CLARIFYING PHYSICIAN SUPERVISION REQUIREMENTS: IS THE THIRD TIME THE CHARM?

For the third time in the past three years, the Centers for Medicare & Medicaid Services (CMS) has decided to tinker with the physician supervision requirements for hospital outpatient therapeutic services. In the 2011 Hospital Outpatient Prospective Payment System Payment Rates final rule (2011 OPPS Final Rule), to be published in the November 24, 2010, Federal Register, CMS has provided some relief to providers by relaxing its stringent interpretation of "direct supervision" for hospital outpatient therapeutic services.

In the 2011 OPPS Final Rule, CMS modified the definition of "immediately available" for all hospital outpatient services so that it does not reference boundaries of a physical location. This is a significant change from the position CMS "clarified" in the 2009 OPPS Final Rule and upheld in a 2010 transmittal. Previously, for physicians to be immediately available in off-campus provider-based sites, CMS required that the physicians be physically located in the department. CMS interpreted the rule to preclude physician supervision from adjacent nonhospital space, such as physician offices. Under the new definition, for services furnished in a hospital or outpatient department, including both on- and off-campus sites, direct supervision will simply require immediate availability, meaning physically present, interruptible and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary. The modified definition reads:

"For services furnished in the hospital or CAH or in an outpatient department of the hospital or CAH, both on- and off-campus . . . 'direct supervision' means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed."

2011 OPPS Final Rule, to be codified at 42 C.F.R. § 410.27(a)(1)(iv).

The 2011 OPPS Final Rule also delayed enforcement of the direct supervision requirement for critical access hospitals (CAHs) and small rural hospitals.

For more information, please contact B. Scott McBride, smcbride@bakerlaw.com or 713.646.1390 or Ameena N. Ashfaq, aashfaq@bakerlaw.com or 713.646.1329.

FINAL REGULATIONS ADDRESS PPACA STARK LAW CHANGES

The Patient Protection and Affordable Care Act (PPACA) revised the Stark Law exceptions for physician ownership in hospitals and ancillary services furnished in physicians' offices. Proposed regulations relating to these two provisions were
published in August of this year. CMS now has published these regulations in final form.

**Physician Ownership of Hospitals**

PPACA eliminated the Stark Law exception permitting physician ownership in hospitals, grandfathering physician-owned hospitals with a Medicare provider agreement in effect as of December 31, 2010. Substantial restrictions were placed on grandfathered hospitals, which are prohibited from increasing their total physician ownership percentages and increasing the number of beds, operating rooms or procedure rooms after the PPACA enactment date — March 23, 2010. PPACA also established a process for grandfathered hospitals to seek an exception to the facility growth restrictions, although availability of an exception is limited to hospitals in high-growth areas and those serving a high Medicaid patient population. Finally, grandfathered hospitals will have to file annual reports identifying physician owners and disclose to referred patients and on the hospital’s website and advertising materials that the hospital is physician-owned.

PPACA changes to the Stark Law whole hospital and rural provider exceptions are addressed in the final OPPS update and ambulatory surgical center payment rule for calendar year 2011, slated for publication in the November 24, 2010, Federal Register. The regulations generally mirror the statutory provisions, confirming that grandfathered hospitals must have a provider agreement in effect on or before December 31, 2010, and that a hospital with no physician ownership before March 23, 2010, cannot qualify for the exceptions. The final regulations do clarify that a physician-owned hospital would qualify for the exception if its provider agreement is issued after December 31, 2010, as long as the effective date is on or before December 31, 2010.

With respect to the restrictions on increase in the percentage of physician investors, the regulations clarify that a physician-owned hospital may add or increase the number of physician owners or replace physician investors, as long as the aggregate percentage does not increase after March 23, 2010. Regarding facility expansion, CMS declined to expand the definition of procedure room from that found in the statute (a room in which catheterizations, angiographies, angiograms and endoscopies are performed). Facilities under construction are advised to use the advisory opinion process to determine whether operating rooms, beds or procedure rooms were in existence as of March 23, 2010.

