

B&B REVIEW

Healthcare News
May/June 2006

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MAY 19, 2006.**

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LEVY AND ROBINSON JOIN BALCH & BINGHAM LLP

Balch & Bingham is pleased to announce that Jack B. Levy and Laura Schiele Robinson have joined the firm and its Health Law Practice Group and its Health Law Practice Group effective May 15, 2006. Jack has practiced law for thirty years and is licensed to practice in Alabama and Georgia. He earned both his Bachelor of Arts and law degrees from Emory University and his Master of Taxation from New York University. Laura received her Bachelor of Arts degree from Columbia College and her law degree from the University of Alabama. Jack and Laura have worked together for the last 12 years.

Jack and Laura concentrate their practices in the areas of physician practice representation, healthcare, employee benefits and executive compensation. Jack and Laura have represented numerous physicians, physician group practices and affiliated entities for many years. Jack also lectures throughout the United States on issues relating to pension and welfare benefits as well as health care matters. Prior to joining Balch & Bingham LLP, both Jack and Laura practiced in the Birmingham office of Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C. Jack Levy can be reached by phone at 205 226 8750, or by e-mail at jlevy@balch.com. Laura Robinson can be reached by phone at 205-226-8751, or by e-mail at lrobinson@balch.com.

FRAUD & ABUSE

Inspector General Sends Open Letter to Providers

On April 24th, the Inspector General of the U.S. Department of Health and Human Services (the IG) issued an "open letter" to healthcare providers which described a new initiative to promote the use of the Self-Disclosure Protocol to resolve civil monetary penalty (CMP) liability under the physician self-referral law ("Stark")

and the Anti-Kickback Statute for financial arrangements between hospitals and physicians.

In the letter, the IG states that he has heard from hospitals that they are discovering, through their compliance programs, improper arrangements under Stark and the Anti-Kickback Statute.

"We are now seeking to increase awareness in the hospital and physician communities of a way to resolve conduct that may result in liability under the IG's CMP authorities for physician self-referral and anti-kickback violations. This new initiative supplements the SDP by providing guidance on how these types of disclosures will be resolved," the letter said.

The IG noted that the initiative is limited to those matters, in the provider's reasonable assessment, involving conduct that subjects the provider to CMP liability under the IG's physician self-referral and anti-kickback authorities. This especially includes "in particular, situations involving a financial benefit knowingly conferred by a hospital on one or more physicians."

In addition, the IG commented in the letter that a provider's liability in these areas typically falls along a continuum depending on the number and dollar value of the improper claims or remuneration. He said it would generally settle SDP matters for an amount near the lower end of the continuum, subject to the particular facts and circumstances.

Other key factors the IG will consider are the degree of the provider's cooperation and its existing compliance program, the letter said.

B&B points out that, while the SDP may assist a provider in resolving an issue with IG, any settlement with IG is not binding upon the U.S. Department of Justice. The Justice Department has not commented on the Open Letter, but it has traditionally supported a policy of self-disclosure among providers.

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IG Addresses “Carving Out” Federal Business from Arrangements

In yet another advisory opinion this Spring, the IG addressed a proposal in which a durable medical equipment (DME) company requesting the opinion desired to offer two business models and written contracts to physician practices. The DME company would give the physician practices a choice between two contractual relationships for the delivery of DME, as well as orthotics, to its patients.

In the first relationship, the physician practice would directly supply the DME to its non-governmental healthcare patients. It would purchase DME exclusively from the DME company, with a negotiated discount arrangement. In addition, the DME company would lease certain devices to the physician practice and provide trained technicians to fit patients for the equipment. The physician practice would bill each item or service leased or purchased from the DME company to its patients and their third party payors. The DME company would also provide comprehensive billing, coding and collection services to the physician practice for a fixed monthly fee. B&B notes that a significant aspect of this first model is that the practice would not furnish DME or orthotic items to its federal healthcare program patients; instead it would refer these patients to community providers.

In the second relationship, the practice would rent storage space to the DME company for a fixed monthly fee that would not exceed the fair market value of such space. The physician practice would be paid by the DME company a percentage of non-governmental revenues generated from the sale or lease of DME in return for "inventory management" and other administrative tasks by the practice. In addition, the physician practice would pay the DME company for the services of a "trained technician" to be available on site to serve its patients.

