures of the arrangement to patients whose care might have been affected and provided patients an opportunity to review the cost saving recommendations prior to admission to the Center.
- Limited Incentives. The financial incentives under the arrangement were reasonably limited in duration and amount.
- Per Capita Payments. Any incentive for an individual surgeon to generate disproportionate costs savings was mitigated by the distribution of profits on a per capita basis.

The OIG further noted that this arrangement is distinct from many other gainsharing arrangements in that it sets specific cost-saving actions and directly ties the remuneration to the actual savings attributable to those actions. Based on these safeguards and the limited duration and scope of the arrangement, the OIG used its discretionary power to determine that it would not seek sanctions for the arrangement.

Anti-Kickback Statute Analysis

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. Although the OIG found the arrangement to be outside the safe harbor for personal services and management contracts, it concluded that it would not seek sanctions based on the following safeguards:

- Reduced Likelihood to Attract Physicians and Referrals. The OIG noted a list of specific limitations which indicated the arrangement was not being used to induce referrals. Those limitations include: participation was limited to surgeons already on the medical staff; potential savings derived from procedures on Federal health care program beneficiaries were capped; and the arrangement terms were limited to one year and admissions were monitored for changes in severity, age, or payor.

- Eliminated Risk of Abuse by Reward to Surgeons. The structure of the arrangement minimized the risk that it may be used to reward physicians who referred patients to the Groups or their surgeons. The arrangement was structured to only involve the specialty surgeons of the Groups and only for surgeons performing spine fusion surgeries. Further, profits were distributed on a per capita basis to each group's constituent members.
- Specific Actions and Increased Risks. The arrangement set forth specific cost-saving actions which would alter the clinical practices of the participating surgeons. The recommendations carried an increased risk and liability for the surgeons making increased payments reasonable, particularly when limited in amount, time, and scope.

Based on these factors, the OIG determined that the arrangement posed a low risk for fraud or abuse under the Anti-Kickback Statute and it would not seek sanctions.

Conclusion

Although the OIG determined that it would not seek sanctions for this arrangement under the CMP or the Anti-Kickback Statute, the OIG continuously emphasized the detailed and specific structure of this particular arrangement and cited features which, even when slightly modified, would lead to sanctions under both regulatory authorities. The most notable elements of this arrangement include: limited duration of one year; limited participation and applicability to one surgical procedure; highly specified remuneration formula to prevent fraud or abuse; and continued monitoring and comparisons to base year costs, patient admissions, and procedures to ensure no significant changes to increase compensation or faltered standards for patient care.

Any proposed gainsharing arrangements should be reviewed by legal counsel to ensure they are appropriately structured to avoid any potential fraud and abuse liability exposure. The Rogers Law Firm is available to review any such proposed arrangements.

Health System Pays \$100,000 for Potential HIPAA Violations

The United States Department of Health and Human Services ("HHS") recently announced a Resolution Agreement (the "Agreement") with Seattle-based Providence Health & Services ("Providence") over potential violations of the HIPAA Privacy and Security Rules. The Agreement requires Providence to pay \$100,000 to HHS and to implement an aggressive Corrective Action Plan. The Agreement is the first-ever between HHS and a healthcare provider in regard to potential violations under HIPAA.

The Agreement with Providence resulted from lost or stolen unencrypted electronic backup media and laptops, which compromised the protected health information of over 386,000 patients of Providence. The media and laptop computers were removed from the Providence premises and were left unattended on several occasions between September 2005 and March 2006.

As part of the Corrective Action Plan, Providence must revise its policies and procedures regarding physical and technical safeguards governing off-site transport and storage of electronic media containing patient information. Also, Providence must also train its workforce on the

safeguards, conduct audits and site visits of its facilities and submit compliance reports to HHS for three (3) years.

According to HHS, Providence's cooperation during the investigation helped it to avoid a civil monetary penalty for the potential HIPAA violations.