Disclosure of ownership interests is required for grandfathered hospitals, and the regulations require hospitals to include such disclosure as a condition to medical staff membership and privileges. The disclosure requirements also are incorporated in the Medicare Conditions of Participation for physician-owned hospitals.

**In-Office Ancillary Services Exception**

PPACA imposes a disclosure requirement when MRI, PET or CT scanning is furnished to patients by physicians under the in-office ancillary services exception to the Stark Law. The new disclosure requirement is addressed in the final regulations implementing the Medicare physician fee schedule update for calendar year 2011, slated to be published in the Federal Register on November 29, 2010. Although CMS solicited comments in the proposed regulations on whether to expand the disclosure requirement to services other than MRI, PET and CT scans, the agency declined to do so.

The final regulations require that written disclosure in a manner sufficient to be reasonably understood be given to patients at the time of referral. The written notice must include a list of five suppliers (reduced from the ten suppliers required in the proposed regulations) located within a 25-mile radius of the physician’s office. The list must include the name, address and phone number of each supplier.

The final regulations remove several requirements set forth in the proposed rules, including the requirement that the supplier’s distance from the physician’s office be
noted on the list and that the physician obtain the patient’s signature on the notice and retain a copy of the disclosure in
the patient’s medical record. Noting PPACA’s use of the term “supplier” rather than “provider,” the proposed regulations
would have prohibited a listing of providers (including hospitals) on the written disclosure. The final regulations permit
listing of providers in the area as long as the requisite number of suppliers is listed.

The disclosure requirement is effective January 1, 2011. Physicians utilizing the in-office ancillary services exception to
protect MRI, PET and CT referrals should initiate development of a disclosure notice to assure compliance by the
deadline.

For questions relating to the PPACA Stark Law revisions, please contact Donna S. Clark, dclark@bakerlaw.com or
713.646.1302.

GINA’S FAMILY HISTORY GROWS – FINAL REGULATIONS ISSUED

The U.S. Equal Employment Opportunity Commission (EEOC) recently issued final regulations implementing the Genetic
Information Nondiscrimination Act of 2008 (GINA). GINA prohibits the intentional and, in many cases, inadvertent
acquisition of genetic information by employers and insurers and the use of genetic information to make decisions about
health insurance and employment, and restricts the disclosure of genetic information.

Genetic information is defined very broadly by the regulations and includes a person’s family medical history. While the
final regulations do not contain any significant changes from the proposed regulations issued on March 2, 2009, the
EEOC’s commentary to the final regulations emphasizes the breadth of an employer’s obligations. Consequently,
employers must exercise care in soliciting information from employees.

Employers should be particularly alert when conducting wellness programs with financial inducements for completing a
health risk assessment. While wellness programs are permitted, all questions related to family medical history must be
identified as voluntary. However, recognizing the challenges this posed to providers, the EEOC added an exception to the
regulations to clarify that when a healthcare provider’s employee receives a medical examination for the purpose of
diagnosis and treatment unrelated to his or her employment, GINA would not cover genetic information obtained.
However, HIPAA and state medical privacy laws likely would preclude the provider’s use and/or disclosure of such
information in most cases.

The final regulations become effective 60 days from formal publication in the Federal Register on November 9, 2010. For
more information on the final GINA regulations, please see the EEOC webpage on genetic information discrimination.

For more information, please contact Robert M. Wolin, rwolin@bakerlaw.com or 713.646.1327.

OHIO SUPREME COURT AFFIRMS DENIAL OF REAL ESTATE TAX EXEMPTION FOR DIALYSIS CENTER

The Ohio Supreme Court recently affirmed the denial of a charitable-use exemption for a dialysis center by the Ohio
Board of Tax Appeals. In a 4-3 decision, the Ohio Supreme Court concluded that an institution is “charitable” under
Section 5709.121 of the Ohio Revised Code (ORC) only if its core activities qualify under the standards for determining
charitable use of property pursuant to ORC Section 5709.12(B). Dialysis Clinic, Inc. v. Levin, Slip Opinion No. 2010-Ohio-
5071 (Oct. 26, 2010).