The IG concluded that these two arrangements posed "a significant risk of fraud and abuse," noting that the first model was a "contractual joint venture" for private pay business", with little or no business risk to the physician practice, and the second was a set of interrelated arrangements that had the potential to "align" the interests of the physician practices with the interests of the DME company. The IG concluded that the first arrangement could actually be a mechanism for "disguising" remuneration for Federal referrals through a scheme ostensibly designed to apply only to non-governmental business. *Note* that the overall arrangement might cause the physician practice to refer federal healthcare business to

the DME company in order to obtain better discount arrangements for the non-federal healthcare business. Although it was to be based solely on non-federal healthcare revenues, the IG expressed concern that the percentage to the physician practice could be established based on referrals for federal healthcare business.

[CLICK HERE](#) to read Advisory Opinion 06-02.

IG Supports Charitable Assistance to Needy Medicare Beneficiaries

In an advisory opinion issued April 27, IG stated that a proposed arrangement by a charitable corporation to help financially needy Medicare beneficiaries with premiums and cost-sharing obligations would not trigger grounds for sanctions under the civil monetary penalties (CMPs) provision of the Social Security Act.

The requesting entity, a nonprofit, tax-exempt, charitable corporation, asked the IG to issue an advisory opinion on its proposal to expand its premium support program by offering financial assistance to beneficiaries under Medicare Part B, Medicare Part D, Medigap, and Medicare Advantage.

The charity helps individuals and families through assistance with funding for treatment of two specific chronic diseases, including financial assistance to subsidize premiums for private insurance and one-time grants of up to \$500 to address urgent needs and lack of financial resources.

In addition, the charity provides non-financial assistance, such as helping families with locating insurance, appealing insurance payment denials, providing personal support services, and acting as a liaison between the patient community and legislators regarding critical issues of importance to patient communities.

The advisory opinion focused on the charity's interposition as an independent body between donors and patients. The IG found that the design and administration of the proposed arrangement provides sufficient insulation so that the charity's proposed subsidies should not be attributed to any of its donors.

Donors will not be assured that the amount of financial assistance their patients, clients, or customers receive will bear any relationship to the amount of their donations and, thus, the IG does not believe the contributions made by donors to the requester can reasonably be construed as payments to eligible beneficiaries of the Medicare program or to the requester.

[CLICK HERE](#) to read Advisory Opinion 06-04.

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Deficit Reduction Act

The recently enacted Deficit Reduction Act of 2005 (the "DRA") provides that any entity that receives annual payments under Medicaid of at least \$5,000,000, as a condition of receiving such payments, shall establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the False Claims Act, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under those laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs. Further, DRA states that, as part of those written policies, the provider should include detailed provisions regarding its policies and procedures for detecting and preventing fraud, waste, and abuse. Finally, the provider must include, in any employee handbook that it maintains, a specific discussion of the laws described above, the rights of employees to be protected as whistleblowers, and the provider's policies and procedures for detecting and preventing fraud, waste, and abuse.

In summary, to the extent not currently found in an employee handbook or policy of a Medicaid provider, the following provisions should be inserted:

- Detailed information about the False Claims Act
- Administrative remedies for false claims
- Whistleblower protections and rights of employees to be protected as whistleblowers
- Policies and procedures for detecting and preventing fraud, waste, and abuse.

President Bush signed the DRA in February, and Medicaid providers must comply with these requirements by January 1, 2007.

Quality of Care Under the False Claims Act

Powerful and effective, the federal False Claims Act ("FCA") has become the "go to" weapon in the government's arsenal of statutes to combat health care fraud. Health care professionals typically have a static view of the FCA as pertaining only to billing misrepresentations, but the government sees it as an evolving vehicle with which to address quality of care, among other issues. Some have questioned whether prosecutions for billing misrepresentations ultimately protect patients and improve care. This may explain the government's increasing focus on quality of care as a violation of the

FCA, typically premised on failure to comply with regulatory requirements, such as conditions of participation. Under this logic, the quality of care actually rendered can be so grossly inadequate as to amount to no care at all, and can expose the provider to liability under the FCA. With successful FCA prosecutions and recoveries on the rise amid increasing regulation, health care professionals who participate in federal health care programs should be aware of the trend to address quality of care, patient safety and patient dignity concerns using the FCA.

Currently, about 80% of all FCA cases target entities in the health care arena. Since 1986 the government has recovered over \$17 billion using the FCA, with \$1 billion of that total coming in the first quarter of FY 2006 alone. With a potential recovery of three times the government's actual loss plus from \$5000 to \$10,000 in civil penalties per false claim, FCA damages can amass quickly. The government touts statistics showing it realizes a 1300% return on its investment in prosecuting FCA cases. Credit for this success goes in part to the whistleblower provisions of the Act, which allow individuals to bring FCA suits on behalf of the government and share in any recovery. With results like this, it is easy to see why the government continues to invest resources to refine and develop its use of the FCA.