SJC Recognizes Loss of Chance Doctrine in Medical Malpractice Actions

On July 23, 2008, the Massachusetts Supreme Judicial Court ("SJC") held that the doctrine of "loss of chance" in medical malpractice actions is considered part of the state's common law torts. In two cases, *Matsuyama v. Birnbaum*⁷ and *Renzi v. Paredes*⁸, the SJC held that patients can recover for a reduction in the chance of survival due to medical malpractice. The Court instructed that damages are to be measured by the "proportional damages method," where a fact finder must first measure the monetary value of the patient's full life expectancy and, if relevant, earnings expectancy as it would in any wrongful death case. The defendant will then be held liable for "the portion of that value that the defendant's negligence destroyed."⁹

In *Matsuyama*, the patient saw the defendant physician for a routine physical exam in 1995, reporting that he had suffered "gastric distress" for years. The physician noted the patient's complaints and recommended that he take over-the-counter medicines to relieve the symptoms of heartburn. However, the patient was actually suffering from early symptoms of gastric cancer. The patient continued to see the physician, who noted a number of disparate symptoms which indicated the growth of the cancer. The physician failed to diagnose the patient's cancer until 1999. A few months after the gastric cancer was diagnosed, the patient died.

The patient's widow filed a medical malpractice action against the physician in 2000. The physician denied that he was negligent in failing to diagnose the cancer until 1999, and also argued that, even if he had been negligent, his malpractice was not the legal cause of the patient's death because, in 1995, the patient was already suffering from "Stage 2" gastric cancer, whereby even with timely treatment, he would have had only a 25%-40% chance of survival.

The jury found in favor of the plaintiff, holding, first, that the physician committed malpractice by failing to diagnose cancer prior to 1999. Second, it held that the physician's malpractice was a "substantial factor" in causing pain and suffering in the patient, and awarded the plaintiff \$160,000. Third, it held that the physician's malpractice reduced the patient's chance of survival by 37.5%, and awarded the widow \$328,125, which was based on the total amount of wrongful death damages she would have normally received (\$875,000) reduced by 62.5%.

The physician appealed to the SJC, which upheld the trial verdict and the trial judge's instructions. The SJC held that, in medical malpractice cases, where a physician's carelessness can be proven to have "caused" the loss of a chance of recovery by a patient from an illness for

⁷ 452 Mass. 1 (2008).

⁸ 452 Mass. 28 (2008).

⁹ *Matsuyama*, 452 Mass. at 26.

which the patient has sought treatment, the patient may recover damages even if he or she cannot prove that the loss of the chance was the “but-for” cause of his or her failure to recover.

In *Renzi*, the SJC found loss of chance damages were recoverable where the physicians’ negligence reduced the decedent’s chances of survival from a better than even chance to less than even, and where the jury found the defendant physicians were not liable for causing the decedent’s wrongful death. The case involved a patient who died from metastatic breast cancer. Her family sued her treating physicians (defendants) for wrongful death. At trial, the jury heard expert testimony that the delay in diagnosing Renzi’s breast cancer reduced her ten-year survival rate from 58% to 30%. The jury found the defendants’ negligence was “a substantial contributing factor in causing” Renzi’s loss of chance of survival and the plaintiffs obtained a \$2.8 million damages award. The SJC stated it would be arbitrary to limit a loss of chance recovery where a patient’s pre-negligence chance of survival was better than even, and thereafter dropped to less than even as a result of the negligence. The Court further held that the jury properly found the defendants liable for causing the patient’s loss of chance to survive and not for causing the patient’s wrongful death, as a “jury may find the defendant liable either for causing the patient’s wrongful death, or for causing the patient’s loss of a chance to survive, but not for both.”

While agreeing loss of chance was recoverable in the case, the SJC nonetheless remanded the case to the Superior Court for further proceedings on the issue of damages. The SJC held that the trial judge’s instructions on damages “conflated ordinary wrongful death and loss of chance of survival as theories of injury, and failed to give the jury any guidance on how to calculate damages for loss of chance of survival.” Thus, the SJC was uncertain whether the jury calculated damages appropriately per the proportional approach it set forth in *Matsuyama*.