The owner of the center, Dialysis Clinic, Inc. (DCI), is a tax-exempt organization under Section 501(c)(3) of the Internal
Revenue Code (IRC). DCI operates 195 outpatient dialysis centers in 26 states, including the West Chester facility in
Butler County. As is common with end-stage renal dialysis centers, the majority of patients are covered by Medicare and
Medicaid.

A key factor in holding against DCI was its indigent policy, which explicitly stated that it was "not a charity or gift to patients
[and that] DCI retains all rights to refuse to admit and treat a patient who has no ability to pay." Although evidence was
given that DCI did not turn away patients for the inability to pay, the majority of the court was not persuaded, given DCI’s
explicit policy statement. The minority opinion disagreed, reasoning that a reservation of the right to refuse treatment is
not proof that DCI denied services to indigents.

In light of the recent Illinois Supreme Court decision in Provena, the question of whether a tax-exempt organization’s
medical facilities should qualify for local real estate tax exemption has become a national issue. Like Provena, the
taxpayer’s request for real estate tax exemption was denied. Similarly, both courts rejected the proposition that as long as an organization is "charitable" under IRC Section 501(c)(3), the property will qualify for local real estate tax exemption.

The similarities between the DCI case and Provena, however, generally end there. In an important victory for the Ohio Hospital Association, both the majority and minority opinions expressly rejected the Ohio Tax Commissioner’s position that a threshold (or minimum) amount of unreimbursed care is required to qualify for real estate tax exemption. In reaching this conclusion, the majority opinion stated: "In the age of Medicare and Medicaid, the usual and ordinary indigent patient may have access to government benefits, and the modern healthcare provider is not required to forego the pursuit of those benefits to qualify for charitable status."

Finally, the majority also concluded that DCI could not base its exemption claim on the donation of surplus revenue to kidney research because such a claim would constitute a type of "vicarious exemption" that was rejected by the court in 1984.

Because it will be extremely unlikely that a tax-exempt hospital will have a written policy statement that explicitly reserves the right to refuse to treat indigent patients, this important decision of the Ohio Supreme Court should be distinguishable by tax-exempt Ohio hospitals.

For more information, please contact Chris Swift, cswift@bakerlaw.com or 216.861.7461, or Ted Bernert, ebernert@bakerlaw.com or 614.462.2687.

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COURT HOLDS FEDERAL LAW PREEMPTS NURSING HOME'S ARBITRATION PROVISION

A healthcare provider’s arbitration agreement that lacked Texas notice provisions was held to be invalid under the McCarran-Ferguson Act (15 U.S.C. § 1012(b)) which prohibits federal laws from preemptioning state insurance laws. In re Sthran, No. 05-10-01176-CV (Tex. App.-Dallas Oct. 29, 2010).

The Texas Court of Appeals, Fifth District, held that the McCarran-Ferguson Act "reverse preempted" the Federal Arbitration Act (FAA), and therefore the provisions of Tex. Civ. Prac. & Rem. Code Section 74.451 were applicable to a healthcare provider’s patient arbitration agreement. The Texas law provides that healthcare providers may not request or require a patient to arbitrate a healthcare liability claim unless the agreement also is signed by an attorney of the patient’s choosing.

The court found that the McCarran-Ferguson Act preempted the arbitration provision because the notice requirement of section 74.451 was contained within the malpractice reform provisions of Texas law which regulates the business of insurance. Following earlier Texas decisions, the court concluded that Texas’ medical malpractice reform act, including its notice provision, was a law enacted to regulate the business of insurance because it possessed the end, intention or aim of adjusting, managing or controlling the business of insurance, e.g., the relationship between malpractice insurers and their insured (health providers).