Recent FCA quality of care cases turn primarily on a theory of a false certification (either express or implied) made in connection with a claim for reimbursement that the care complied with all Medicare or Medicaid requirements -- for example, claims accompanied by a certification that the care was medically necessary or was supervised as required for payment. The highly regulated nursing home industry found itself in the government's crosshairs in early quality of care investigations, but over time all kinds of providers have been investigated, and prosecuted. In one case the court permitted the government to argue that a psychiatric hospital violated the FCA by submitting claims for services when it had failed to provide the "reasonably safe environment" required by law. In another, the government successfully argued that a nursing home provided systemic substandard care because it was so understaffed that it could not possibly have administered the care consistent with Medicare and Medicaid requirements. In yet another case, a lab company was indicted for collecting blood for unnecessary tests that provided no medical or economic benefit other than to the lab company's bottom line, while subjecting the patients to admittedly incremental risk. Moreover, physical harm is not a requirement for a successful FCA prosecution. Recent high profile settlements with pharmaceutical companies illustrate that purely

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financial harm to patients will be actionable under the FCA, even in the absence of physical injury.

Currently, prosecutors are concentrating FCA quality of care investigations in six general areas, according to James Sheehan, an Assistant U.S. Attorney in Pennsylvania. First, reported cases of abuse and neglect continue to be investigated. Second, the government is mining medical records for evidence of falsification, which may be easier to prove than the abuse and neglect they cover up. Third, the government is monitoring the failure by providers to report adverse outcomes in those states that require such reports. Currently, Alabama is not one of those states, except for some facility license regulations. Fourth, the improper use of physical and chemical restraints will continue to receive government attention. Fifth, intentional misconduct, such as the murders of several patients by a registered nurse in Pennsylvania, will subject an employer to FCA scrutiny as a quality of care issue. Finally, according to Sheehan, the government will be scrutinizing corporate governance to see how management responds to quality of care concerns raised by caregivers.

What should providers take away from this discussion? Patient-centered quality issues, which involve patient protection, safety and dignity, inherently have the emotional appeal that comes with a real victim. Human nature dictates these cases will have greater appeal for prosecutors and juries than cases involving, for example, violations of technical quality standards. There are some red flags that should prompt an appropriate internal investigation, such as employees discussing patient-centered quality problems within the organization, patient or employee complaints, and the management's and medical staff's failure to take timely and appropriate action to address patient-centered quality problems. A commitment by management to support and maintain a diligent compliance program will go a long way towards keeping the government at bay. Otherwise, caregivers that find management unwilling to hear about quality of care problems may find the government has a willing ear.

TAX EXEMPTION & CHARITY CARE

Catholic Health Association and AHA Respond to Sen. Grassley

On May 1st, the American Hospital Association (AHA) sent a letter to Senate Finance Committee Chairman Charles Grassley (R-IA), responding to an inquiry made by Grassley in March to gather more information about hospitals' charitable care.

In the letter, AHA noted that hospitals have been justifiably concerned about how discounting charges or failing to maintain vigorous collection policies for uninsured patients of limited means might put them in the crosshairs of the Medicare program and/or Office of Inspector General (IG). However, AHA has developed, and urged its members to adopt voluntary guidelines on hospital billing and collection practices that contain specific policies to provide increased financial assistance or discounts, the letter said.

AHA also noted that it has worked with its members "to foster greater community involvement on all levels, including innovative ways to provide care and services to uninsured patients of limited means." In addition, AHA urges its members to follow certain guidelines regarding community benefit, the letter said.

The Catholic Health Association (CHA) sent its response letter to Grassley in the last week of April, claiming that most hospitals take their responsibilities as tax-exempt organizations very seriously.

Although CHA does not impose any sanctions or measures of compliance on its members, it does sponsor programs to help improve the understanding of and compliance with the Community Benefit guidelines. CHA gave several examples of the charity care and discounting policies for the uninsured of some of its member hospitals.

CHA noted that its members have adopted conflict of interest policies that require "members of boards and certain employees in management or executive positions to adhere to those entities' standards governing conflicts of interest."

[CLICK HERE](#) to review the AHA Letter.

[CLICK HERE](#) to review CHA Letter.