If you have any questions regarding the SJC’s recognition of the “loss of chance” doctrine, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Joint Commission Issues Sentinel Event Alert

In July of 2008, the Joint Commission on the Accreditation of Healthcare Organizations (“Joint Commission”) issued a Sentinel Event Alert on “Bad Behavior” pertaining to healthcare professionals and their behavior in the workplace. The Joint Commission believes that disruptive behavior by healthcare professionals creates an unhealthy or hostile environment which is evident to patients and their families. As part of the Sentinel Event Alert, the Joint Commission announced a new accreditation standard effective January 1, 2009, which will force hospitals to identify and deal with disruptive behavior by healthcare professionals.

The Joint Commission identifies “bad behavior” as intimidating or disruptive conduct which may include overt actions such as verbal outbursts or physical threats as well as passive-aggressive behavior such as refusing to perform assigned tasks or quietly demonstrating an uncooperative attitude during routine work activities. As part of the Sentinel Event Alert, the Joint Commission cites research showing that these disruptive behaviors commonly occur not only among physicians and nurses but across other health care professions as well. Evidence indicates that this behavior is not limited to either gender but is often expressed by professionals in positions of power who may refuse to answer questions or return phone calls and pages; use condescending language or voice intonation; or simply convey impatience with questions. The

study referenced by the Joint Commission found that 38.9 percent of survey participants stated that physicians in their entity who generate high amounts of revenue are treated more leniently in regard to such behavioral problems.

Along with the Sentinel Event Alert, the Joint Commission also announced the implementation of new accreditation requirements to obligate health care entities to address the bad behavior by healthcare professionals. The new Leadership Standard (LD.03.01.01) addresses this inappropriate behavior in two (2) of its elements for performance:

- EP 4: The hospital/organization has a code of conduct that defines acceptable and disruptive and inappropriate behaviors.
- EP 5: Leaders create and implement a process for managing disruptive and inappropriate behavior.

The Joint Commission believes these new accreditation requirements will help healthcare entities structure a system which does not let such behavior continue without being addressed and remedied while simultaneously allowing a procedure for employees to acknowledge the occurrence as well.

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APPENDIX to “CMS Releases 2009 Final Rule for Hospital IPPS”

National Quality Forum “Never Events”

Surgical Events
Surgery performed on the wrong body part
Surgery performed on the wrong patient
Wrong surgical procedure performed on a patient
Unintended retention of a foreign object in a patient after surgery or other procedure
Intraoperative or immediately post-operative death in an ASA Class 1 patient ¹⁰
Product or Device Events
Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
Patient Protection Events
Infant discharged to the wrong person
Patient death or serious disability associated with elopement (disappearance)
Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility
Care Management Events
Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
Patient death or serious disability due to spinal manipulative therapy
Artificial insemination with the wrong donor sperm or wrong egg

¹⁰ American Society of Anesthesiologists classification scale of 1-6, Class 1 indicating a “normal healthy patient.”

Environmental Events
Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility
Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
Patient death or serious disability associated with a fall while being cared for in a healthcare facility
Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
Criminal Events
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
Abduction of a patient of any age
Sexual assault on a patient within or on the grounds of the healthcare facility
Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility
Additional CMS Events not Listed with NQF Conditions
Catheter associated urinary tract infection
Vascular catheter associated infection
Surgical site infection – Mediastinitis (infection in the chest) after coronary artery bypass graft surgery
Surgical site infections following certain elective procedures
Legionnaires' disease (type of pneumonia caused by a specific bacterium)
Iatrogenic pneumothorax (collapse of the lung)
Delirium
Ventilator-associated pneumonia
Deep vein thrombosis / Pulmonary Embolism (formation/movement of a blood clot)
<i>Staphylococcus aureus</i> septicemia (bloodstream infection)
<i>Clostridium difficile</i> associated disease (bacterium that causes severe diarrhea and more serious intestinal conditions such as colitis)