Therefore, healthcare providers should evaluate the validity of their arbitration agreements and consider adding backstop provisions to address concerns which may arise in judicial proceedings, such as a jury waiver agreement.

For more information, please contact Robert M. Wolin, rwolin@bakerlaw.com or 713.646.1327.

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DAVID L. SCHICK AND JESSICA L. CAPTAIN JOIN NATIONAL HEALTHCARE TEAM

Baker Hostetler is pleased to announce the addition of Orlando-based attorneys, David L. Schick and Jessica L. Captain, to the firm’s National Healthcare Team.

David L. Schick

David L. Schick recently joined the Orlando office of Baker Hostetler as a partner in the firm’s healthcare industry team. Previously a shareholder at GrayRobinson, P.A. for over twenty years, David represents numerous individuals, small and large corporations, family-owned businesses and professional associations, in addition to his specialty -- representing physicians. His practice experience spans healthcare, business and corporate law, with an emphasis in mergers and acquisitions, entity formation/dissolution and sophisticated business agreements.
His healthcare experience entails setting up ambulatory surgical centers, imaging centers and joint ventures for MRI, PET and CT scanners, as well as physician recruitment agreements. He also specializes in the complexities of Medicare reimbursement issues, HIPAA and fraud and abuse, including false claims and Stark Law requirements and corporate compliance plans.

His wide scope of experience, which includes designing ERISA-qualified retirement plans, tax planning, IRS and Florida tax controversies, tax litigation and estate planning, makes David unique in the state of Florida, and he has utilized his extensive background to develop sophisticated techniques designed to help physicians, business owners and their corporate entities protect their assets (particularly accounts receivable, equipment and real estate) from the claims of creditors.

David L. Schick can be reached at dschick@bakerlaw.com or 407.649.4084.

**Jessica L. Captain**

Healthcare associate Jessica L. Captain recently joined Baker Hostetler's Orlando office from GrayRobinson, P.A. Jessica has experience in mergers and acquisitions, entity formation and dissolution and the preparation of sophisticated business agreements, including operating, partnership, buy-sell, purchase and sale, joint venture, management, employment, independent contractor and hospital-based exclusive service agreements.

Jessica is experienced in handling complex tax controversies with the IRS for individual and corporate clients, including negotiating installment agreements with the IRS, preparing the requisite IRS forms, requesting abatement of penalties and interest of personal and employment tax liabilities and evaluating liability in connection with the Trust Fund Penalty.

Born and raised in Fort Lauderdale, Florida, Jessica graduated summa cum laude from the University of Florida in 2004 with a Bachelor of Arts in English. While at the University of Florida, Jessica was inducted as a member of Phi Beta Kappa and served as a Teaching Assistant for Russian Masterpieces.

In 2007, Jessica graduated from the University of Miami School of Law. During law school, Jessica interned for the Honorable William M. Hoeveler, United States District Court, Southern District of Florida. She also worked with the IRS as a certified volunteer to prepare tax returns for low income, disabled and elderly persons.

Jessica L. Captain can be reached at jcaptain@bakerlaw.com or 407.649.4025.

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**HOLIDAY PUBLICATION NOTICE**

Please be advised that the *Health Law Update* will not publish Thursday, November 25, due to the Thanksgiving Day holiday. We will resume publication Thursday, December 9.

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**EVENTS CALENDAR**

**November 18**

Houston partner Susan Feigin Harris will speak on "Back to the Future: Accountable Care Organizations, Clinical Integration, Medical Homes and Emerging Models for Delivery System Reform" at the Healthcare Rx New Business of Healthcare Summit in Flower Mound, Texas.

**January 27-28**

Houston partner Susan Feigin Harris will speak on "Taking the Lead in ACO Development: The Academic Medical Center’s Role in ACO Development" at the Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions program sponsored by the American Health Lawyers Association in Washington, DC.