IMMIGRATION

Georgia Passes New Immigration Bill

Georgia Governor Sunny Purdue signed the Georgia Security and Immigration Compliance Act (the "Act") into law on April 17, 2006. The Act contains nine (9) different sections, each amending a different body of law as applied to Georgia immigrants. Although several apply to healthcare providers in the State, none interferes with hospitals' obligations under EMTALA if an undocumented immigrant comes to the hospital in an emergency condition. In fact, the most significant burden of the Act is placed upon Georgia providers as employers.

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Section 9 requires every agency or political subdivision administering a state, local, or federal public benefit to verify the legal immigration status of any person applying for such benefits. Rather than define "public benefit", the Act incorporates the definition already used by the federal government in 8 U.S.C. §§ 1611 and 1621. Federal law defines "public benefit" as including any health benefit "for which payments or assistance are provided to an individual, household, or family eligibility unit" by a government agency. Violation of the Act is a criminal offense. The Act does not clarify whether a county hospital authority constitutes a political subdivision of the state, but it is clear that Section 9 does not apply to the delivery of healthcare services by a private entity, even one that is non-profit and tax-exempt.

Section 2 of the Act imposes new requirements on public employers, which it defines as "every department, agency, or instrumentality of the state or a political subdivision of the state." Public employers are now required to register and participate in the federal work authorization program to verify the immigration status of all new employees. While a private healthcare facility is not a public employer, Section 2 also imposes new requirements on any contractor or subcontractor that enters into a contract with a public employer for the physical performance of services within Georgia, like participating in Medicaid. Specifically, public employers are now prohibited from entering into such contracts with a contractor or subcontractor unless the contractor or subcontractor participates in the federal work authorization program. The federal work authorization program requires the contractor or subcontractor to register and verify that all of its new employees are legally in the United States.

Section 2 of the Act is not immediately effective. After July 1, 2007, Section 2 will be enforced against any public employer, contractor or subcontractor with 500 or more employees. Entities with 100 or more employees are not required to verify employee status until July 1, 2008. Finally, on or after July 1, 2009, all public employers, contractors, and subcontractors within Georgia will be required to verify the immigration status of all new employees.

Section 7 of the Act amends Georgia's tax and revenue code. After January 1, 2008, a tax paying entity can claim the wages of an individual, totaling \$600.00 or more per year, as a deductible business expense only if the individual is an "authorized employee".

Rather than define "authorized employee", the Act incorporates the definition used by the federal government in "paragraph (2) of

subsection (a) of 8 U.S.C. § 1324(a)." Although this section does not define "authorized employee", the intent of the statute appears to be to prohibit private entities from deducting as a business expense the wages of an employee that is illegally within the United States.

Section 8 of the Act also amends Georgia's tax and revenue code. All withholding agents, including private companies, are now required to withhold state income taxes at a rate of 6% of compensation when an individual cannot provide a taxpayer identification number or IRS issued taxpayer identification number issued to nonresident aliens. Any withholding agent who fails to comply with this requirement will be liable for the taxes that should have been withheld.

MEDICARE REGULATIONS

Enrollment in Medicare

The Centers for Medicare and Medicaid Services (CMS) published a final rule on April 21st requiring all providers participating in the Medicare program complete an enrollment form, and submit and periodically update certain information to CMS in order to maintain Medicare billing privileges.

CMS issued the rule because the stated documentation and associated verification methods it uses to determine whether to grant a provider or supplier billing privileges are necessary to ensure compliance with Medicare requirements and prevent abuse of the Medicare program, as well as the "inappropriate use of Medicare funds."

The rule also states that CMS may perform on-site inspections of all providers and suppliers in order to ensure compliance with Medicare enrollment requirements.

Providers must also certify that they comply with title XVIII of the Medicare Act and applicable regulations, as well as comply with all applicable federal and state licensure and regulatory requirements that apply to the specific provider or supplier type (relating to providing healthcare services). In addition, Providers must not employ or contract with individuals or entities excluded from participation in federal healthcare programs for the provision of items and services reimbursable under these programs.

[CLICK HERE](#) for the Final Rule on Medicare Enrollment.



HIPAA

HHS Issues Final Enforcement Rule

The Department of Health and Human Services (DHHS) published a final rule February 16th under authority from the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification provisions. The rule extends the enforcement provisions currently applicable to the HIPAA privacy standards to apply to all HIPAA Administrative Simplification rules.

The final rule includes same changes from the proposed rule. For example, the final rule “clarifies that the method for determining the number of violations of an identical requirement is grounded in the substantive requirement or prohibition violated, while the proposed rule included variables to count the number of violations of an identical requirement or prohibition.”

In addition, the rule retains joint and several liabilities for violations by the members of an affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

[CLICK HERE](#) for the Final HIPAA Enforcement Rule.

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