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BRACH EICHLER

Health Law

UPDATE



FEDERAL UPDATE

OIG Issues Opinion Approving Hospital Program Providing Lodging, Transportation and Meals

The United States Department of Health & Human Services Office of Inspector General (OIG) recently issued an advisory opinion (Advisory Opinion 11-16) approving a children's hospital's "Domiciliary Services Program" that provides assistance for treatment-related travel, meals and other miscellaneous services to certain patients and their families/caregivers.

The hospital is an internationally-known, not-for-profit institution dedicated to finding cures for catastrophic diseases in children. The majority of patients are on clinical research protocols and travel to the hospital from around the world, often temporarily relocating to the hospital area for treatment. The highly complex nature of many of the clinical trials demands patient participation and compliance. The hospital does not bill patients; seventy percent of the cost is raised through a hospital-affiliated charity, with the remainder paid by third-party payors, including federal health care programs.

The OIG determined that, although the program implicates the federal anti-kickback statute, it would not subject the hospital to sanctions for the following reasons:

- The hospital is reimbursed for less than a quarter of the costs it expends to care for federal health care program beneficiaries and is faced with more qualified applicants than it can accommodate
- The hospital focuses on the treatment and cure of catastrophic diseases in children, services typically not susceptible to overutilization
- Program services ease the hardships of patients and their families during treatment and permit the hospital to closely monitor patients and their research protocol compliance

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- Lodging facilities offer a clean, safe environment for immunocompromised patients, and meal assistance ensures that patients are able to satisfy basic nutritional requirements
- Program services are not advertised or marketed
- Program costs are not borne, directly or indirectly, by any federal health care programs

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OIG Sneezes at Allergy Testing Arrangement

The United States Department of Health & Human Services Office of Inspector General (OIG) declined to approve an arrangement for a laboratory management company to set up shop in a primary care physician's office (Advisory Opinion 11-17). The plan involved an entity providing laboratory personnel, equipment, supplies, training and billing/collection services to a physician's office in order to furnish allergy testing and immunotherapy laboratory services on an exclusive and as-needed basis. Educational materials would be provided to patients, and file reviews would be conducted to identify candidates likely to benefit from such services. The medical practice would provide space to operate the laboratory, administrative staff, supplies, malpractice insurance, and physician supervision and interpretation of laboratory results. All services provided under the proposed arrangement would be billed under the physician provider's identification number and the management company would receive a fee for items and services provided in the amount of 60% of gross collections from allergy testing and immunotherapy.

The OIG found that the arrangement had the potential to generate prohibited kickbacks under the anti-kickback statute. While safe harbors exist to protect arrangements with little likelihood of resulting in fraud or abuse, the OIG concluded that this proposal failed to meet the terms of a safe harbor, primarily on two points:

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- In order to meet the safe harbor for equipment leases and personal services, the contract between the parties would have to specify the exact schedule of intervals in which services would be provided and the precise length and charge for such intervals; the proposed arrangement was on an as-needed basis
- The equipment/personal services safe harbor requires that aggregate compensation payable for items and services be set in advance and not be based on the volume or value of business generated between the parties; this arrangement would base the manager's fee on a percentage of gross collections from allergy and immunotherapy and would be based, in part, on the volume or value of federal health care program business

The OIG also concluded that reviewing patient files to identify candidates for allergy testing services would be a suspect marketing activity and could encourage physicians to order medically unnecessary tests, posing a risk of patient harm and overutilization.

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CMS Releases 2012 Medicare Physician Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) recently published the Medicare Physician Fee Schedule (MPFS) for calendar year 2012. Some key provisions include:

- Unless the federal government acts otherwise, Medicare's payment to physicians will be reduced across the board by 27.4% due to the Sustainable Growth Rate formula imposed under the Balanced Budget Act of 1997
- Providers must conduct a health risk assessment as part of the annual wellness visit, and Medicare will increase payment for the HCPCS codes associated with the health risk assessment to take into account the additional time and paperwork involved
- The Multiple Procedure Payment Reduction policy currently reduces payment by 50% for the technical component associated with the second and any subsequent advanced diagnostic imaging tests performed on the same patient on the same day. For 2012, this policy will be expanded to apply to the professional component as well, and payment will be reduced by 25% for the professional component associated with the second and any subsequent advanced diagnostic imaging tests, including MRI, CT and ultrasound
- The Geographic Practice Cost Indices will incorporate different data sources to determine the various cost differences among localities in connection with the physician work RVU, the practice expense RVU and the malpractice RVU

- Certain aspects of the Physician Quality Reporting System, the e-Prescribing incentive program, and the Electronic Health Records incentive program have been updated and modified to allow for increased participation
- The quality and cost measures to be used in establishing a new value-based modifier have been finalized, which will be used to reward physicians for providing higher quality and more efficient care, commencing with specific physicians and groups in 2015 and expanding to all physicians by 2017.

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STATE UPDATE

NJ Medicaid Fraud Division Releases 2012 Work Plan

The Medicaid Fraud Division in the Office of the State Comptroller recently released its Fiscal Year 2012 Work Plan. Initiatives include:

- Auditing of home health and hospice agencies, nursing facilities, hospitals, laboratories, medical transportation services, physicians, partial care, pharmacies, personal care services and managed care organizations to determine the suitability of billing, medical necessity, documentation and care plans to support Medicaid billing
- Spot checks of hospital records
- Compliance with new Affordable Care Act obligations related to overpayments
- Publication of compliance guidance in adult medical day care
- Provider training
- Oversight of self-disclosures of Medicaid overpayments
- Review of *qui tam* complaints in collaboration with the Attorney General

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Proposed Legislation Requiring Surgical Practices to be Licensed Referred Out of Assembly Committee with Amendments

Legislation that would require surgical practices to be licensed by the NJ Department of Health and Senior Services

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(DHSS) as ambulatory care facilities was recently reported from the Assembly Health and Senior Services Committee, with amendments, and now heads to the full Assembly for consideration.

Under the current “Codey Law,” surgical practices are not required to be licensed. Instead, they must register with the DHSS and obtain either certification by the Centers for Medicare & Medicaid Services (CMS) as an ambulatory surgery provider or ambulatory care accreditation from an accrediting body recognized by CMS.

This bill, A-4099, would repeal the registration requirement and instead mandate that all surgical practices be licensed by the DHSS as ambulatory care facilities within one year of its enactment. As amended, the bill provides, however, that surgical practices in operation prior to the date of its enactment will not be subject to the ambulatory care facility assessment or to DHSS regulations pertaining to physical plant and functional requirements for ambulatory care facilities.

The bill’s counterpart in the Senate, S-2780, was passed by the Senate earlier this year.

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DHSS Proposes New Rules to Protect the Elderly from Abuse, Neglect and Exploitation

The NJ Department of Health and Senior Services (DHSS) is proposing new rules to govern the provision of Adult Protective Services (APS). APS are those services aimed at curbing the abuse, neglect and exploitation of adults (defined as those over the age of 18) who are unable to protect themselves.

The APS Program is supervised by the state, while implemented at the county level, with agencies in each county that are either county-run or operated by a county-designated public or non-profit entity. The proposed rules would establish minimum criteria for approval of APS provider agencies, and would establish requirements for, among other things, client confidentiality, APS program functions and certified APS worker training, qualifications and supervision.

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Lawsuit Alleges UMDNJ Required Nurses to Assist with Abortions Despite their Objections

A group of nurses at the University of Medicine and Dentistry of New Jersey (UMDNJ) filed a lawsuit and a request for a temporary restraining order against the hospital, alleging they were forced to assist in abortions in violation of federal law. In *Danquah v. University of Medicine and Dentistry of New Jersey*, 11-cv-06377, the plaintiffs allege that UMDNJ violated 42 U.S.C. 300a-7(c), which permits individuals to refuse to participate or assist in the performance of abortions for religious or moral reasons and prohibits entities that receive federal funds from discriminating against them for doing so. The nurses argue that despite their objections, UMDNJ, which receives approximately \$60 million dollars each year in federal health and research funding, refused to follow the law and instead threatened all of them with termination if they did not agree to assist in the performance of abortions at the hospital.

The lawsuit also alleges that UMDNJ violated New Jersey law, N.J.S.A. 2A:65A-1, which provides that no person shall be required to perform or assist in the performance of an abortion.

A temporary restraining order preventing the hospital from requiring unwilling nurses to assist with abortions was granted pending a full hearing. UMDNJ has denied any wrongdoing.

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Brach Eichler In The News

Keith Roberts has joined Brach Eichler as a member of the Health Care Practice Group, concentrating in insurance litigation and arbitration matters.

For the third consecutive year, Brach Eichler sponsored *New Jersey Monthly's* annual *Top Doctors* reception, honoring the 785 physicians recognized as the best in the state. Dr. Howard Holtz was the recipient of the second annual Burton L. Eichler Award, presented by Brach Eichler at the reception. The award honors the legacy of the health care law pioneer and firm founder by recognizing a Top Doctor’s civic contributions. Holtz was recognized for his continuing work with St. Philip’s Academy in Newark, Jersey Battered Women’s Services, the American College of Physicians, the South Orange/Maplewood School District and Remote Area Medical Volunteer Corps. Holtz received a plaque and a check in the amount of \$1,000 to be donated to Remote Area Medical.

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Mark Manigan served as a panelist at the first annual *New Jersey: State of the State 2011 - Revitalizing Our Economy* conference, presented by the Council on State Public Affairs, which promotes conversation on New Jersey public policy. Manigan moderated the discussion *Healthcare in New Jersey: Who Will Pay the Bill?*

John Fanburg recently spoke at the annual meetings of the Radiological Society of New Jersey and the New Jersey Society of Pathologists.

The November 28, 2011 edition of the *New Jersey Law Journal* features an article authored by Chad Ehrenkranz in which he discusses business expansion and regulatory compliance within the context of a dental practice. Among the topics covered are turning regulatory obstacles into business opportunities and how to protect a practice from violating the Fair Labor Standards Act.

HIPAA CORNER

The Health Information Technology for Economic and Clinical Health Act, contained within the 2009 Stimulus Act, requires that periodic audits are conducted to determine compliance with the HIPAA Privacy and Security Rules and Breach Notification standards. The Office for Civil Rights (OCR) recently announced that to implement this mandate, it is piloting a program to perform up to 150 audits of covered entities to

assess privacy and security compliance. According to the OCR, audits conducted during the pilot phase will begin in November 2011 and conclude by December 2012.

As part of the audit process, the OCR intends to ask parties to provide information and documentation of their privacy and security compliance efforts. Site visits with interviews of key personnel and observations of processes and operations are also contemplated. Covered entities selected for audit will be provided with a written notice providing the identity of the audit contractor and description of the audit process. Audited entities will be provided with a draft report and comment period, with the auditor providing the final report to the OCR within 30 business days thereafter.

The OCR has indicated that the audits are to be used primarily as a compliance improvement activity in order to identify best practices, risks and vulnerabilities and generally improve Privacy and Security. Notwithstanding this, the OCR clearly reserves its right to pursue a compliance review if serious compliance issues are identified. Given the significant penalties that may be imposed as a result of not taking privacy and security seriously, we recommend that your practice revisit its HIPAA policies and procedures so that you are prepared in the event the OCR comes knocking on your door.

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